On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, 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 Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

FDA notes that in particular, the QMSR does not utilize certain terms from the previous QS regulation, such as "Design Change," and "Design History File (DHF)." The elements that comprise those terms are now described in ISO 13485:2016, Clause 7.3 and its subclauses, which are incorporated by reference in the QMSR.

On June 14, 2023, FDA issued a guidance titled "Content of Premarket Submissions for Device Software Functions."[1] This final guidance supersedes the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005. The final guidance issued on June 14, 2023, provides information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. In particular, the final guidance includes information to help determine a device's Documentation Level (formerly known as Level of Concern). The purpose of the Documentation Level is to help identify the minimum amount of information that would support a premarket submission that includes device software functions.

Within the framework of the superseded guidance, electrosurgical devices intended for use in general surgery were considered a device with a Major Level of Concern. Based on the device's risk in the context of the device's intended use, as discussed in the final guidance "Content of Premarket Submissions for Device Software Functions," electrosurgical devices intended for use in general surgery should generally address the recommendations for an Enhanced Documentation Level. The actual Documentation Level for your device may vary based on the specifics of your device. For more information about the Documentation Level and recommended documentation for a premarket submission, sponsors are encouraged to review the guidance "Content of Premarket Submissions for Device Software Functions."

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-device-software-functions.

Contains Nonbinding Recommendations

Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery

Guidance for Industry and Food and Drug Administration Staff

Document issued on March 9, 2020.

Document originally issued on August 15, 2016.

The draft of this document was issued on March 24, 2014.

For questions about this document, contact OHT4: Office of Surgical and Infection Control Devices/ DHT4A: Division of General Surgery Devices, 301-796-6970.



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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2014-D-0217. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 19029 and complete title of the guidance in the request.

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Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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

FDA has developed this guidance document to assist industry in preparing premarket notification (510(k)) submissions for electrosurgical devices intended for use in general surgery. These devices are designed to cut and/or remove tissue and control bleeding through the use of high-frequency electrical current. For the purpose of this guidance, electrosurgical devices may also be called radiofrequency (RF) devices or high-frequency (HF) devices.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[1] For more information regarding use of consensus standards in regulatory submissions, refer to the FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[2]

FDA's guidance documents, including this 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 guidance means that something is suggested or recommended, but not required.

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

II. Scope

The scope of this document is limited to the Class II electrosurgical devices and accessories classified under the following regulation number:

> **Section 878.4400 Electrosurgical cutting and coagulation device and accessories.** An electrosurgical cutting and coagulation device and accessories is a device intended to remove tissue and control bleeding by use of high-frequency electrical current.

Electrosurgical devices under this regulation are indicated for general tissue cutting and/or coagulation. If your device has specific indications, it may require additional information (e.g., additional bench and/or clinical data) or may be found to have a new intended use. For more information on this topic, refer to FDA's "Guidance for Industry: General/Specific Intended Use."[3]

There are electrosurgical devices that have been classified under other medical panels (e.g., 21 CFR part 872 for dental devices). This guidance is not applicable to devices classified under the following regulations:

- Section 872.4920 Dental electrosurgical unit and accessories
- Section 876.4300 Endoscopic electrosurgical unit and accessories
- Section 882.4400 Radiofrequency lesion generator
- Section 882.4725 Radiofrequency lesion probe
- Section 884.4150 Bipolar endoscopic coagulator-cutter and accessories
- Section 884.4160 Unipolar endoscopic coagulator-cutter and accessories
- Section 886.4100 Radiofrequency electrosurgical cautery apparatus
- Section 886.4115 Thermal cautery unit

This guidance is applicable to electrosurgical devices that may have multiple uses or indications, if one of those indications includes tissue cutting and/or coagulation. In addition, some electrosurgical devices may include both open and minimally invasive uses; in those cases, this guidance document would apply. This guidance also applies to devices that may include an arthroscopic indication. In addition, please be aware that there is supplemental guidance for electrosurgical devices for other specific indications (e.g., RF vessel sealers). In such instances, the supplemental guidance may provide additional recommendations or supersede this guidance. We recommend that you search FDA's guidance database[4] for any device specific supplemental guidance or contact the Division of General Surgery Devices for more information.

