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Robotically-Assisted Surgical Devices - Premarket Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This draft guidance provides recommendations for premarket submissions for certain robotically-assisted surgical devices (RASDs). RASDs are teleoperated, software-controlled systems that integrate robotic technologies and subassemblies that are designed to assist qualified practitioners in precisely positioning and controlling one or more surgical instruments to safely and effectively perform open, minimally invasive, or endoluminal procedures. RASDs are used under direct control or supervision of a qualified practitioner. RASDs utilize robotic technologies comprised of a leader/follower control system architecture and may contain some level of automated functions to enhance and augment user capabilities.

RASDs generally have the following three subassemblies:[1]

- An operator console (i.e., surgeon console), where a qualified practitioner controls the system. The operator console is the control center of the system and allows a qualified practitioner to view the surgical field and to control movement of the surgical instruments and cameras (e.g., laparoscope);

[1] RASDs with different physical architectures are within the scope of this guidance if they meet the definition of a RASD.

- A bedside/patient subassembly (e.g., cart, pedestal) with a sterile-nonsterile interface that has working arms that control, activate, or actuate cameras (e.g., laparoscope), surgical instruments, accessories,[2] and/or third party devices inside the patient that a qualified practitioner controls during the surgical procedures. It may also have attachments, connections, controls, and safety features accessible to a bedside surgical assistant; and

- An operating room (OR) staff subassembly (e.g., tower) that contains supporting hardware and software components, such as an electrical surgical unit (ESU), suction/irrigation pumps, a secondary vision display, an insufflation unit, and light source for the endoscope.

For the current edition of the FDA-recognized standards referenced in this document, see the FDA Recognized Consensus Standards Database Web site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, please refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."

Throughout this guidance, the terms "FDA," "the Agency," "we," and "us" refer to the Food and Drug Administration and the terms "you" and "yours" refer to RASD manufacturers.

In general, FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended but not required.

II. Scope

The scope of this document includes premarket submissions for RASDs except as follows:

Note that pre-operative planning systems and stereotaxic systems are not RASDs and are outside the scope of this document. Examples of pre-operative planning and stereotaxic systems include systems that consist of a computer user interface, tracking sensor, navigated instruments, and a patient reference to detect the 3D position of the navigated instruments and patient reference in relation to patient's anatomical landmarks (e.g., orthopedic stereotaxic instruments [product code OLO], neurological stereotaxic instruments [product code HAW], and ear, nose, and throat stereotaxic instruments [product code PGW] under 21 CFR 882.4560).

[2] For more information see the FDA guidance "Medical Device Accessories - Describing Accessories and Classification Pathways."

The guidance also does not address RASDs intended to assist in performing surgical tasks involving the placement or use of interventional devices, such as interventional catheters. Nevertheless, some of the non-clinical recommendations in the guidance may apply to these RASDs. Within the scope of this guidance, "endoluminal" use refers to use through existing luminal cavities and is not intended to include positioning and controlling multiple surgical instruments or interventional devices through blood vessels or via an intravascular approach. Finally, this guidance also does not address remotely teleoperated RASDs, or autonomous robots that perform significant aspects of operative procedures independent of qualified practitioners. Certain recommendations in this guidance, however, may be relevant to remotely teleoperated RASDs or RASDs that are capable of decision-making and independent execution of tasks.

For RASDs outside the scope of this guidance, we strongly recommend that manufacturers engage with FDA via the Q-Submission Program to obtain more detailed feedback regarding your device. For more information on Q-Submissions, please refer to FDA's guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

If you are unsure about whether your device is considered a RASD, you should contact FDA via the Q-Submission Program.

III. Glossary

The following terms are defined for the purposes of this guidance:

Autonomy – The ability of a robotic device system to perform tasks and make decisions based on current state and sensing without user intervention.

Bedside/Patient Subassembly – A subassembly of the RASD with a sterile-nonsterile interface that has working arms that control, activate, or actuate surgical instruments, cameras (e.g., laparoscope), accessories, and/or third-party devices inside the patient used to assist in performing surgical procedures. The bedside/patient subassembly typically has controls, connections, attachments, and safety features accessible to a scrubbed surgical assistant to allow, for example, aseptic surgical instrument exchange or aseptic movement of the working arm.

Covered Procedure – A surgical procedure in the same surgical specialty (e.g., general surgery) as the umbrella procedure, but one that is of lesser complexity and risk than its umbrella procedure. Covered procedures leverage data from the cited umbrella procedure, and additional *in vivo* performance testing data for a covered procedure may not be needed to support the authorization of the RASD for that use.

Haptics – Any feature that provides some form of tactile, force, or other sensory feedback to the user during the operation and that is intended to mimic or simulate the feel of manual surgical instruments.

Local Teleoperation – A locally teleoperated system consists of an operator console that is co-located in the same operating room as the bedside/patient subassembly. Using the operator

console, a qualified practitioner can remotely control the bedside/patient subassembly by wired or wireless signal.

Operating Room (OR) Staff Subassembly – A subassembly of the RASD that contains supporting hardware and software components, such as an electrical surgical unit (ESU), suction/irrigation pumps, a secondary vision display, an insufflation unit, and light source for the endoscope.

Operator Console – A subassembly of the RASD where a qualified practitioner controls the RASD. The operator console allows the qualified practitioner to view the surgical field and to control movement of the surgical instruments and cameras (e.g., laparoscope).

Robotically-assisted Surgical Device (RASD) – A teleoperated, software-controlled system that integrates robotic technologies and subassemblies that are designed to assist qualified practitioners in precisely positioning and controlling one or more surgical instruments to safely and effectively perform open, minimally invasive, or endoluminal procedures. RASDs are used under direct control or supervision of a qualified practitioner. RASDs utilize robotic technologies comprised of a leader/follower control system architecture and may contain some level of automated functions to enhance and augment user capabilities.

Remote Teleoperation – A remotely teleoperated system is comprised of an operator console that is not co-located in the same operating room as the bedside/patient subassembly. Remote teleoperation systems may have variable distances between the operator console and the bedside/patient subassembly.

Service Life – The time period specified by the manufacturer during which the RASD is expected to perform as intended.

Singularity – A configuration of a robotic manipulator in which the kinematic Jacobian matrix loses rank, resulting in the loss of one or more degrees of freedom in the end-effector's motion and limiting the robot's ability to move or exert forces in certain directions.

Umbrella Procedure – A surgical procedure of sufficient complexity and risk such that performance data derived from the umbrella procedure may be leveraged to support the use and authorization of the RASD for covered procedures (i.e., procedures of lesser complexity and risk).

Use Life – The pre-defined duration of active use or number of repeated uses during which instruments, accessories and compatible devices are expected to perform as intended.

IV. Submission Recommendations

This guidance provides recommendations to support the premarket submissions for certain RASDs. Given the broad range of RASDs within the scope of the guidance, specific device types and devices are not discussed in each section below, and we note that certain requirements and recommendations discussed may not be applicable to a specific device type or device. You should be aware of the different premarket submission and other requirements (e.g., special controls) applicable to your device and you can engage with FDA via the Q-Submission Program to obtain more detailed feedback regarding your specific device.

A. Device Description

For all RASD submissions, you should provide a clear and concise device description that describes all the major functional components of the RASD. For 510(k) submissions, we recommend you also identify the classification regulation number and product code of your device based on the proposed predicate device. The device description should be organized starting with the whole system overview, followed by subassemblies and other components.

You should provide written descriptions and images, when applicable, of the following:

- Whole system overview
  - The entire RASD set-up for its intended use
  - Principle of operation
  - Kinematic diagram
  - Connections diagram (including how the subassemblies are connected to each other and external services/servers)
  - Data transmission representation
  - Physical dimensions
- System subassemblies
  - Operator Console
    - User detection
    - Location of sensors and their accuracy and sensitivity
    - Edge of usable workspace notification
    - RASD features that enhance operator capability
  - Bedside/Patient Subassembly
    - Working arms: axes of movement, number of passive and motorized parts, degrees of freedom, force range, velocity limit, etc.
    - Reach of working arm(s) in different patient configurations
    - Registration of working arm locations
    - Linking of working arm to port/trocar
    - Emergency/safety stop button
    - Emergency patient-access capability and emergency removal procedure
    - Patient positioning/optimization features
    - Surgical assistant positioning/optimization features
    - RASD features that enhance surgical assistant capability
  - OR Staff Subassembly
    - Compatible third-party devices and accessories
    - RASD features that enhance OR staff capability
- Other
  - Sterile-Nonsterile interface
  - Surgical instruments
    - Surgical tasks for each instrument
    - Axes of movement
    - Range of movement

    - Range of grasping forces and pre-specified grasping force, if applicable
    - Number of uses allowed by the system
    - Power rating for relevant components
  - Cameras
  - Accessories
  - Power sources/requirements
  - Connections
  - Attachments
  - Drapes
- Safety features and their locations within the system should be individually described
- For 510(k)s, technological characteristics not present in the predicate device

The list above may not be comprehensive, and each section may include multiple subsections as needed. You should also add or omit sections as applicable.

Videos demonstrating overall use of the RASD may be helpful to further explain your written device description, specifically videos focused on the device user interfaces and novel technological features. You should place any device features enhancing or augmenting human capabilities (e.g., tremor reduction, motion scaling, and/or visual magnification) in their own sections and describe these features in detail.

B. Predicate Comparison (for 510(k)s only)

Each premarket notification submission must contain certain information, including "a statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution" (21 CFR 807.87(f); see section 513(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. § 360c(i)). For RASDs reviewed under the 510(k) process, you must compare your new device to a legally marketed predicate device to support its substantial equivalence (SE).[3] This comparison should provide information to show how your device is similar to and different from the predicate device. See Table 1 below for an example of how this information may be organized. This table is not intended to represent an exhaustive list of comparative parameters. We recommend that you provide, whenever possible, side-by-side comparison of all relevant device description characteristics as outlined in the Section IV.A above.

When providing the SE comparison information and when writing a narrative analysis, the terms "identical" or "same" should only be used for features that are demonstrably identical or the same (i.e., same manufacturer, same design, same materials, same functions). You should describe any differences in technological characteristics between the subject and predicate devices and provide a rationale as to why the differences do not affect SE to the predicate device. Where there are technological differences, your SE analysis should include information

[3] See 21 CFR 807.87(f)

demonstrating that the subject device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

Table 1. Example of Substantial Equivalence (SE) Comparison Table

Description	Subject Device	Predicate Device (Kxxxxxx)	SE Comparison
(Example) Dissector Monopolar	• Diameter 5 mm • Length 400 mm • Monopolar RF 200 kHz 60 Watts • Snake joint • 3rd party Generator (Brand X) • 4 degrees of freedom (DOF)	• Diameter 5 mm • Length 350 mm • Monopolar RF 225 kHz 65 Watts • Wristed joint • 3rd party Generator (Brand Y) • 4 DOF	• *Identical diameter* • *Not significantly different lengths; or such differences do not raise different questions of safety or effectiveness and information provided shows device is as safe and effective as the predicate* • *Although joints have different designs (i.e., snake vs. wristed), they both have the same DOF and generator requirements*
(Example) Grasper	• Diameter 5 mm • Length 400 mm • Atraumatic curved grips • Snake joint • 4 DOF	• Diameter 5 mm • Length 350 mm • Atraumatic straight grips • Wristed joint • 4 DOF	• *Identical diameter* • *Not significantly different lengths; or such differences do not raise different questions of safety or effectiveness and information provided shows device is as safe and effective as the predicate* • *Although grips and joints have different designs (i.e., curved vs. straight, snake vs. wristed), they both have the same DOF*

Due to the inherent complexity of RASD submissions, it may be helpful to supplement the SE comparison table (Table 1) if used, with an additional submission overview table summarizing the features that are distinct or modified from the predicate device. Table 2 below provides example information that could be helpful, including a brief description of the differences, impact of the differences, summary and location of the performance testing, and rationale to support SE to the predicate device despite the differences.