For a new device that combines an electrosurgical device with another device(s) (e.g., mechanical massager or low level light source) into a single system, and is designed to operate simultaneously or in sequence to achieve a desired clinical effect in tissue, additional data are

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[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/generalspecific-intended-use-guidance-industry.
[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

usually necessary to demonstrate that the new device is substantially equivalent to the predicate devices working independently. We recommend that you contact the Agency through the Q-submission process to obtain further guidance for data recommendations in such cases. For information on the Q-submission process, see FDA's guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."[5]

III. Device Description

We recommend that you identify your device by the applicable regulation number described in Section II and include the following information:

A. Indications for Use

You should provide a clear statement of your device's Indications for Use. The Indications for Use as stated on the Indications for Use Statement page should be identical to that in the 510(k) Summary (if provided in lieu of a 510(k) Statement) and the device labeling. You should also state if the device is a prescription (including home use) or over-the-counter (OTC) device, and indicate this accordingly on the Indications for Use Statement page.

B. Device Design

You should provide a brief description of the device's operating principle(s) and mechanism of action for achieving the intended effects. If the device will be labeled for use with multiple components or accessories, and the components/accessories are part of the submission, you should provide a list of all components/accessories with accompanying model numbers and/or part numbers. For the purpose of this guidance, components/accessories of electrosurgical devices refer to the electrosurgical unit (ESU), active component/active accessory, neutral electrode, and miscellaneous components/accessories. If there are components/accessories that have received prior 510(k) clearance or are exempted from the 510(k) requirement, you should provide the 510(k) numbers or indicate their exemption status, respectively.

You should provide the following information regarding device design:

1. Device Components

We recommend you provide a brief description of all major components or accessories where applicable to your submission:

- ESU (i.e., the generator and control console) major functions, performance specifications, and physical specifications

[5] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

- Active components/active accessories (generally comprised of one or more active electrode(s), active connector or cables, and active handle or hand piece) design, physical specifications, and patient contacting materials
- Neutral electrodes (also commonly called dispersive electrodes, grounding pads, patient return electrodes, or passive/plate electrode) design, physical specifications, and patient contacting materials
- Miscellaneous accessories such as foot pedal, irrigation pumps, suction or smoke evacuation, etc.

2. **Submission for Specific Components/Accessories**

   If your submission is requesting clearance for a specific component or accessory, but not the entire electrosurgical device, you should describe the component/accessory. You should discuss how you intend or expect this component/accessory to be used. For example, if the submission is for an active electrode and will only be labeled for use with your own legally marketed devices, you should provide performance testing (see Section XI, Performance Data) to demonstrate compatibility with your own legally marketed devices. Also, you should address the potential that this active electrode could be used with other manufacturers' electrosurgical devices and identify the associated risk(s). In your risk assessment, you should identify whether you have incorporated into your device design a way to prevent using your active electrode with other manufacturers' devices for which compatibility has not been established. Based on your risk assessment, you may need to provide additional performance testing to demonstrate this component will be safe and effective when used with other manufacturers' devices.

3. **Photograph and/or Drawing of the Device**

   We recommend you provide high-level drawings, diagrams, and/or photographs of the device that can help explain the functions and features. We also recommend you provide an exploded or assembly view diagram or connection diagram, including all components clearly labeled.

IV. Predicate Comparison

For devices reviewed under the 510(k) process, manufacturers must compare their new device to a similar legally marketed predicate device to support its substantial equivalence (section 513(i) (21 U.S.C. 360c(i)) of the FD&C Act; 21 CFR 807.87(f)). This comparison should provide information to show how your device is similar to and different from the predicate. Side-by-side comparisons for each major component using a tabular format such as shown in Table 1, whenever possible, are desirable. See below for an example of how this information may be organized. For each identified difference, you should provide further discussion of the difference compared to the predicate and why this difference will not significantly affect safety or effectiveness. You may need to provide performance data to support that, even with significant differences, the device is as safe and effective as the predicate.

Table 1. Example Comparison Table

Description	Your Device	Predicate Device
Indications for Use		
Prescription or OTC		
ESU • Major functions (e.g., bipolar, monopolar, temperature sensors, impedance monitor, continuity monitor) • Performance specifications (e.g., output frequency, waveform, power output, voltage output, crest factor) • Physical specifications		
Active accessory • Monopolar or bipolar • Physical dimensions and design (e.g., size, length, connector type) • Rated voltage • Materials (electrode, insulation, coating, etc.)		
Neutral electrodes • Conductive or capacitive • Physical specifications • Materials		
Miscellaneous accessories • Functions • Performance specifications • Physical specifications • Materials		

When more than one predicate device is identified to establish substantial equivalence of your device, you should provide justification for the use of each predicate. You should address why the combination of features and/or functions into one device does not raise different types of safety and effectiveness questions for each predicate identified. An example of where multiple predicates could be used is if the device includes different technologies that can stand alone but can also be used together for the intended use of cutting and coagulating tissue. If there is a predicate device for each of the technologies, then the combination of these technologies, assuming that the use of one of the functions does not interfere with the others, could be found substantially equivalent. In such an instance, you may need to provide performance data to support your justification. For more information on the appropriate use of multiple predicates,

see FDA's guidance "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[6]

V. Software

Significance: Software in electrosurgical generators ensures that appropriate energy is delivered to the patient. Adequate software performance testing provides assurance that the device is operating within safe parameters.