Table 2. Example of Summary of New/Altered Features in the Subject Device

New/Altered Feature	Design Change	Functional Change	Impact of Changes	Performance Testing (*location in submission*)	SE Analysis
(*Example*) Flexible Wristed Grasper	• Smaller diameter • Increased number of linkages • New materials, *x, y, z* • Instrument RFID	• Increased range of motion/ flexibility • Improved access to confined spaces • Improved durability • Increased number of uses	• Reduced grasping and lifting strength (overload) • Cleaning/ Reprocessing smaller channels • Instrument damage from higher use frequency	• Biocompatibility (*Section N*) • Reprocessing *(Section O)* • Sterilization *(Section P)* • Software V&V *(Section Q)* • Bench *(Section R)* • Cadaver *(Section S)*	• 25% increase in range of motion • 15% decrease in diameter • 18% increase in durability • Nominal change in strength • No increase in risk of harm

Any reference devices should also be listed and described. We recommend that you review the FDA guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," for additional information on the use of predicate and reference devices to demonstrate SE.

C. Accessories and Compatible Devices

Any accessories or compatible devices intended to be used with a RASD should be described in detail in the premarket submission for the RASD. For accessories or compatible devices (including third party devices) that have previously received a marketing authorization in a standalone submission, you should provide the submission number for each accessory or compatible device in your RASD submission. The RASD proposed labeling should also explicitly list each accessory or compatible device, including relevant identifying information (e.g., manufacturer name, device name, version/model number).

Whether you manufacture the accessories or compatible devices to be used with your RASD or they are manufactured by a third party, you should demonstrate the compatibility and interoperability of the accessory or compatible device and your RASD through performance testing, as applicable. The whole RASD (i.e., subassemblies, surgical instruments, cameras) should be tested for its intended use. You should document compatibility (e.g., connections, attachments, interoperability, functionality) of the RASD with accessories or compatible devices intended to be used with your RASD when applicable. Any adapters or drapes needed for such compatible devices should also be described and included in performance testing.

For more information on considerations for interoperable medical devices, please refer to FDA's guidance, "Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices."

D. RASD-Specific Non-Clinical Performance Testing

Significance: Well-designed non-clinical performance testing should be used for design verification and validation prior to *in vivo* testing. Non-clinical performance testing for RASDs should comprehensively evaluate the system-level performance characteristics that are critical to safe and effective device operation. These characteristics typically include teleoperation functionality, system control behavior, kinematic and dynamic motion performance, visualization and display capabilities, additional RASD-specific features, and system and surgical instrument reliability.

Recommendation: Non-clinical performance testing activities may include *in vitro, in silico, ex vivo,* cadaver*,* mechanical, electrical, thermal, radiation, and functional testing. Where possible, tests may be combined to reduce burden.

Non-clinical performance testing should test all functional components and compatibility of the RASD; therefore, we recommend that you perform testing for each subassembly, and for the system as a whole (including all the major components, surgical instruments, and cameras), and the system when used with accessories and compatible devices.

You should provide full test reports for each test conducted. A full test report includes the objective of the test, a description of the test methods and procedures, sample size, pre-defined pass/fail criteria with relevant clinical justification (e.g., literature) for the set criteria, justification for the specific surgical instrument tested, test results, and conclusions. For 510(k) submissions, you should also provide an explanation of how the data generated from the test support a finding of SE to the predicate device, as appropriate. For information on recommended content and format of test reports for non-clinical performance testing in premarket submissions, refer to FDA's guidance, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions."

Non-clinical performance test conditions should simulate the worst-case conditions that your device is likely to encounter during clinical use. When designing your device-specific performance testing, you should consider the use(s) being sought for authorization and the device's design specifications. Bench performance testing should be representative of typical clinical use to demonstrate full device functionality and verify design inputs and outputs. Cadaveric studies may be useful for evaluating system fit and function within the human anatomy.

The following sections are recommended non-clinical performance testing for each subassembly and for the entire system. This list may not be comprehensive, as your RASD may include additional features and functions not specifically addressed in this guidance.

(1) System Teleoperation

Significance: RASD is a leader-follower, teleoperated system that is controlled by wired electrical signals over cables or wireless transmission. Timely and accurate information exchange between the user interface and working arms/surgical instruments is essential for safe device performance.

Recommendation: Factors contributing to teleoperation performance include signal transmission integrity, system latency, and accurate translation of user input into scaled and filtered instrument motion. Your performance testing should demonstrate connection integrity and timely control signal transmission. RASDs should have fail-safe operation in the event of teleoperation faults (e.g., cable disconnection, electromagnetic interference). If wireless signal transmission is implemented for user interface controls, please refer to additional recommendations in Section IV.G on Wireless Technology.

As applicable, you should design and conduct performance testing for each of the following system teleoperation characteristics using representative surgical configurations consistent with the intended use. This list may not be comprehensive, as your RASD may include additional teleoperation features or functions not specifically addressed in this guidance.

a) Total System Latency

Significance: Total system latency refers to the cumulative delay from the surgeon's hand input at the operator console to instrument motion, and from instrument motion to the corresponding visual feedback displayed on the main visualization and display system. Latency testing ensures there is no significant time delay between the hand-input device, the instrument response, and the visual feedback from the camera system. Latency is critical for RASDs because it directly affects the operators' ability to perform precise, safe movements in real-time.

Recommendation: Latency testing should demonstrate that the total system latency between the hand-input device, instrument motion, and displayed visual feedback remains within pre-defined, clinically justified limits. It is recommended that latency be measured under representative and worst-case operating conditions, including maximum processing loads and typical clinical configurations. Testing should account for translational and rotational motion (i.e., roll, yaw, pitch) and end-effector actuation (e.g., open/close) of the surgical instruments. Testing should verify that the system provides real-time, synchronized feedback sufficient to support safe and effective surgical performance. FDA recommends testing a minimum of three RASDs. If a smaller sample size is proposed, we recommend that a rationale be provided for the number of samples on which these tests are performed to demonstrate consistent performance across different manufacturing productions.

b) Motion Enhancement and Operator Input Processing Functions

Significance: RASDs typically incorporate computational processing of operator inputs to enhance precision, stability, and control of instrument motion. These functions modify or condition the surgeon's hand inputs before transmission to the working arms and surgical instruments. Common examples include motion scaling (i.e., reducing the magnitude of operator inputs to allow finer instrument movement) and tremor reduction (i.e., filtering physiological tremor frequencies while preserving intentional motion). Other input-processing features may include motion smoothing, force modulation, or haptic filtering. Such motion enhancement and filtering functions enable the operator to execute complex tasks, including suturing and knot tying, in confined anatomical spaces while minimizing complications from involuntary movements or abrupt input changes.

Recommendation: For any operator input processing functions implemented in the RASD, you should provide performance testing to characterize their behavior and verify consistent, predictable operation within predefined tolerances.

For motion scaling, testing should measure the scaling ratio between operator console inputs and instrument outputs across the full range of scaling conditions, verifying that the device maintains accurate and consistent scaling throughout the workspace. Testing should include assessment at various speeds, directions, and positions within the surgical envelope to ensure linearity and predictability of the scaling function.

For tremor reduction or other filtering functions, testing should demonstrate the device's ability to attenuate unintended input frequencies (e.g., physiological tremor) while preserving intentional surgical movements. This may be accomplished by introducing controlled sinusoidal inputs at various frequencies and amplitudes to the hand-input device at the operator console and measuring the corresponding output at the surgical instrument tips.

(2) System Controls

Significance: RASDs are controlled by complex computational, electrical, and mechanical control systems. Accurate control and system stability are essential to ensure that the user inputs are accurately translated into the intended working arm and surgical instrument motion, even when the system is unexpectedly perturbed. Because these systems rely on integrated software, hardware, sensors, actuators, and feedback loops, failures or instability in the control architecture may result in unintended motion, loss of control, delayed system response, or inability to safely access the patient during emergency situations. Therefore, it is critical that control systems maintain stability, enforce safe operational limits, and provide predictable fault detection, response, recovery and emergency access capabilities to protect patient safety.

Recommendation: To characterize and demonstrate the performance of the system controls, testing should be conducted to assess the integration of software, hardware, and overall system functionality. This applies to any system with input and output controls governed by feedback

loops and the calculation of discrepancies between input and output signals. Testing should demonstrate that the control system maintains stability during disturbances, activates safety stop mechanisms appropriately, detects and responds to fault conditions, and supports system recovery and emergency removal procedures in a predictable and safe manner.

As applicable, you should devise and conduct performance testing for each of the following system control functions using representative surgical configurations consistent with the intended use. This list may not be comprehensive, as your RASD may include additional control features or safety mechanisms not specifically addressed in this guidance.

a) System Stability and Control Performance

Significance: Control system stability is critical to ensuring predictable and safe device performance. In designing your control system, you should account for uncertainty and instability that may arise during clinical use. For example, if your system encounters an unexpected force (e.g., a jolt or bump of the user hand controls), the accidental impulse force should not be transmitted to the surgical instruments in a manner that could cause patient injury or result in motion calculation errors leading to a system fault (e.g., control malfunction or stoppage).

Recommendation: Testing should demonstrate that the control system maintains stability under representative disturbances and fault conditions. Your testing should demonstrate the stability of your control system under sudden input or signal noise. It should also evaluate the device's stability under fault conditions, particularly when primary control mechanisms fail, and demonstrate that the system remains stable or transitions to a safe state without causing hazardous motion.

b) System Recovery and Emergency Removal

Significance: The ability of the RASD to detect, respond to, and recover from fault conditions is critical to maintaining patient safety. Faults may result from hardware malfunctions, software errors, power interruptions, or environmental factors. Inadequate fault detection or recovery may lead to unintended motion, loss of control, or system instability that could cause patient harm.

In addition, in certain emergency situations, rapid access to the patient may be necessary. Robotic systems that interface with the patient may require removal of instruments, undocking, or repositioning of robotic arms before direct access can be achieved. Delays in these procedures could compromise patient outcomes during time-critical events.