Recommendation: Refer to the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"[7] for a discussion of the software documentation that you should provide in your submission. The software guidance outlines the type of documentation to be provided based on the "level of concern" associated with the device. FDA generally considers the software for electrosurgical device generators that are intended for general surgery indications to present a "major" level of concern. If you believe that the software in your device presents a lower level of concern (e.g., "moderate" or "minor") as defined in the software guidance, you should provide a scientific justification that supports your rationale of the level of concern based on the possible consequences of software failure.

We recommend that you provide a full description of the software/firmware supporting the operation of the subject device following the software guidance, commensurate with the appropriate level of concern. This recommendation applies to original device/systems as well as to any software/firmware changes made to already-marketed devices. Changes to software must be re-validated and re-verified in accordance with Design Controls, 21 CFR 820.30(i), and documented in the Design History File (see 21 CFR 820.30(j)). Some software changes may warrant the submission of a new 510(k). In such cases, it is recommended that you consult the FDA guidance, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."[8]

As appropriate, you should also provide information on the cybersecurity aspects of your device, including, but not limited to, the following facets of information security with respect to communications features of your device and associated software: confidentiality, integrity, availability and accountability.

Confidentiality assures that no unauthorized users have access to the information.

Integrity is the assurance that the information is correct—that is, it has not been improperly modified.

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[6] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[8] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device.

Availability suggests that the information will be available when needed.

Accountability is the application of identification and authentication to assure that the prescribed access process is being done by an authorized user.

The FDA guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices,"[9] provides additional information regarding cybersecurity and medical devices.

If the device includes off-the-shelf software, you should provide the additional information as recommended in the FDA guidance titled "Off-The-Shelf Software Use in Medical Devices"[10] and "Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software."[11]

Overall, the documentation related to the software contained in the medical device should provide sufficient evidence to describe the role of the software included in the device, and performance testing to demonstrate that the software functions as designed.

VI. Biocompatibility

Significance: Electrosurgical devices contain patient-contacting materials that, when used as intended, i.e., given the contact type and duration, may induce a harmful biological response.

Recommendation: You should determine the biocompatibility of all patient-contacting materials present in your device. For polymeric materials, you should identify each material by trade name and manufacturer. If your materials are identical in composition and processing methods to materials used in a predicate device or another device with the same contact type and duration (e.g., tissue contacting, less than 24 hours) for electrosurgical applications, you may reference previous testing experience in lieu of new testing.

We recommend that you follow the FDA guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'"[12] which identifies the types of biocompatibility assessments that should be considered and recommendations regarding how to conduct related tests.

Differences in formulation, processing, sterilization, or device surface properties that could affect biocompatibility of the final product may warrant additional biocompatibility testing.

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[9] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[10] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices.
[11] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-healthcare-organizations-about-fdas-guidance-industry-cybersecurity-networked-medical.
[12] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

Most active electrodes should be considered external devices that contact tissue/bone/dentin for a limited contact duration (less than 24 hours). As a result, we recommend evaluation for:

- Cytotoxicity (see ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for* in vitro *cytotoxicity*);
- Intracutaneous reactivity (see ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*);
- Delayed type sensitivity (see ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*); and
- Consideration of acute systemic toxicity testing, either by inclusion of the testing or a rationale for its omission (see ISO 10993-11, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity)*.

Most neutral electrodes should be considered surface devices that contact only intact skin for a limited contact duration (less than 24 hours). As a result, we recommend evaluation for:

- Cytotoxicity (see ISO 10993-5, *Biological evaluation of medical devices – Part 5: Tests for* in vitro *cytotoxicity*);
- Dermal irritation (see ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*); and
- Delayed type sensitivity (see ISO 10993-10, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*).

For biocompatibility testing conducted using extraction samples, we recommend that you:

- Determine the appropriate amount of test material as outlined in ISO 10993-12, *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*, or an equivalent method, using surface area to extractant volume ratios (mass to extractant volume ratios should only be used if surface area cannot be calculated);
- Use both polar and nonpolar extractants;
- Describe the condition of the extraction vehicle (e.g., color, presence of any particles);
- Explain any changes in the post-extraction vehicle (compared to pre-extraction); and
- Describe the details of storage conditions, if applicable.