Recommendation: Recovery testing should demonstrate that the system can detect, respond to, and recover from representative hardware, software, and environmental fault conditions in a timely, predictable, and safe manner. Testing should verify that faults are detected within clinically justified timeframes and that appropriate safety responses are initiated (e.g., controlled shutdown, position hold, transition to a safe state, or activation of backup systems). Testing should also verify the system's ability to safely transition from a fault condition to normal

operation or a predetermined safe state, including maintaining instrument control and enabling both automatic and manual recovery procedures.

In addition, emergency removal testing should demonstrate that emergency removal procedures allow timely and safe access to the patient, including assessment of the time needed to remove relevant system components to enable emergency access to the patient and demonstrate that the device does not introduce unacceptable delays that could adversely affect patient outcomes.

c) Emergency and Safety Stops

Significance: Safety stops are intended to prevent the RASD from exceeding safe operational limits or continuing uncontrolled movement that could cause serious injury to the patient or damage the device. These mechanisms may be triggered manually or automatically in response to unsafe conditions and are critical to ensuring that the system transitions to a predictable and safe state.

Recommendation: Testing should demonstrate that safety stops function reliably under both normal and fault conditions. The RASD should stop motion and deactivate any active instruments' functions within a predefined safe limit. This should be verified by measuring the actual distance traveled or function performed following activation of the safety stop. Testing should encompass worst-case scenarios, including maximum operational speeds, accelerations, and the most challenging trajectories that the device may encounter during clinical use. Testing should also verify that activation of safety stops does not introduce unintended motion and that the system maintains or transitions to a safe state following stop activation.

(3) Kinematics and Dynamics

Significance: RASDs typically have working arms that control and manipulate surgical instruments and cameras. Understanding motion capabilities, positional accuracy, dynamic behavior, and mechanical interactions of the working arms and instruments is essential to the safety of the device (e.g., trocar wound tension) and to the effectiveness of the device for its intended use (e.g., access to confined anatomy).

Recommendation: The evaluation of robotic arm motion is divided into kinematics and dynamics. Kinematic analysis is used to quantify the range of motion of working arms and surgical instruments, while dynamics analysis evaluates the effect of forces and torques involved in these movements. You should provide a kinematic diagram of all parts of the device used to perform surgery (e.g., working arms, surgical instruments, camera systems) with singularity points identified, and a dynamic analysis of support joints and moving parts of these features. You should perform bench testing to verify and validate your RASD's performance characteristics, including positional accuracy and repeatability, system resolution, reachable workspace and range of motion, as well as its safety-related performance characteristics.

As applicable, you should devise and conduct performance testing for each of the following kinematics and dynamic characteristics using representative surgical configurations consistent with the intended use. This list may not be comprehensive, as your RASD may include additional motion-related features or functions not specifically addressed in this guidance.

a) Accuracy, Repeatability and Resolution

Significance: Accuracy determines how closely the RASD's surgical instruments' and cameras' actual positions match the intended target positions. Repeatability refers to the RASD's ability to return to the same position across multiple attempts. Resolution defines the smallest incremental movement that the RASD's surgical instruments can make. These three parameters are critical for robotically-assisted surgery because they directly impact patient safety, surgical outcomes, and overall effectiveness of the system.

Recommendation: Accuracy, repeatability, and resolution testing should be conducted using software-driven commands to ensure operator independence. You should independently assess both translational motion along the X, Y, and Z axes and rotational motion about the yaw, pitch, and roll axes of the end effectors. FDA recommends testing a minimum of three RASDs. If a smaller sample size is proposed, we recommend providing a rationale for the number of samples on which these tests are performed to demonstrate consistent performance across different manufacturing productions.

b) Workspace and Reachability

Significance: Workspace and reachability testing are fundamental to ensuring that the RASD can effectively be used to perform its intended procedures while maintaining patient safety. Workspace defines the three-dimensional volume within which the working arms and surgical instruments can operate. Reachability testing ensures that the working arm can reach the intended target anatomy. Additionally, such testing helps identify potential collision zones where robotic arms might interfere with each other, OR staff, the patient, the operating table, or other OR equipment.

Recommendation: Workspace verification testing should demonstrate that the system meets its design requirements in a bench setup, including clearly defining the total working volume. Testing should also verify that the system's safety mechanisms, such as hard stops or software limits engage appropriately when approaching the boundaries of the allowable range of motion. FDA recommends testing a minimum of three RASDs. If a smaller sample size is proposed, we recommend that a rationale be provided for the number of samples on which the workspace verification tests are performed to demonstrate consistent performance across different manufacturing productions. Additionally, you should validate the RASD's reachability in a relevant model of the human anatomy to demonstrate that the system can reach its intended target anatomy. Reachability testing should validate performance across the intended patient population, including clinically relevant extremes of body mass index, anatomical variations, and different positioning requirements.

c) Surgical Instrument Range of Motion

Significance: Surgical instrument articulation replicates the natural wrist motion that surgeons rely on in open surgery. Testing these ranges ensures that the surgical instrument can achieve the orientations necessary for tissue manipulation, suturing, and dissection at various angles within the surgical field. Adequate articulation is critical to enabling precise maneuvering in confined anatomical spaces without introducing excessive force or unintended tissue interaction.

Recommendation: This testing should demonstrate that the surgical instrument can reach both the upper and lower bounds of its specified limits of motion within a pre-defined error tolerance for yaw, pitch, roll, and opening (if applicable). It is recommended that the range of motion is evaluated at the beginning and end of its use life. This can be accomplished by simulated use testing.

d) Velocity Limits

Significance: Velocity limits are essential for maintaining stable, predictable behavior and preventing situations where the system's dynamics could become unstable or unmanageable. Velocity constraints help ensure smooth motion profiles, reduce mechanical wear on the RASD, minimize vibrations that could affect surgical performance, and prevent sudden accelerations that might trigger emergency stops or system faults.

Recommendation: Testing should be conducted to assess the maximum velocity limits for your device. You should evaluate the device's peak operational velocities across all axes of movement (i.e., translational and rotational), as well as velocity control algorithms and fail-safe mechanisms. Testing should demonstrate that the system limits the motion of the robotic arms to predefined velocity thresholds and maintains consistent velocity limits under various operating conditions. Testing should also verify system behavior when maximum velocities are approached or exceeded.

e) Position Tracking

Significance: Accurate position tracking is critical to ensuring that the physical motion of the robotic system corresponds appropriately to the operator's input commands. Discrepancies between commanded and actual position may result in unintended instrument motion, or loss of control, which could lead to tissue damage, bleeding or injury to critical structures.

Recommendation: You should provide performance testing to verify position tracking accuracy, error detection, and system response. You should also provide information on the accuracy and sensitivity of the sensors used for position tracking. Testing should demonstrate that when commanded and actual positions are not within a predefined tolerance, the user is notified and/or the system stops, limits, or transitions to a safe state. Testing should evaluate both normal and fault conditions to ensure that position tracking errors are reliably detected and that appropriate mitigation strategies are implemented to maintain patient safety.

f) Working Arm Collision Detection/Avoidance

Significance: During surgery, multiple working arms operate simultaneously within the confined space of the patient's body. Unintended contact between these arms, OR staff, or equipment can cause uncontrolled movements that may damage delicate tissues, blood vessels, or organs, potentially leading to complications such as bleeding, perforation, or trauma to structures adjacent to the surgical site.

Recommendation: Collision detection/avoidance functionality should be evaluated through comprehensive testing demonstrating that the collision detection system performs reliably across the full range of expected operating conditions and potential collision scenarios. Additionally, such testing should verify that surgical instrument motion remains minimal during a collision event.

g) Motion Safety and Singularity Avoidance

Significance: A singularity is a configuration of a robotic manipulator in which the kinematic Jacobian matrix loses rank, resulting in the loss of one or more degrees of freedom in the end-effector's motion and limiting the robot's ability to move or exert forces in certain directions. At or near a singularity, the operator may experience a loss of control where small movements of the operator console controls result in unexpectedly large or unpredictable movements at the instrument tip, or conversely, where desired movements become impossible to execute. These sudden, uncontrolled movements can cause tissue damage, bleeding, or injury to critical structures. In addition to kinematic singularities, unexpected or uncontrolled end-effector motion may also occur due to software failures, electromagnetic interference, or system faults. These conditions may result in unintended instrument motion that could cause tissue damage, bleeding, or injury to critical structures, and therefore should be appropriately mitigated.

Recommendation: You should provide a kinematic diagram identifying all singularity points within the system and conduct comprehensive testing to demonstrate how potential issues arising from kinematic singularities are adequately resolved. Additionally, you should describe the mitigation strategies implemented to prevent unexpected motion near these critical configurations. You should also verify that the system avoids configurations where the end effector may move in an unexpected manner due to software failure, electromagnetic interference, or fault conditions. Testing should evaluate end-effector motion during fault conditions to demonstrate that unintended or hazardous movements are prevented or mitigated. The testing should encompass all components used to perform surgery, including working arms, surgical instruments, and camera systems.

h) Physical Stability

Significance: The bedside/patient subassembly needs to remain stable during procedures to prevent unintended movements that could cause tissue damage, bleeding, or other surgical complications. Any wobbling, shifting, or flexing of the cart could translate into millimeter-level

deviations at the surgical site, which can result in serious injury to the patient when working near vital structures such as blood vessels or nerves.

Recommendation: You should evaluate the bedside/patient subassembly stability under various disturbance conditions that may occur during clinical use. Testing should encompass scenarios and forces that represent realistic clinical conditions such as personnel moving around the surgical field or inadvertent contact with system components and should account for external environmental factors (e.g., vibrations). Testing should ensure that external forces do not cause significant surgical instrument movement.

(4) Visualization and Display System

Significance: The RASD visualization system allows the user to view the surgical field. Accurate, timely, distortion-free, and high-resolution visual information is essential for enabling qualified practitioners to safely use the RASD. A visualization system may or may not have interactive elements, such as eye tracking, medical image overlays, heads-up display, 3-dimensional views, surgical instrument selection, working arm selection, and magnification.

Recommendation: Visualization and display system performance testing should demonstrate clear, accurate, timely, and reliable performance with respect to image resolution, image distortion, field of view, depth of field, color rendition, and thermal safety. Performance testing should also demonstrate reliable visualization in response to electromagnetic disturbances. For RASD visualization systems, we recommend following the FDA recognized consensus standard: IEC 60601-2-18: *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.*

(5) Additional RASD Features

Significance: Your device may include additional RASD features that provide enhanced functionality, such as eye-tracking capabilities, haptic feedback, integration of additional imaging modalities (e.g., X-ray, MRI), or built-in artificial intelligence/machine learning (AI/ML) algorithms (e.g., image segmentation, image augmentation, critical structure identification, or instrument tracking). While these features may improve visualization, control, situational awareness, or procedural efficiency, they may also introduce unique technical and clinical risks that should be appropriately evaluated.