VII. Sterility

Significance: Electrosurgical devices for general surgery indications come in contact with blood and body tissue and should be adequately sterilized to minimize infections and related complications.

Recommendation: For electrosurgical devices labeled as sterile, we recommend that you provide sterility information for the finished device. For information on sterility information in 510(k) submissions for devices labeled as sterile, see the FDA guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."[13] You should sterilize the device to a sterility assurance level (SAL) of $1x10^{-6}$. Please note that your sterilization process must be validated in accordance with the Quality System Regulation (21 CFR part 820).

VIII. Reprocessing

Significance: The patient contacting components of electrosurgical devices that are reused should be adequately cleaned, disinfected, and sterilized between uses to minimize infections and prevent device degradation.

Recommendation: Under FDA labeling regulations (21 CFR part 801), a device must have adequate directions for use, which include instructions on preparing a device for use. Instructions on how to reprocess a reusable device or a 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. For information on the development and validation of reprocessing instructions in your proposed device labeling, see FDA's guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[14]

IX. 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, electrosurgical devices labeled as "non-pyrogenic" should follow the recommendation in Section VII, Sterility. Recommended pyrogen limit specifications have been identified in FDA's guidance, "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."[15]

To address the risks associated with material-mediated endotoxins, it is recommended that you follow the recommendations in the FDA guidance, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.'"[16]

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[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.
[14] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.
[16] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.

For devices intended to be labeled as "non-pyrogenic," we recommend that both the bacterial endotoxin and rabbit material-mediated pyrogen testing be conducted.

X. Shelf Life

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, a description of the package integrity test methods, and a summary of the package integrity test results. FDA recommends that package integrity test methods include simulated distribution and associated package integrity, as well as simulated (and/or real-time) aging and associated seal strength testing, to validate package integrity and shelf life claims. We recommend you follow the methods described in the FDA-recognized series of consensus standards AAMI/ANSI/ISO 11607-1: *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* and AAMI/ANSI/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 physical and mechanical properties of the device that are necessary 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 XI, Performance Data, and repeat all tests that evaluate design components or characteristics that are potentially affected by aging. For example, aging can affect the performance of most polymeric materials used; therefore, tests that evaluate the integrity and performance of the insulation should be repeated after aging. For those bench tests that you do not repeat, you should provide a rationale explaining why the performance characteristics assessed by the tests are not expected to be affected by aging.

We recommend that you provide a summary of the test methods used for your shelf life testing, results and the conclusions drawn from your results. If you use devices 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 per the currently 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 conduct testing on real-time aged samples to confirm the results of the accelerated aging study. This testing should be conducted in parallel with 510(k) review and clearance, with results documented to file in the design history file (i.e., the test reports do not need to be submitted to FDA).

XI. Performance Data

We recommend that nonclinical testing be performed to demonstrate that each individual component of the device, as well as the electrosurgical device with all the components connected (system), meets all the design and performance specifications. In the case where the 510(k) submission is for one or more components of the electrosurgical device but not the entire electrosurgical device (e.g., electrosurgical generator only or active electrodes only), nonclinical testing as a system should be provided using legally marketed components with which your device is labeled as compatible. Depending on the substantial equivalence comparison to the predicate(s) above, nonclinical testing may be accomplished with bench testing alone, or an *in vivo* or *ex vivo* animal model may be necessary.[17] The following are recommended nonclinical tests for each major component and for the system.

A. ESU

For each mode, you should provide a graphical display of the output waveform at the rated load, identifying the associated mode, amplitude, frequency, duty cycle, load used, and crest factor.

For each mode, you should provide a graph displaying the power output at maximum and half-of-maximum intensity over the range of expected loads (e.g., 100 Ω to 2000 Ω for monopolar). This information should be derived from experimental test data and not theoretical values, and it should include a comparison of these curves to the corresponding mode of the predicate device(s).

B. Active Components/Accessories

Mechanical testing of electrosurgical instruments is important to minimize the risks associated with mechanical failure and short circuiting. Although the methods will vary based on the device design, you should assess the potential for damage to the device both before use (e.g., drop tests of the instrument in its packaging) and during use (e.g., bending force). Different considerations will also be necessary for single-use instruments versus reusable instruments. For reusable instruments, testing should demonstrate both adequate mechanical strength and electrical performance (e.g., insulation integrity) after multiple reuse and reprocessing cycles. For instruments with actuating parts, we recommend simulated repeated-use testing of the actuating part, including grasping force and force to jaw failure. Force to jaw failure is defined as the force required to cause the articulating component to no longer be able to grasp or close on the target tissue. This testing is important to ensure that the device can appropriately grasp the target tissue under worst case scenarios. Testing of the cutting performance of any instrument that includes a mechanical cutting function should also be performed, where applicable. For

[17] FDA supports the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors 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.

reusable instruments, this testing should be conducted after the maximum number of simulated use and reprocessing cycles.