Recommendation: You should perform a robust risk assessment of any additional RASD features specific to your system (e.g., eye-tracking, haptics, additional imaging modalities, and/or AI/ML-enabled features) to determine the appropriate performance testing to support each feature. A comprehensive performance testing plan should be developed based on the level of risk associated with each feature. For critical components, redundancy and fail-safe designs should be considered and tested to ensure reliability of the system. If your RASD is intended to be used concurrently with high energy imaging modalities or incorporates AI/ML-enabled

features, we recommend that you discuss your proposed approach with FDA through the Q-submission program.

For AI-enabled device software functions, FDA's draft guidance "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" provides recommendations on data management, model description, performance validation, and transparency, which will reflect FDA's current thinking once finalized. Where you anticipate post-authorization modifications to AI-enabled or other software functions of the RASD, you may propose a Predetermined Change Control Plan (PCCP) as described in FDA's guidance "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions."

(6) Reliability

Significance: Robust reliability testing is a crucial component to characterizing the consistent safety and performance of the RASD over a period of time. Reliability includes all aspects of the RASD, including hardware integrity (e.g., computers, robotic arms, actuators, sensors, surgical instruments, and surgeon console), software stability, and mechanical and electrical integrity. Reliability applies to RASDs, subassemblies, surgical instruments and other parts under cyclic loads, activations, or actuations. Reliability testing should demonstrate that the system will maintain its integrity over its service life and will not cause harm to the patient due to system or component failure.

Recommendation: Reliability testing should be performed for cyclically loaded or used RASDs, subassemblies, parts, hardware and software. You should be able to characterize the expected reliability (e.g., mean time between failures for repairable systems and subassemblies, mean time to failure or the time point at which 10% of the non-repairable components and instruments have failed (B10)) or demonstrate that the system and all its components are capable of safe and proper operation over the expected service life of the RASD and use life of accessories and compatible devices, as specified in the device labeling. Reliability is mentioned in many clauses of ANSI/AAMI ES60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.* In addition to testing consistent with ANSI/AAMI ES60601-1, particular considerations that should be addressed for RASDs include worst-case scenario loading, activation, or actuation to challenge reliability.

Reliability testing should demonstrate maintenance of control over surgical instruments and maintenance of the integrity of system information essential to perform surgery over the expected service life or service interval of your RASD. Over the expected service life or service interval of the RASD, you should have objective evidence, with a prespecified and justified acceptance criteria, that surgical instruments will remain under control at all times during use in patients, and that system information essential to perform surgery by qualified practitioners is not degraded to an unacceptable level. For instruments with actuating parts, testing should evaluate the instrument's ability to reliably perform its intended function (e.g., grip, cut) over its use life, and that the shaft maintains mechanical integrity under repeated flexural stresses. Instrument

reliability should be demonstrated using clearly defined acceptance criteria and well-defined test methods. A justification should be provided for the instrument selected for testing, if multiple instruments of the same type are compatible with your RASD.

For grip and cutting reliability testing, acceptance criteria should include specification of required grip force and quantitative performance criteria for cutting (e.g., maximum cutting force, completeness of cut, maintenance of cutting performance). The number of grip and cut cycles should be clinically justified within the methods section of your protocol. For reusable instruments, testing should include reprocessing between uses over the labeled use life. Sample size should be justified, and FDA recommends sufficient sample size for grip and cutting reliability testing to demonstrate 95% reliability with 95% confidence.[4] For grip reliability, testing should include worst-case loading conditions. For cutting reliability, the selected cutting material should be clinically justified. For shaft bending (i.e., cantilever) reliability, acceptance criteria should ensure that the device does not permanently deform or break under expected use conditions. Testing should subject the instrument to controlled cyclic bending forces that simulate the mechanical stresses expected during intended surgical procedures, and sample size should be justified.

Instrument failure modes, including jaw failure (e.g., articulating component can no longer effectively grasp or close on target tissue) and structural failure (e.g., shaft fracture or permanent deformation), should also be evaluated with defined acceptance criteria that ensure the instrument maintains functional and structural integrity under worst-case use. Jaw failure testing should include (1) quantification of the force required to cause jaw failure, and (2) cyclic loading (i.e., fatigue testing) to determine the number of loading cycles that result in jaw failure. Structural failure testing should quantify the maximum load that induces shaft fracture or permanent deformation beyond functional limits. Instruments should be tested under worst-case loading conditions. We recommend you refer to FDA's guidance, "Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery," for additional performance testing recommendations for electrosurgical instruments.

E. Software

Significance: Software utilized in a RASD provides the means to enable qualified practitioners to control the RASD to perform as intended in a safe and effective manner. Software also provides essential information to qualified practitioners and other trained OR staff through graphical user interfaces (GUI) or other means. Adequate software verification and validation that includes performance testing provides assurance that the device operates within safe parameters and functions as intended.

[4] A different reliability and confidence level may be appropriate depending on the circumstances (in such instances, we recommend that a rationale for the difference be provided).

Recommendation: Overall, the documentation related to the device software function(s) should provide sufficient evidence to describe the role of the device software function(s) in the context of the device's intended use and testing to demonstrate that the device software function(s) performs as designed. Refer to the FDA guidance, "Content of Premarket Submissions for Device Software Functions," (Premarket Software guidance) for a discussion of the software information that you should provide in your submission. The Premarket Software guidance outlines the recommended information to be provided in a premarket submission based on the "Documentation Level" associated with the device. We think generally the device software functions for a RASD warrant an "Enhanced" Documentation Level. If you believe that your device warrants a "Basic" Documentation Level as defined in the Premarket Software guidance, you should provide scientific explanation that supports your rationale for the Documentation Level based on the risks of the device software function(s) in the context of the device's intended use.

We recommend that you provide a comprehensive description of the device software function(s) supporting the operation of the RASD as described in the Premarket Software guidance, including the software's functionality, architecture, and risk management approach. This recommendation applies to original devices, and any software changes made to already-marketed devices when the submission of a new 510(k) is warranted. For further information on this topic, refer to "Deciding When to Submit a 510(k) for a Software Change to an Existing Device." Regardless, all changes to software must be verified and validated in accordance with the applicable clauses in ISO 13485:2016.[5]

Software verification and validation should include testing at the unit, integration, and full system levels for the RASD. At the full system level, you should employ objective metrics of performance, and include a rationale of how the testing would be representative of real-world use cases. Safety features warrant particular attention, including testing of safety notifications, communications, warnings to users, and resolution (e.g., notification on the graphical user interface). For device software function changes, submissions should include an analysis of appropriate testing strategies, methodologies, and justification for the selected testing approach. For example, the submission should explain whether regression testing versus full system testing is appropriate for the modified version of the device software function(s) based on the specific set of changes implemented. The impact of device changes on affected software system, units, and subunits should be identified and characterized.

[5] FDA issued a final rule that amends the majority of the requirements previously in 21 CFR Part 820 (Part 820) and incorporates by reference the 2016 edition of the International Organization for Standardization (ISO) 13485, Medical devices - Quality management systems – Requirements for regulatory purposes, in Part 820. As stated in the final rule, the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the previous Part 820, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the FD&C Act. 89 FR 7496.

If the device contains unresolved software anomalies, we recommend defining and utilizing a classification system for risk prioritization and having traceability for each anomaly. Additionally, we recommend that you include mechanisms to communicate mitigation strategies and other work-arounds to end users, as appropriate. This may include warnings and cautions for certain anomalies (e.g., system faults, unintended motion, system restarts).

We recommend using the final software version intended for commercial use in testing of the device. Version control and update deployment strategies should be documented, along with associated verification and validation requirements. Traceability should be maintained, which links software requirements to design, testing, and risk controls throughout the device lifecycle.

If the device includes off-the-shelf (OTS) software, you should provide the additional information as recommended in the FDA guidance, "Off-the-Shelf Software Use in Medical Devices," as well as any information about open-source components and proprietary modules used in the device.

A RASD may be a multiple function device product. A multiple function device product contains at least one device function and at least one "other function." FDA may assess the impact the "other function" has on the device function when assessing the safety and effectiveness of the device function (see section 520(o)(2) of the FD&C Act). Accordingly, manufacturers should consider the recommendations in the FDA guidance "Multiple Function Device Products: Policy and Considerations" (Multiple Functions guidance), which is applicable to all multiple function device products. For example, if you add non-device software functions (e.g., tracking surgical procedure time, recording endoscopic surgical procedure videos) to a RASD, you should assess the impact of your non-device software functions on your device function. This may include consideration of whether the non-device software functions impact the safety or effectiveness of the device function, such as whether the functions share underlying computational resources, data dependencies, or any other type of relationship, as interference between them could potentially degrade the performance of the device function. If there is an impact that could result in increased risk or have an effect on performance of the device function, then you should consider whether additional documentation should be provided in your marketing submission. For additional information, please refer to the Multiple Functions guidance.

For device software functions that interface with and control physical device components, appropriate non-clinical performance testing should be conducted to verify performance specifications in addition to software testing.

F. Cybersecurity

Significance: RASDs contain software, firmware and programmable logic, and may include interoperability, creating the ability to connect to the internet/network either directly or indirectly through the connectivity features present in the device design, or exchange and use information through an electronic interface. This can increase the surface area for cyber vulnerabilities and attack vectors. Failure to maintain cybersecurity can result in risks such as compromised device

functionality, loss of device availability, loss of data (medical or personal) availability and/or integrity, or exposure of other connected devices or networks to security threats. This in turn may have the potential to result in patient injury.

Recommendations: If a RASD meets the definition of a cyber device under section 524B(c) of the FD&C Act, then the premarket submission must meet the cybersecurity requirements under section 524B(b) of the FD&C Act. Refer to the FDA cybersecurity guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions," for a discussion of the cybersecurity documentation that you should provide in your submission.

In addition to the recommendations in the cybersecurity guidance referenced above, premarket submissions for RASDs should address several specific cybersecurity considerations. Submissions should identify all relevant assets, potential threats, and vulnerabilities on device functionality, end users, and patients, as well as an assessment of exploitability for device vulnerabilities. Based on this analysis, submissions should determine risk levels for identified threats and vulnerabilities and describe suitable mitigation strategies.

The cybersecurity assessment, including penetration testing, should take into consideration all network elements communicating with the RASD (including all sub-assemblies and other components), accessories, and compatible devices intended to connect to or interact with the system during pre-deployment, normal operation and maintenance. Submissions should identify relevant network elements connected to the RASD. This should include all back-end infrastructure, such as servers, databases, and cloud-based services, as well as all public and private networks used by the RASD for communication, such as data transmission, remote access and teleoperation, or system updates. For example, the assessment should include simulations where the RASD is communicating with a compromised hospital network.

G. Wireless Technology

Significance: In the design, testing, and use of wireless medical devices or devices with wireless technology capabilities, the correct, timely, and secure transmission of medical data and information is essential for the safe and effective use of both wired and wireless medical devices and systems.

Recommendation: We recommend that you consult FDA's guidance, "Radio Frequency Wireless Technology in Medical Devices," for recommendations on this topic.

In addition, we recommend that you follow the FDA-recognized consensus standards AAMI TIR69 *Risk Management of Radio-Frequency Wireless Coexistence for Medical Devices and Systems* for a risk management approach to addressing wireless coexistence and IEEE ANSI USEMCSC C63.27 *American National Standard for Evaluation of Wireless Coexistence* for the test methods used in evaluating wireless coexistence.