C. Neutral Electrodes

Neutral electrode thermal performance, contact impedance, and adhesion testing should be performed in accordance with the currently FDA-recognized version of IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*. If alternative test methods and test procedures are developed, a detailed description of the testing and test results should be provided. In addition, you should provide a discussion regarding why the testing and test results are comparable to the currently FDA-recognized version of the IEC 60601-2-2 standard.

For reusable neutral electrodes, the above testing should be performed following simulated reuse and reprocessing cycles according to the instructions for use.

D. Miscellaneous Components/Accessories

When your electrosurgical device also includes accessories such as a foot pedal, irrigation pump, suction device, or smoke evacuation device, you should provide test results to show that each of those accessories meets all of the design and performance specifications.

If a component/accessory has been previously cleared by FDA, you may provide the original 510(k) as a reference, rather than conducting additional tests for the referenced component/accessory. However, compatibility between the component/accessory and the proposed device should still be addressed.

E. System Testing

In addition to the component testing, testing of the electrosurgical device with all the components and accessories working together as a system may be necessary. The following are examples of system testing that may be needed for electrosurgical devices:

1. **Thermal Effects on Tissue**

   For each mode and each representative active component or electrode, you should provide a measurement (under magnification) of the size (length, width, and depth) of the thermal damage zone, i.e., coagulation necrosis. This testing may be performed on *ex vivo* animal tissue.

   To support a *specific* soft tissue indications for use, testing should be performed in tissues relevant to the specific indications for use. The target and surrounding tissues should be used to provide the most clinically applicable thermal data. In some cases, other tissue type(s) with comparable thermo-physiological properties may be considered for testing if accompanied by a scientific justification.

To support a *general* soft tissue indication, testing should include at least three tissue types. FDA recommends testing liver, kidney, and muscle tissue to cover a range of tissue densities, but other tissue types may be appropriate based on the proposed indicated treatment location. We recommend measuring thermal damage under magnification using histology; however, if another method is used, a rationale for that measurement method should be provided.

If active components or electrodes are grouped into a device family for test purposes, you should provide the rationale for identifying a family representative or otherwise pooling data from multiple active components in the test protocol. At a minimum, each test should be performed in triplicate at the minimum, default, and maximum power settings. We recommend providing the results in a chart and/or graph that indicates the width and depth of thermally damaged zone in relation to the power setting, and duration of activation for different tissue types.

Thermal damage is a function of spatial temperature distribution over time (i.e., "temperature-time history"), which involves heating as well as cooling. Therefore, testing should be performed such that the tissue is exposed to relevant (best-case, realistic-case, and worst-case) temperature-time history as expected *in vivo*. The tissue should be maintained at the baseline temperature relevant for the indications for use (e.g., core body temperature for internal tissues) prior to application of the active component or electrode. After application of the device, the tissue should be allowed to cool back down to baseline temperature as it would under clinical conditions of use in order for the energy to flow and the thermal damage to develop.

The tissue under test should be such that the flow of energy and thus, the development of thermal damage, is not impeded by the boundary conditions. For example, during testing in *ex vivo* tissue, if the tissue sample is too small or too thin, then the tissue would not be large enough for the thermal damage to fully develop. Also, during *ex vivo* tissue testing if the tissue is kept at baseline temperature using a water bath, but the flow rate in the water bath is set too high, the flow may impede the development of thermal damage by removing the energy reaching the tissue boundaries faster than what is typically permissible physiologically.

We recommend providing graphs of temperature versus time at relevant locations in the tissue of interest to show that the thermal damage was produced in response to the temperature-time history relevant for the clinical conditions of use. The temperature-time history should be measured using temperature probes that are calibrated and that have appropriate response time to be able to accurately measure the temperatures. Data and/or justification should be provided regarding the appropriateness of the temperature probes in measuring temperatures with sufficient spatial and temporal resolution.

Thermal damage should be assessed using histological stains, such as Hematoxylin-Eosin (H&E), lactate dehydrogenase (LDH), or triphenyl tetrazolium chloride (TTC). Your choice of stain should be appropriate to fully assess the extent (depth, thickness, width, and volume) of the adversely affected tissue region. You should provide data

and/or a scientific justification to show that your choice of stain(s) enables you to accurately quantify the full extent of the adversely affected tissue region.