H. Training

Significance: The safety and effectiveness of RASDs is highly dependent on ensuring that the user can safely and effectively operate the system in accordance with the device labeling (i.e., achieve competency). Each RASD manufacturer should develop a training program that has been validated to facilitate users achieving device competency prior to clinical usage. Training should focus on the user's ability to work with the device user interface to perform specific tasks.

Recommendation: You should create and deliver an effective training plan for users consistent with the uses being sought for authorization, and provide an overview of the training plan in the premarket submission for your RASD. The training should be comprehensive and should have demonstrated effectiveness in developing device competency for users with varying levels of experience and clinical background. The training program and competency expectations should not only focus on surgeons, but also include other OR staff, such as bedside assistants and surgical scrub nurses, who interact with RASDs. For existing RASDs, the need for updates to existing training should be evaluated when changes are introduced to the device user interfaces, including addition of new instruments and new user groups.

When designing your training, you should consider the different user groups interfacing with the RASD, including their clinical background, familiarity with other robotically-assisted devices, and role in the procedure. Once appropriate user groups are identified, a variety of training modalities may be used, such as didactic training on the capabilities and features of the RASD, using a robotic surgical simulator, and use of the RASD in bench, animal and/or cadaver models. It is important to establish specific criteria to evaluate the success of training delivery and ensure that different user groups are able to effectively interface with the system. For example, the number of procedures generally necessary for surgeons to achieve competency on the RASD for the uses being sought for authorization.

I. Human Factors

Significance: Use-related hazards are hazards that might result from aspects of the user interface design that cause the user to fail to adequately or correctly perceive, read, interpret, understand or act on information from the RASD. They generally do not involve specific failure modes associated with faulty mechanical, electrical, and/or software components that are previously known or reasonably anticipated. To understand the use-related hazards associated with the RASD, it is necessary to have an accurate and complete understanding of the device user interfaces, use scenarios, the tasks within these scenarios that could lead to serious harm to the patient or user, where harm is defined to include compromised medical care (i.e., critical tasks), and how the RASD supports the user to complete these tasks in a safe manner.

Recommendation: To address use-related hazards, human factors evaluations should start early in the device design process and should occur iteratively. When designing and developing RASD technology, human factors processes and evaluations are important to identify use-related device hazards, implement risk mitigation strategies to minimize use-related hazards, and demonstrate

that the device can be used without serious use errors by the intended users, for the intended uses and under the expected use conditions. This RASD draft guidance provides RASD-specific recommendations on human factors information to be included in the premarket submission for a RASD. There are various methods for the preliminary human factors analyses and evaluations, which are discussed further in FDA's guidance, "Applying Human Factors and Usability Engineering to Medical Devices."

If during actual use of the RASD, participants from more than one user group (e.g., surgeons, OR staff such as bedside assistants, surgical scrub nurses) will work simultaneously with the RASD, then this factor should be considered when identifying participants for your human factors validation study to further demonstrate that the device user interface supports the safe and effective use in such a use scenario. We recommend recording and reporting all available and used device features in each device use scenario.

We recommend that you conduct use-related risk assessments and include preliminary analysis and evaluations throughout the life cycle of your device development. Once you have a device user interface that represents the final design, you should perform human factors validation testing. All points of interaction between the user and the device (e.g., those parts of the device that users see, hear, touch) should be included in your human factors validation testing. All sources of information transmitted by the device (including packaging and labeling), training and all physical controls and display elements (including alarms, the logic of operation of each device component, and of the user interface system as a whole) should also be included in the validation testing. In this testing, you should focus on real world use of your device in a realistic environment with representative users, which may include teams working together as they would in a normal operating room.

Specifically, for RASDs, the following use-related hazards should be considered and addressed:

- Potential hazards associated with surgical planning, instrument preparation and connection to other systems
- Potential hazards associated with device reprocessing
- Impact of no experience with RASD technology on the user's task performance
- Impact of experience with other RASDs to determine if potential use errors associated with negative knowledge transfer impact the user's task performance and/or mental models of the subject device system
- Potential hazards associated with instrument removal, exchanges, and port switching (each instrument should be assessed separately)
- Interaction between the surgeon and surgical team during use of the RASD
- Motions and positions of the RASD will not interfere with intended user workflow (e.g., staff will be able to abort the RASD in the event of an emergency, interact with the device to change or service instruments, and effectively communicate during RASD use)

You should also consider the following:

- All the features enhancing or augmenting human capabilities should be included in the testing even if they are optional to the user. You should provide testing that is representative of actual use to ensure that the users can perform critical tasks without use error under realistic conditions.
- If multiple set-up options are available (e.g., different robotic arm configuration, integration of different surgical instruments or accessories or compatible devices, multiple users), you should include testing to show that users would be able to set-up and deploy the appropriate configurations for the various specialties, procedures and tasks.
- Emergency procedures (e.g., conversion to open or laparoscopic procedures, emergency withdrawal of the device from the patient, power loss, emergency stops) to ensure that your risk mitigations, safety features, and emergency instructions in the labeling are appropriate.

FDA's guidance, "Content of Human Factors Information in Medical Device Marketing Submissions" includes recommendations for the content of human factors engineering and usability engineering (HFE/UE) information included in marketing submissions. The marketing submission should, where appropriate based on the applicable statutory and regulatory criteria, demonstrate that the device design adequately meets the needs of the intended users and that the device is appropriately safe and effective for the intended users, uses, and use environments. It should also include, where appropriate, information that explains the presence or absence of critical tasks, human factors validation testing to assess the effectiveness of risk control strategies, and a discussion of residual risks.

J. Electrical Safety and Electromagnetic Compatibility (EMC)

Significance: RASDs are medical electrical equipment and therefore may expose the operator and patient to hazards associated with the use of electrical energy or may fail to operate properly in the presence of unforeseen electromagnetic disturbance.

Recommendation: RASDs should be tested to demonstrate that they perform as anticipated in their intended use environment. The device-specific essential performance (i.e., performance of a clinical function, other than that related to basic safety, in which loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk) of the RASD should be defined and clearly outlined in the risk analysis in the premarket submission. For the RASD, the essential performance should include its ability to accurately and reliably perform the robotic functions within specified limits. The electrical safety and EMC information (e.g., test protocols, test results, risk management activities, evidence of conformance with consensus safety standards) should demonstrate that the risk associated with the essential performance of the device is adequately mitigated under normal or single fault conditions, and that the device performs as anticipated in its intended use environment. We recommend that this testing be

performed as described in the currently FDA-recognized versions of the following standards for medical electrical equipment safety and electromagnetic compatibility:

- ANSI/AAMI ES60601-1: *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- ANSI/AAMI/IEC 60601-1-2: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests*
- IEC 80601-2-77: *Medical electrical equipment – Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT*

In addition, unforeseen risks (e.g., thermal, capacitive coupling, excessive leakage current) may result from the combined use of endoscopes and other energized devices. For high frequency energized devices, thermal hazards present a greater risk to the patient and operator than risks associated with electric shock. We also recommend testing consistent with the following additional standards as appropriate:

- IEC 60601-2-2: *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories*
- IEC 60601-2-18: *Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

If submitting a Declaration of Conformity to the above standards, we recommend that appropriate supporting documentation such as an assessment of the results and how conformity was determined be provided. Information regarding test methods used should be provided because this series of standards includes general methods with multiple options and, in some cases, does not include specific acceptance criteria or address assessment of results. For additional information on providing electromagnetic compatibility information in a premarket submission, see FDA's guidance, "Electromagnetic Compatibility (EMC) of Medical Devices."

K. Optical Radiation Safety

Significance: Exposure to electromagnetic energy delivered by RASD in the form of ultraviolet (UV), visible (VIS), or infrared (IR) radiation may have negative health effects on the patient or user. This could result in corneal or retinal injuries, photochemical or thermal injuries of the skin or internal organs, or other injuries.

Recommendation: Your submission should identify optical radiation hazards specific to the design of the RASD and mitigate these hazards through performance testing, verification and validation, and labeling. We recommend that RASDs demonstrate conformance with applicable FDA recognized optical radiation safety consensus standards. In addition, all laser emitting RASDs must comply with all applicable requirements of 21 CFR Chapter I, Subchapter J -

Radiological Health. For additional information regarding regulation of laser products and instruments, see FDA's website Laser Products and Instruments, and refer to FDA's guidance, "Laser Products – Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 (Laser Notice No. 56)."

L. Sterility

Significance: Many RASD components come in contact with blood, sterile tissue, and/or are used in the sterile field. Therefore, every part of the device that will be within the sterile field should be adequately sterilized to minimize infections and related complications or covered with an appropriate sterile drape.

Recommendation: For devices labeled as sterile, we recommend that you provide the information outlined below.[6]

1. For the sterilization method, the manufacturer should provide the following:
   a. A comprehensive description of the sterilization method/process;
   b. A description of the sterilization chamber if not rigid, fixed (e.g., flexible bag);
   c. The sterilization site;
   d. In the case of radiation sterilization, the radiation dose; and
   e. For chemical sterilants (e.g., ethylene oxide (EO), H_2O_2), the maximum levels of sterilant residuals that remain on the device, and an explanation of why those levels are acceptable for the device type and the expected duration of patient contact.

      For additional information on EO sterilization, and specifically EO residuals, please see the currently recognized version of the standard, ISO 10993-7 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*.

2. For the sterilization method used, you should provide a description of the method used to validate the sterilization cycle (e.g., the half-cycle method) as well as the sterilization validation data. The submission should also identify all relevant consensus standards used and identify any aspects of the standards that were not met. In the absence of a recognized standard, a comprehensive description of the sterilization process and the complete validation protocol should be submitted for review.

3. You should state the sterility assurance level (SAL) of 10^{-6} for devices labeled as sterile, unless all parts of the device are intended only for contact with intact skin. You should

[6] For 510(k) submissions, we recommend that you provide information for the final sterile device as described in FDA's guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."

state the SAL of 10^{-3} for devices labeled as sterile that are intended only for contact with intact skin.

M. Reprocessing

Significance: Many RASD components are reused and should be adequately cleaned, disinfected, and sterilized between uses to minimize infections while preventing device degradation. RASD components can also be single-use medical devices initially supplied as non-sterile to the user and necessitate the user to process the device prior to its use.

Recommendation: Validated instructions on how to reprocess a reusable device or single-use device that is provided non-sterile to the user are critical to ensure that a device is appropriately prepared for its initial and/or subsequent uses. Any RASD components (e.g., operator console or other user interface) that are used outside the sterile field and whose surfaces contact only intact skin should be adequately cleaned and disinfected prior to use. Any RASD components that are used in the sterile field but are too large to be practicably sterilized (e.g., component of the bedside/patient subassembly that is too large to fit inside a legally-marketed sterilizer) should be cleaned and disinfected prior to use and covered with a sterile drape. For RASD components that contain small lumens, small components, and/or difficult-to-reach inner surfaces, an ultrasonic washing step (or an alternative method validated to achieve equivalent cleaning efficacy) should be included to ensure adequate cleaning of all surfaces, along with instructions for flushing the inner surfaces. For recommendations regarding the development and validation of processing/reprocessing instructions in your proposed device labeling, please refer to FDA's guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," (Reprocessing guidance).

If an automatic washer/disinfector is used during the reprocessing of your RASD, an additional separate validation of the automatic washer/disinfector should be performed for cleaning your RASD. The automatic washer/disinfector may have specific attachments and components, such as a rack system designed for your RASD components. We recommend validating all automatic reprocessing using the same automatic washer/disinfector and cycle as described in the RASD labeling instructions. We recommend that you perform this validation testing using real world in-use and simulated use conditions (e.g., using an adequate soil and soiling technique) to ensure that the automatic washer/disinfector adequately cleans/disinfects the device and meets the pre-specified cleaning and disinfection acceptance criteria. As described in the Reprocessing guidance, as part of your general reprocessing validation processes, a visual inspection using appropriate magnification (e.g., 10x) should be conducted to ensure adequate cleaning.

Performance testing should demonstrate that the RASD continues to perform according to original device specifications (i.e., un-reprocessed) after each reprocessing procedure, including at the end of its service life (i.e., after the end-of-life, final reprocessing as described in the labeling).

N. Shelf Life and Packaging

Significance: Shelf-life testing is conducted to support the proposed expiration date through evaluation of the package integrity for maintaining device sterility and/or evaluation of any changes to device performance or functionality.

Recommendation: With respect to package integrity for maintaining device sterility, you should provide a description of the packaging, including how it will maintain the device's sterility, the protocol(s) used for your package integrity testing, the results of the testing, and the conclusions drawn from your results.[7]

We recommend that a package validation study include simulated distribution and associated package integrity testing, as well as an aging process (accelerated and/or real time), and associated package integrity testing (e.g., seal strength testing). We recommend you follow the methods described in the FDA-recognized series of consensus standards ISO 11607-1 *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* and ISO 11607-2 *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.*

With respect to evaluating the effects of aging on device performance or functionality, shelf-life studies should evaluate the critical device properties to ensure it will perform adequately and consistently during the entire proposed shelf life. To evaluate device functionality, we recommend that you assess each of the bench tests described in Section IV.D and repeat all tests that evaluate design components or characteristics that are potentially affected by aging using aged devices.

We recommend that you provide the protocol(s) used for your shelf-life testing, the results of the testing, and the conclusions drawn from your results. If you intend to extend the shelf life of the RASD after an initial premarket approval, we recommend that you provide the protocol(s) to support the extension in the original submission (see 21 CFR 814.39(a)(7)). We recommend that real-time aging be conducted to confirm the results of any accelerated aging to determine definitively the effects of aging on the maintenance of sterility and device performance. If you use devices that have been subject to accelerated aging for shelf-life testing, we recommend that you specify the way in which the device was aged and provide a rationale to explain how the results of shelf-life testing based on accelerated aging are representative of the results if the device were aged in real time. We recommend that you age your devices as described in the current FDA-recognized version of ASTM F1980: *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices* and specify the environmental parameters established to attain the expiration date. For devices or components containing polymeric materials, you should plan to conduct testing on real-time aged samples to confirm that the accelerated aging is reflective of real-time aging. This testing should be conducted in parallel

[7] For 510(k) submissions, you should provide a description of the packaging, including how it will maintain the device's sterility, and a description of the package integrity test methods, but not the package test data.

with FDA's review of your submission with results documented to file in your design and development file[8] (i.e., complete test reports do not need to be submitted to FDA).

O. Pyrogenicity

Significance: Pyrogenicity testing is used to help protect patients from the risk of febrile reaction due to gram-negative bacterial endotoxins and/or chemicals that can leach from a medical device (e.g., material-mediated pyrogens).

Recommendation: To address the risks associated with the presence of bacterial endotoxins, RASDs and accessories that are in contact directly or indirectly with the cardiovascular system, the lymphatic system, or cerebrospinal fluid, or have similar systemic exposure should meet applicable pyrogen limit specifications by following the recommendations outlined in FDA's guidance, "Pyrogen and Endotoxins Testing: Questions and Answers." To address the risks associated with material-mediated pyrogenicity, you should follow the recommendations in FDA's guidance, "Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

For devices intended to be labeled as "non-pyrogenic," we recommend both bacterial endotoxins and material-mediated pyrogens be addressed.

P. Biocompatibility

Significance: RASDs contain patient-contacting materials that, when used for their intended purpose (i.e., contact type and duration), may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all direct and indirect patient-contacting materials present in your device. If your materials are identical in chemical composition, manufacturing, and processing methods (including sterilization) to materials with a history of successful use in another RASD with the same contact type and duration for similar applications in the same patient population, you can reference previous testing experience or the literature, if appropriate. For some device materials, it may be appropriate to provide a reference to either a recognized consensus standard, or to a Letter of Authorization (LOA) for a device Master File (MAF). You should refer to the following FDA webpage for additional information on using device MAFs: https://www.fda.gov/medical-devices/premarket-approval-pma/master-files. For polymeric materials, you should identify each material by trade name and manufacturer.

[8] 21 CFR 820.10(c) requires that manufacturers of class II, class III, and certain class I devices comply with the design and development requirements in ISO 13485, clause 7.3. For design and development file requirements, see ISO 13485:2016 subclause 7.3.10.

If you are unable to identify a legally marketed device with the same nature of contact (e.g., location, duration) that uses the same materials and manufacturing process as used in your device, we recommend that you conduct and provide a biocompatibility evaluation as recommended in FDA's biocompatibility guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'." The evaluation should explain the relationship between the identified biocompatibility risks, the information available to mitigate the identified risks, and knowledge gaps that remain. You should then identify any biocompatibility testing or other evaluations that were conducted to mitigate remaining risks. We recommend that you consider the recommendations in this guidance, which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

As described in ISO 10993-1: *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and Attachment A of FDA's biocompatibility guidance, RASDs are typically external communicating devices in contact with tissue/bone/dentin for a limited contact duration. However, some RASD components may come into contact with either blood path, indirect and/or circulating blood, and should be tested for the appropriate biocompatibility endpoints. Therefore, the following endpoints should be addressed in your biocompatibility evaluation for these RASD components:

- cytotoxicity;
- sensitization;
- irritation or intracutaneous reactivity;
- acute systemic toxicity;
- material-mediated pyrogenicity;
- hemocompatibility (based on contact); and
- genotoxicity (based on contact).

ISO 10993 provides specific recommendations regarding particulates observed in extracts during biocompatibility testing. Please note that FDA considers particulates to encompass any suspended particles in the extract (e.g., fragments) or other matter that were not present prior to extraction. All particulates found in the extract should be characterized, or an adequate rationale should be provided as to why the particulates do not raise biocompatibility or safety concerns. Additional testing may be requested to ensure the biocompatibility of the subject device, if adequate characterization and rationale cannot be provided for the presence of particulates.

Some test methods for the above endpoints are part of the Accreditation Scheme for Conformity Assessment (ASCA) Program, which can be leveraged by manufacturers to streamline the review of these test results. For more information, see the ASCA Program website.

If your device has a different contact classification than listed above, we recommend that you consult FDA's biocompatibility guidance to determine the applicable endpoints.

For certain components of your RASD that may have incidental contact, it is still important to evaluate these components as indirect contacting components. We recommend that you discuss the different components of your system with the Agency via the Q-submission program to clarify whether biocompatibility assessment is needed if you have uncertainty.

For RASD components or accessories (e.g., surgical drapes) that will come in contact with the patient and/or surgical team (i.e., contact with intact skin), we recommend the following biocompatibility endpoints to be evaluated:

- Cytotoxicity;
- Sensitization;
- Irritation or intracutaneous reactivity

We recommend that biocompatibility testing be performed on the final, finished device. If your device is reusable, we recommend that you perform biocompatibility testing on your subject device after the maximum number of use cycles to demonstrate that repeated use and reprocessing do not adversely affect the biocompatibility of your device over the course of its service life.

Q. *In Vivo* Evaluation

Significance: An *in vivo* evaluation of the device performance is important for assessing the safety and effectiveness of the RASD for the uses being sought for authorization. To support authorization of a broad use of the device (e.g., general surgery, gynecology, urology, otolaryngology, or anatomical region) or a more specific use (e.g., colectomy, total radical hysterectomy, radical prostatectomy, transoral robotic surgery (TORS)), *in vivo* evaluation should demonstrate that the device can reliably function in an operative environment and assist in performing the coordinated maneuvers necessary to complete these surgical procedures.

Recommendation: *In vivo* evaluation may encompass non-clinical or clinical data. FDA's data requests typically follow a stepwise analytical process to ensure the information requested to support a premarket submission reflects the least burdensome approach.[9] Non-clinical *in vivo* studies generally are requested when a description of technological characteristics and other forms of non-clinical bench performance testing are not sufficient to support a premarket submission for the device. Clinical data may be requested for new RASDs or when changes in device user interface and/or robotic technology in existing RASDs raise questions that can only be addressed by clinical data, due to a lack of non-clinical *in vivo* models with validated clinical endpoints for the procedures in question, variable clinical experience due to differences in patient demographics or co-morbidities, and clinical scenarios not encountered in non-clinical *in vivo* models.

[9] See the FDA guidance "The Least Burdensome Provisions: Concept and Principles."

In the context of RASDs, when seeking authorization for use of the device for a surgical specialty (e.g., general surgery, gynecology), you should include the full range of extirpative and/or reconstructive elements in the intended anatomical location. When seeking authorization for use of a RASD for a specific procedure, you should provide evidence of a successfully completed surgical procedure in its entirety. If you are seeking authorization of your RASD for multiple procedure types, we recommend that you consider using an umbrella and covered procedure approach to extrapolate device use data from procedures of higher complexity and risk to ones with lesser complexity and risk (see Appendix A for detailed examples of the umbrella and covered procedure paradigm). For this last category of RASDs, when submitting a 510(k), we recommend that you include all procedures in the indications for use statement. Alternatively, you may choose to describe the full range of procedures outside of the indications for use statement, such as in a proposed instructions for use. If the list of procedures is not located in the indications for use statement, your indications for use statement should reference the specific proposed labeling document where this information is located.

(1) Non-Clinical *In Vivo* Data

Well-designed non-clinical *in vivo* animal studies may be used to evaluate RASD safety and performance of specific surgical tasks and procedures that cannot be evaluated through bench performance testing. The types and locations of the surgery performed depend upon the uses being sought for authorization for the RASD. Both acute and chronic studies, in which all functional surgical capabilities and surgical tasks are tested in a coordinated fashion, are recommended. During these evaluations, the RASD should be tested as a whole, using all of the instruments within a particular system to perform surgical tasks in a coordinated fashion, to demonstrate the device's ability to complete the entire surgical procedure safely and effectively using pre-specified tasks, endpoint measures, and success criteria. We recommend that each surgical procedure be broken down and evaluated based on procedure steps, surgical tasks, anatomy/tissue involved, and instruments used. Specific endpoints testing should focus on device compatibility (with individual instruments and system as a whole), usability, adverse events, complications, and other relevant observations. The sample size for your animal studies should be based upon your chosen endpoints and include enough animals to provide a meaningful interpretation.