Note that for specific tissue and/or anatomic location type indications (e.g., lung, colorectal tissue, skin, mucosa, neural tissue), additional testing may be necessary in a chronic animal study. If you believe a chronic animal study is necessary, we highly recommend that you contact the Agency through the Q-Submission process to obtain early feedback on your study design considerations (see FDA guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program").[18]

2. **Temperature Monitoring**

   For electrosurgical devices that include temperature sensing, you should provide testing to demonstrate that this feature works as intended. Although the methods will vary based on the device design, your testing should demonstrate that the temperature sensing under simulated conditions meets your design specification and performance requirements.

3. **Contact Quality Monitoring (CQM) and/or Continuity Monitoring**

   For electrosurgical generators and neutral electrodes with contact quality and/or continuity monitoring capabilities, you should provide testing to demonstrate that these features work as intended. Although the methods will vary based on the monitoring design, your testing should provide data on conditions where the monitoring is effective in order to write adequate instructions for use.

4. **Capacitive Coupling**

   If the proposed device design includes monopolar electrosurgical electrodes for use in minimally invasive surgery, we recommend you test for active coupling resistance between the subject device and a conductive cannula/trocar device under simulated normal use conditions. This testing should be performed as recommended by the currently FDA-recognized versions of IEC 60601-2-18, *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment* and IEC 60601-2-2. For electrosurgical electrodes and accessories, we also recommend you address the risks of leakage currents through insulation as well as capacitive coupling with other surgical equipment (e.g., pulse oximeter probes, invasive blood pressure transducers, temperature probes camera systems) as a part of your risk management process (e.g., cross-coupling between different HF patient circuits).

You should provide complete test reports for each test conducted. For information on recommended content and format of test reports for non-clinical bench performance testing in

[18] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

premarket submissions, refer to FDA's guidance, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions."[19]

FDA recommends that complete test reports be provided for all tests performed because the IEC 60601-2-2 and IEC 60601-2-18 series of standards include general methods with multiple options, and in some cases they do not include acceptance criteria or address assessment of results. Therefore, when a declaration of conformity (DOC) is submitted with respect to IEC 60601-2-2 and IEC 60601-2-18, a copy of the supplemental information used to support the declaration (e.g., a copy of the study test report) should be provided. For additional information regarding the use of consensus standards and a DOC, refer to the FDA guidance, "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices."[20]

You should also provide an explanation of how the data generated from the test support a finding of substantial equivalence. For any tests involving tissue effects, you should describe the clinical relevance of the acceptance criteria for each test and explain why the test results demonstrate acceptable clinical performance of your device. Nonclinical test conditions should simulate the worst-case conditions that your device is likely to encounter during clinical use. For those nonclinical tests that do not rely on FDA-recognized consensus standards, the results of the testing on the proposed device should be compared to those of your predicate device(s).

XII. Electrical Safety and Electromagnetic Compatibility

Significance: Electrical safety is the ability of a device to operate properly in its intended use environment without operating unexpectedly due to electrical fluctuations from either battery or mains power. Electromagnetic compatibility (EMC) is the ability of a device to operate properly in its intended use environment without operating unexpectedly due to electromagnetic disturbances or introducing excessive electromagnetic disturbance into that environment.

Recommendation: All electrosurgical devices should undergo basic electrical, thermal, and EMC testing to evaluate the potential for insufficient electrical safety and EMC. We recommend that you conduct your testing and comply with the labeling provisions outlined in the currently FDA-recognized versions of the 60601 series of standards listed below. Given the potential variability in the test setup due to different designs and multiple components, you should submit the complete test reports for your device in reference to these standards.

- AAMI/ANSI ES60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

[19] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.
[20] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

- 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 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

Additionally, endoscopic/laparoscopic electrosurgical instruments should demonstrate compliance with IEC 60601-2-18, *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*.

For additional information on providing EMC information in a premarket review, please see the FDA guidance, "Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices."[21]

In addressing EMC, please be aware that according to IEC 60601-2-2, high frequency surgical instruments are intentional emitters of electromagnetic energy and, therefore, emissions testing to IEC 60601-1-2 is only needed for power generators in the idle state (i.e., powered on but surgical energy not activated). However, even during idle testing, particular attention should be paid to the effects of connected accessories and instruments, such as cord length (for resonant frequency) and instruments that contain electronics. For instruments with different cord lengths, connection types, or electronic components, it may not be appropriate to use a single "representative" instrument model for testing purposes.

If your submission is for a specific component of the electrosurgical device, you are still expected to evaluate your component while connected to other components of the electrosurgical device system. This should be performed consistent with how you intend or expect your component to be used and the intended environment of use.

If your electrosurgical device incorporates wireless technology including RFID (radio frequency identification) technology, meeting the IEC 60601 standards is insufficient to demonstrate that your device will not be susceptible to electromagnetic interferences and that your wireless technology will perform reliably. Review FDA's guidance, "Radio Frequency Wireless Technology in Medical Devices,"[22] for a discussion on risks associated with wireless technology and suggestions regarding how to address these risks.

XIII. Clinical Testing

Clinical data are generally not necessary to support 510(k) submissions for electrosurgical devices that are intended for general surgery indications. However, if your device indications for use or device technology and/or mechanism of action is significantly different when compared to

[21] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices.
[22] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.

the predicate device(s), and if nonclinical testing is insufficient to establish substantial equivalence, clinical testing may be necessary to establish substantial equivalence to a predicate device. For example, many electrosurgical devices for aesthetic use have utilized clinical data to demonstrate that the devices are as safe and effective as the predicate. For additional information regarding this topic, refer to Section F of the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[23]

If you believe that clinical data are necessary, or if you are uncertain, we highly recommend that you contact the Agency through the Q-Submission process to obtain early feedback on study design considerations (see the FDA guidance, "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program").[24]

XIV. Labeling

The premarket notification must include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Proposed labels, labeling, and advertisements sufficient to describe the electrosurgical device, its intended use, and the directions for use must be provided with a specific intended use statement and any warnings, contraindications, or limitations clearly displayed as described in 21 CFR 807.87(e). Please consider the following suggestions for assistance in preparing labeling that satisfies the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing acceptable labeling.

Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109.

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Labeling must, however, include adequate information for practitioner use of the device, including indications, effects, routes, methods, frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions (21 CFR 801.109(d)).

As stated above in Section XII, Electrical Safety and Electromagnetic Compatibility, we recommend that all electrosurgical device submissions demonstrate compliance with the labeling sections of the currently FDA-recognized versions of the 60601 series of standards, including AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-2, and (when applicable) IEC 60601-2-18. We also recommend that you include the information below in your labeling. Please note that some of the recommended labeling content is already included in the standards but has been repeated for emphasis. Other recommended content has been modified from the standards.

Electrosurgical systems generally consist of several different interchangeable components used together to create the desired effect, including the ESU, active accessory, neutral electrodes,

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[23] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[24] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program.

footswitches, etc. Some of the labeling recommendations below may apply to only a single component or to each component in a system. You should determine which labeling is appropriate, depending on the indications for use, the individual component, and how the components may be packaged (together or separately). If your submission is for a specific component, your labeling should describe compatibility recommendations and results from your risk assessment, as it relates to device compatibility.

The list below is not intended to be exhaustive of all the labeling requirements under part 801.

A. Instructions for Use (User Manual)

1. Indications for Use

Your labeling should clearly state the indications for use of your device as specified in your Indications for Use Statement. This information should be prominently located in the beginning of your directions for use. If your device consists of multiple components with different indications, please specify this in your labeling.

2. Warnings

We recommend including the following warnings, as applicable, in the instructions for use. Sample language is provided in italics. If you believe any of these warnings are not applicable to your device, you should provide a justification for each omission.

a. *DO NOT USE in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (e.g., cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.*

b. *DO NOT USE in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N_2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.*

c. *DO NOT place instruments near or in contact with flammable materials (such as gauze or surgical drapes). Instruments that are activated or hot from use may cause a fire.*

d. *When not using instruments, place them in a clean, dry, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.*

e. *INSPECT instruments and cables for damage prior to each use, especially the insulation of laparoscopic/endoscopic instruments. This may be done visually under magnification or with a high voltage insulation testing device. Insulation failures may result in burns or other injuries to the patient or operator.*

f. *The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated.*

g. *Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used in both open and laparoscopic procedures.*

h. *Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.*

i. If the device is argon enhanced, you should include warnings and recommendations regarding gas embolisms.

j. If the instrument is reusable, you should also include a warning that visual inspection alone may not be sufficient to ensure that the insulation is intact.

k. *DO NOT activate the instrument when not in contact with target tissue, as this may cause injuries due to capacitive coupling with other surgical equipment.*

The following additional warnings should be included for monopolar instruments:

l. *ASPIRATE fluid from the area before activating the instrument. Conductive fluids (e.g., blood or saline) in direct contact with or in close proximity to an active electrode may carry electrical current or heat away from target tissues, which may cause unintended burns to the patient.*

m. *DO NOT USE with hybrid trocar systems, i.e., a combination of metal and plastic, when using monopolar active components. This may result in alternate site burns due to capacitive coupling. Use only all-metal or all-plastic trocar systems.*

n. *Prior to increasing the intensity, check the adherence of the neutral electrode and its connections. Apparent low output or failure of the device to function correctly at the normal operating settings may indicate faulty application of the neutral electrode or poor contact in its connections.*

o. If the device uses a neutral electrode and does not have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm.

p. If the device uses a neutral electrode and does have a CQM, you should include a warning that loss of safe contact between the neutral electrode and the patient will not result in an alarm unless a compatible monitoring neutral electrode is used.