We recommend chronic studies for assessing morbidity and mortality, time to return to normal activity, wound healing, surgical instrument effects (e.g., vessel sealing, stapling), and the durability and success of surgical reconstructive elements (e.g., suture line, anastomosis). Criteria for chronic studies should be clear and specific. For both acute and chronic studies, FDA recommends that a comprehensive, systematic necropsy (including gross and histologic assessments) be performed by a board-certified veterinary pathologist on all animals enrolled in the study to identify and describe any abnormal findings that may be a result of the device or the procedure. FDA recommends performing histology on all tissues potentially affected, directly and indirectly, by the device. Refer to the FDA guidance, "General Considerations for Animal Studies Intended to Evaluate Medical Devices," for additional information.

FDA supports the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage manufacturers to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method.

We encourage manufacturers to use the Q-submission Program to obtain feedback on the design of an animal study if an animal study is warranted, and to discuss any proposed use of non-animal test methods. Additionally, for general information and recommendations regarding animal studies used to support medical device submissions, refer to the FDA guidance, "General Considerations for Animal Studies Intended to Evaluate Medical Devices."

(2) Clinical Data

In some cases, non-clinical evaluation does not fully characterize all clinical experience associated with the RASD, including clinical risks and device performance (e.g., usability and outcomes). Clinical data can be obtained from a number of sources, including clinical performance testing (e.g., prospective clinical studies), real-world evidence (RWE), or clinical literature. For new RASDs (i.e., have not previously received marketing authorization in the U.S.), clinical data are often needed to support premarket submissions. For modifications to RASDs that have previously received a marketing authorization in the U.S., clinical data may be requested in situations such as the following:

- new intended use or indications for use;
- intended use in special populations, such as pediatric patients (see also FDA guidance, "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices");
- different technology;
- cases where non-clinical performance testing raise issues that warrant further evaluation with clinical evidence; and/or
- specific statements about device performance, such as superiority, or treatment of a specific disease or condition.

a) Clinical Performance Testing

Clinical investigations of devices to determine safety and effectiveness are subject to the Investigational Device Exemptions (IDE) regulation at 21 CFR Part 812. For such investigations, an IDE approved under 21 CFR 812.30 or considered approved under 21 CFR 812.2(b) exempts the device from certain requirements of the FD&C Act and the regulations issued thereunder. Generally, FDA believes the investigational RASDs addressed by this guidance document are significant risk devices (see 21 CFR 812.3(m)), and that such investigations would not be eligible for the abbreviated requirements of 21 CFR Part 812.2(b). Please see the FDA guidance, "Significant Risk and Nonsignificant Risk Medical Device Studies." In addition to the requirements of 21 CFR Part 812, such investigations are subject to the regulations governing

institutional review boards (21 CFR Part 56) and the protection of human subjects (21 CFR Part 50), including informed consent of human subjects (21 CFR Part 50, subpart B).

When data from clinical investigations conducted outside the U.S. are submitted to FDA to support an IDE or a device marketing application or submission for RASDs, the requirements of 21 CFR 812.28 may apply.[10] 21 CFR 812.28(a) outlines the conditions for FDA acceptance of data from clinical investigations conducted outside the U.S. to support an IDE or a premarket submission. For more information, see the FDA guidance, "Acceptance of Clinical Data to Support Medical Device Applications and Submissions: Frequently Asked Questions." To support marketing your RASD in the U.S., it is important for the clinical data to be representative of the intended U.S. patient population and evaluate how the RASD will be used within a typical U.S. operating room. Sponsors should demonstrate that outside the U.S. patient cohorts have similar demographic characteristics and comorbidities as the intended U.S. patient populations, and outside the U.S. investigators and surgeons have similar training, experience, and practice patterns as the targeted U.S. user groups. The clinical data should also evaluate how different user groups interact with the RASD, including whether the training is effective to ensure different users can competently use the system and whether previous experience, either clinical background or familiarity with other robotic systems, can impact the different users.

If you expect that information from first-in-human or early feasibility studies could influence the development of your device, such as refinement of your indications for use, structuring your performance testing plan, and/or configuring your risk mitigation strategy, the FDA guidance, "Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Studies, Including Certain First in Human (FIH) Studies," may be useful.

Clinical study design elements will vary depending on the device, surgical procedure(s), and clinical risk involved. However, FDA generally recommends an evaluation of the following surgical endpoint measures, particularly for the surgical RASD applications referenced as umbrella and covered procedures in Appendix A. Other RASD uses, such as intravascular procedures, may warrant different or additional endpoints:

1. Length of Hospital Stay
2. Intraoperative Adverse Events
3. Transfusion Rate (Estimated blood loss)
4. Conversion Rate
5. Post-Operative Adverse Events (through 30 days)
6. Readmission Rates (through 30 days)
7. Reoperation Rates (through 30 days)
8. Mortality
9. Operative Time

[10] 21 CFR 812.28 applies to relevant clinical investigations that enroll the first subject on or after February 21, 2019, and that support an IDE or a device marketing application or submission to FDA.

The data used to support these procedural endpoints may come from a combination of different sources, including clinical performance testing, RWE, and clinical literature. Study endpoints should be analyzed alongside comparator information when it is available. Comparator information can be from robotic, laparoscopic or open surgical procedures. When choosing a comparator, clinical data from robotic procedures is preferred over laparoscopic or open data. If robotic data is unavailable, laparoscopic clinical data is preferred over data from open procedures. As noted above, while these endpoints are typically recommended for general surgery RASD applications, the relevant endpoints for your study may vary depending on the specific indications for use and labeled procedure(s) you intend to seek. Additional endpoints may be requested based on unique clinical risks related to specific procedures, anatomic locations, anticipated pathology and/or surgical specialties. Please see Table 3 below for specific examples.

Table 3. Recommended Additional Procedural Endpoints for Clinical Evaluation of RASDs

Procedure	**Additional Procedural Endpoints**
Pancreaticoduodenectomy (Whipple)	Pancreatic leak/fistula rate*
Roux-en-Y Bypass	Anastomotic leak rate* Anastomotic stricture rate*
Hysterectomy	Vaginal Cuff dehiscence** Vaginal Bleeding**
Microvascular Anastomosis Creation in Free-Flap Tissue Reconstruction	3-day Reoperation rate Free Flap Survival rate*
Endoscopic Submucosal Dissection for Colorectal Lesions	Perforation rate* Bleeding rate* requiring conversion or transfusion as treatment
Transurethral Excision of Bladder Lesions	Rate of detrusor muscle in pathologic specimen Rate of evaluable margin in specimen Bladder perforation rate*

*Through 30 days
**Through 6 weeks

For additional information on pivotal clinical study design recommendations, refer to the FDA guidance "Design Considerations for Pivotal Clinical Investigations for Medical Devices."

b) Real-World Evidence

In some cases, "real-world data" (RWD) may be used to support regulatory decision-making for RASDs. You should refer to the FDA guidance "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices" to identify factors that FDA considers important to demonstrate whether the RWD are relevant and reliable for a particular regulatory

decision relating to medical devices, as well as information on how FDA intends to assess these factors.

c) Clinical Data from Literature

In some cases, clinical data from literature (e.g., literature that describes the use of your specific device in humans) may be used to support the uses being sought for authorization in lieu of clinical studies that you conduct under an IDE. In some cases, judicious use of clinical literature may reduce the burden of clinical performance testing. For example, published clinical literature can be used as a comparator for evaluating RASD performance, or to support the expansion of the authorized uses (e.g., to add a procedure).

Supporting clinical literature should address the safety and effectiveness of the device when used in humans. You should clearly summarize the key safety and effectiveness findings of each source and how they support your submission. This data may include near-term, mid-term, or long-term follow up data demonstrating the performance and outcomes associated with use of the device. You should also report any adverse events described in the literature.

To ensure the reliability and reproducibility of any systematic literature review, you should clearly describe your methodology for paper selection and analysis, and whether you have adhered to any guidelines (e.g., Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA)). If you select review papers or meta-analyses over original research articles, you should provide a rationale. If other reference resources have been used, we recommend that you include a list of these references. You should identify and explain how you have mitigated bias in the literature. You should summarize the limitations of the research described in the papers and how these may or may not affect your conclusions.

When leveraging clinical data from the literature, you should disclose any relationships you have with the authors and potential conflicts of interest, including if you have financially supported the work described in the literature or have business ties with any of the authors.

(3) Post-Market Clinical Data

If the totality of the premarket clinical data includes uncertainties in the characterization of the safety and effectiveness of the RASD, such as long-term outcomes, rare adverse events, or performance of the device in certain subgroups of patients or user populations, FDA may require additional post-market clinical data collection. This data may consist of post-market data collection on specific adverse events, safety events, certain surgeon groups (e.g., varying experience), or certain patient demographics (e.g., race, sex, comorbidities) that are expected in the intended U.S. patient population.

R. Labeling

A premarket notification, premarket approval application, and de novo classification request must include proposed labeling. See 21 CFR 807.87(e); 21 CFR 814.20(b)(10); 21 CFR 860.220(a)(18). Proposed labels and labeling should describe the RASD, its intended use, and the directions for use in sufficient detail so as to clearly facilitate safe use of the device when used as intended.

All currently authorized RASDs are prescription devices, and thus are exempt from having adequate directions for use under section 502(f)(1) of the FD&C Act, 21 U.S.C. § 352(f)(1), as long as the conditions in 21 CFR 801.109 are met. For instance, 21 CFR 801.109(d) requires that labeling that furnishes information for use of the prescription device must, among other things, include "adequate information for such use, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended."

The user manual or instructions for use for a RASD should include the following:

- Consistent indications for use throughout;
- All appropriate warnings, precautions, and contraindications;
- Prominent emergency withdrawal procedures;
- Information on patient selection for each RASD procedure;
- Information on learning curve for the device's intended use. If the umbrella and covered procedure paradigm is being used, learning curve information should be included for the umbrella procedure(s);
- Information on device sterility (Refer to Section IV.L for details);
- Instructions and recommendations for reprocessing device components (Refer to Section IV.M for details);
- Information on electrical safety and electromagnetic compatibility (see FDA's guidance "Electromagnetic Compatibility (EMC) of Medical Devices" for more details);
- Recommendations for cybersecurity (Refer to Section IV.F for details);
- Identifying information (e.g., manufacturer name, device name, and model number) for all accessories and compatible devices that are for use with your RASD; and
- Prominent display of manufacturer contact information and labeling revision number.

Your labeling should contain a summary of all *in vivo* evaluations performed, including any non-clinical and clinical data. The summary should briefly describe the study protocol(s), including the number of subjects and type of procedures performed in each study. Summaries of clinical data (e.g., clinical studies, real world evidence, clinical literature) should include results for the nine primary surgical endpoints, and any additional endpoints if applicable, as described in Section IV.Q(2) Clinical performance testing.

For recommendations on training materials and their description in the device labeling, refer to Section IV.H Training.

To clarify that marketing authorization is limited to the execution of specific surgical procedures, you should also include the following statement, if applicable, in your device labeling:

Outcomes related to the specific treatment of underlying disease or patient condition were not evaluated as part of the marketing authorization for this robotically-assisted surgical device. Clinical data for the authorization were based on evaluation of the device as a surgical system that assists in the accurate control and performance of coordinated surgical tasks in the form of specific surgical procedures.

RASDs are generally not safe for use in a Magnetic Resonance (MR) environment and, absent testing demonstrating otherwise, should be labeled as "MR Unsafe." If your RASD will be labeled for use in an MR environment (i.e., MR Conditional), we recommend obtaining feedback from FDA via the Q-submission Process. For additional information regarding this topic, please refer to the FDA guidance, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment."

Appendix A. Umbrella and Covered Procedure Paradigm

The umbrella and covered procedure paradigm is intended to be a least burdensome approach for developing the minimum amount of data necessary to support a finding that a RASD is appropriately safe and effective for its uses.

An umbrella procedure is a surgical procedure of sufficient complexity and risk such that performance data derived from the umbrella procedure may be leveraged to provide support for the safe and effective use of the RASD for covered procedures. A covered procedure is a surgical procedure in the same surgical specialty (e.g., general surgery) as the umbrella procedure, but one that is of lesser complexity and risk than its umbrella procedure. Specifically, *in vivo* data from a procedure with sufficient complexity and higher risk (i.e., umbrella procedure) often can be leveraged to support the authorization of the device for procedures of lesser complexity and risk (i.e., covered procedures) within the same surgical specialty without additional specific performance data for that procedure. In general, the benefit-risk profile of the RASD for umbrella procedures should be similar or greater than for covered procedures. Note that this paradigm may be appropriate to support premarket submissions to add specified surgical procedures but not for seeking marketing authorization for other changes in indications for use, such as for the treatment of a specific disease or condition.

There is no set list of appropriate umbrella and covered procedures. However, umbrella procedures generally contain identical or very similar procedural steps as the associated covered procedures. Additionally, umbrella and covered procedures are generally under the same surgical specialty as stated in the indications for use and may be performed in similar anatomic locations. You should consider designing your performance testing strategy based on how the procedures chosen may be representative of the device uses being sought for authorization. Illustrative examples for how data from umbrella procedures could be leveraged to support the authorization of the RASD for specific covered procedures are provided in the tables below and broken down by surgical specialties. You should note these examples do not represent the only ways to apply the umbrella and covered procedure paradigm for a given surgical specialty.

Although the provided examples of umbrella and covered procedures are based within the same surgical specialties, in the future, there may be circumstances where one umbrella procedure may be able to cover more than one anatomical area or surgical subspecialty (e.g., if the procedural complexity, risks, and tasks are similar within the different anatomical areas). Additionally, a combination of umbrella procedures and/or covered procedures within a surgical specialty or subspecialty may be appropriate to support the marketing authorization of a RASD for an entire surgical specialty. Examples of this are included within each specialty category in the tables below.

The following examples are not intended to be fully representative of all possible umbrella/covered procedures or all procedure combinations that may support marketing authorization of a RASD for different surgical specialties. The examples also are not intended to signify that leveraging data from these umbrella procedures to covered procedures will always be

appropriate. Given the complexity of choosing umbrella and covered procedures, FDA encourages interaction through the Q-submission process to obtain feedback regarding these topics.

Table 4. Example Umbrella and Covered Procedures for Colorectal Surgery

Umbrella Procedures	Covered Procedures
Low anterior resection/inter-sphincteric resection (LAR/ISR)	Low anterior resection/total mesorectal excision (LAR/TME), Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy), Small Bowel Resection, Lysis of adhesions, Rectopexy, Abdominoperineal Resection (APR), and Appendectomy
Low anterior resection/total mesorectal excision (LAR/TME)	Colectomy (Right, Left, Transverse, Total, Hemi & Sigmoidectomy), Small Bowel Resection, Lysis of adhesions, Rectopexy, Abdominoperineal Resection (APR), and Appendectomy
Right Hemicolectomy	Small bowel resection, Appendectomy, Lysis of adhesions

Clinical data from the combination of procedures outlined in Table 5 below might be used to support authorization of a RASD for the colorectal subspecialty.

Table 5. Example Procedure Combination for Colorectal Subspecialty

Colorectal Subspecialty Procedures
Low Anterior Resection/Total Mesorectal Excision (LAR/TME)
Right Hemicolectomy

Table 6. Example Umbrella and Covered Procedures for Gastric Surgery

Umbrella Procedures	Covered Procedures
Roux-en-Y Bypass (might be used to support authorization for the gastric subspecialty)	Gastrectomy, Cholecystectomy, Splenectomy, Gastric Sleeve, Lysis of adhesions, Nissen Fundoplication, Hiatal Hernia repair
Gastrectomy	Gastric Sleeve, Lysis of adhesions
Nissen Fundoplication	Splenectomy, Cholecystectomy, Lysis of adhesions

RASDs may be authorized for either ventral or inguinal hernia repair alone, or clinical data from the combination of procedures outlined in Table 7 below might be used to support authorization of a RASD for general hernia repair.

Table 7. Example Procedure Combination for General Hernia Use

General Hernia Procedures
Ventral Hernia
Inguinal Hernia

Clinical data from the combination of procedures outlined in Table 8 below might be used to support authorization of a RASD for the general surgery specialty.

Table 8. Example Procedure Combination for General Surgery Specialty

General Surgery Specialty Procedures
Roux-en-Y Gastric Bypass
Ventral Hernia
Inguinal Hernia
LAR/TME
Right Hemicolectomy

Table 9. Example Umbrella and Covered Procedures for Gynecology

Umbrella Procedures	Covered Procedures
Radical Total Laparoscopic Hysterectomy	Benign/radical/simple total laparoscopic hysterectomy, salpingectomy, salpingostomy, oophorectomy, pelvic and/or paraaortic lymphadenectomy, endometriosis resection, adnexectomy, omentectomy, parametrectomy, ovarian cystectomy, and lysis of adhesions,
Total Laparoscopic Hysterectomy	Benign/simple total laparoscopic hysterectomy, salpingectomy, salpingostomy, oophorectomy, adnexectomy, ovarian cystectomy
Sacrocolpopexy	Endometriosis resection, lysis of adhesions

Table 10 below outlines an example procedure combination that might be used to support authorization of a RASD for the gynecology specialty.

Table 10. Example Procedure Combination for Gynecology Specialty

Gynecology Specialty Procedures
Radical Total Laparoscopic Hysterectomy
Sacrocolpopexy
Myomectomy*

*Should reflect various sizes and locations for anticipated target populations.

Table 11. Example Umbrella and Covered Procedures for Urology

Umbrella Procedures	Covered Procedures
Radical Prostatectomy	Simple Prostatectomy Lymphadenectomy
Radical Cystectomy with urinary diversion	Partial Cystectomy Ureteral Reimplantation
Partial Nephrectomy	Donor Nephrectomy Adrenalectomy Pyeloplasty Cyst Removal

Table 12 below outlines an example procedure combination that might be used to support an authorization for a RASD for the urology specialty.

Table 12. Example Procedure Combination for Urology Specialty

Urology Specialty Procedures
Radical Prostatectomy
Radical Cystectomy with Urinary Diversion
Partial Nephrectomy

Table 13. Example Umbrella and Covered Procedures for Thoracic Surgery

Umbrella Procedures	Covered Procedures
Lobectomy, Lymphadenectomy	Wedge Resection, Segmentectomy
Esophagectomy	Thymectomy/Mediastinal Mass Excision

Table 14 below outlines an example procedure combination that might be used to support authorization of a RASD for the thoracic specialty.

Table 14. Example Procedure Combination for Thoracic Specialty

Thoracic Specialty Procedures
Lobectomy, Lymphadenectomy
Esophagectomy

Table 15. Example Umbrella and Covered Procedures for Cardiac Surgery

Umbrella Procedures	Covered Procedures
Mitral Valve Repair	Mitral Valve Replacement Patent Foramen Ovale Closure Atrial Septal Defect Repair Left Atrial Appendage Closure/Occlusion Atrial Myxoma Excision Tricuspid Valve Repair Epicardial Pacing Lead Placement
Totally Endoscopic Coronary Artery Bypass Surgery	Internal Mammary Artery Mobilization for Cardiac Revascularization

Table 16 below outlines an example procedure combination that might be used to support the authorization of a RASD for thoracoscopically-assisted cardiac surgery. An alternative to totally endoscopic coronary artery bypass surgery, minimally invasive coronary revascularization procedures combined with mitral valve repair might be used to support the authorization of a RASD for thoracoscopically-assisted cardiac surgery in certain circumstances.

Table 16. Example Procedure Combinations for Thoracoscopically-Assisted Cardiac Surgery

Thoracoscopically-Assisted Cardiac Procedures
Mitral Valve Repair
Totally Endoscopic Coronary Artery Bypass Surgery

Appendix B. 510(k) Summary (for 510(k)s only)

Significance: The 510(k) Summary is a public document that summarizes the basis for a determination of SE (see 21 CFR 807.92(a)). As noted in the FDA guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," in an effort to improve the transparency and predictability of the 510(k) program and to ensure that the 510(k) Summary reflects the information provided in a 510(k) submission to support a SE determination, FDA intends to verify the accuracy and completeness of the information included in a 510(k) Summary.

Recommendation: We recommend that you include a complete 510(k) Summary for review in your premarket notification. Since RASDs are complex devices, it is important to list all major technological features in the 510(k) Summary.[11] This may include a table similar to Table 1 in Section IV.B of this guidance document. It is of equal importance to clearly and accurately summarize all performance testing conducted,[12] including:

- A list of each bench performance testing performed
    - A list of each consensus standard to which the device conforms, when a Declaration of Conformity is used,
- A summary of human factors validation studies performed
- Cybersecurity information in accordance with section 524B of the FD&C Act and the FDA guidance, "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions."
- A summary of any *in vivo* non-clinical studies performed, which includes a summary of the study protocol(s), an evaluation of the primary and secondary endpoints, and the gross necropsy and histopathology results.
- For any *in vivo* clinical evaluation performed, a summary of the study protocol(s) and state if the evaluation included clinical performance testing, clinical literature, and/or real-world evidence. The summary should include the number and type of subjects and procedures performed in each study. The summary should include results for the nine primary surgical endpoints described in Section IV.Q(2) Clinical Data.

Please see Appendix C in the FDA guidance, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," for an example of a 510(k) Summary compliant with 21 CFR 807.92.

[11] See 21 CFR 807.92(a)(4) and (6).
[12] See 21 CFR 807.92(b)

Guidance History*	Date	Description
Level 1 Draft Guidance	September 2026	See Notice of Availability for more information.**

*This table was implemented, beginning September 2026 and previous guidance history may not be captured in totality.

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

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