3. Cautions

We recommend including the following cautions in the instructions for use. Sample language is provided in italics.

a. *The intensity should be set as low as is necessary to achieve the desired effect.* [unless there is a risk associated with low settings, e.g., argon coagulation]

b. *Keep the active electrodes clean. Build-up of eschar may reduce the instrument's effectiveness. Do not activate the instrument while cleaning. Injury to operating room personnel may result.*

4. Operating Information

Operating instructions should contain detailed information such that the practitioner can set up and use the device safely and for the purposes for which it is intended. In addition, we recommend that you include instructions concerning the proper selection and use of accessories in order to avoid incompatibility and unsafe operation. In particular, you should include advice concerning the compatibility between CQMs and neutral electrodes and direct the user to verify that the generator's output voltage does not exceed the rated accessory voltage. For any accessories that may need to be replaced (e.g., disposable electrodes), you should also provide instructions in your labeling for obtaining replacements (e.g., model number and contact information).

B. Device Labels

In your submission, we recommend that you provide illustrations to show how each component of your device is labeled to demonstrate that all controls, switches, and connections (including those for hand switched active electrodes and foot switches) are clearly, concisely, and permanently labeled to identify their function and other important information (e.g., Type BF Applied Part). In the submission and the labeling, you should also describe the color of any controls or connections (e.g., blue "coag" button) so that the function of each is apparent.

C. Package Labels

We recommend that you provide draft package labels, which should include the manufacturer, model number, and important information about device reuse, sterility, shelf life, etc.

D. Labeling for Specific Components

1. ESU

Your directions for use should include information on the output specifications of your device so that the user can easily understand the energy that is being delivered. We recommend including the following information for each output mode of your device:

a. Graphs or tables illustrating the actual power output (under a specified impedance). These graphs or tables should be provided for each intensity setting if multiple intensity settings are available.

b. Graphs displaying the power output at maximum and half-of-maximum intensity over the range of expected impedances.

c. The maximum output voltage and instructions regarding selecting accessories with appropriate voltage ratings.

2. Active components and active accessories

Your directions for use should include information on the compatibility of your active electrodes with other components of the electrosurgical device. We recommend including the following information:

a. The rated accessory voltage.

b. The compatible generator model or adequate instructions and criteria for the user to identify an adequate generator.

c. The limitations on generator output settings and duration of activation.

d. A statement referring users to the generator and neutral electrode user manuals for additional instructions.

e. If the instrument is monopolar, clearly communicate to the user that the hand piece is a monopolar device, and that a neutral electrode should be used with the generator to prevent burns/injury to the patient.

f. For ablation of tissue, the labeling should include a recommended ablation time per lesion size, a lesion size and shape range for which the device is effective, directions on how to perform multiple ablations on a single lesion including how you relocate the probe in a lesion, a time versus temperature versus lesion size created chart to inform users of the expected performance, and directions on how the user knows when an ablation is complete.

3. Neutral Electrodes

For monopolar devices, your directions for use should include information on the compatibility of your neutral electrodes with other components of the electrosurgical device. We recommend including the following information:

a. The surface area and size.

b. Adequate instructions for the user to identify a compatible CQM or a warning that it is not compatible with CQMs.

c. The compatible generator model or adequate instructions and criteria for the user to identify an adequate generator.

d. The limitations of generator output settings and typical, tested, or demonstrated times.

e. The appropriate patient population (e.g., size, weight).

f. Detailed instructions on how to apply the electrode to the patient, including recommendations for application site selection and preparation, warnings and precautions, and pre-application tests.

4. Components and Accessories

Your directions for use should include information on the compatibility for each of your accessories with the electrosurgical device. For some accessories, such as suction/irrigation pumps and smoke evacuation devices, separate instructions for use should be considered.

5. Reusable Devices

For any reusable components and accessories, you should provide adequate reprocessing instructions and information, as recommended in Section VIII.

Appendix A: Glossary of Terms

The following terms are defined for the purpose of this guidance only and may or may not correspond to their broader usage.

Active accessory – The component of the electrosurgical device used by the operator to produce surgical effects at the intended site on the patient. Generally comprised of an active handle, the cord or cable, and the active electrode (monopolar or bipolar).

Active electrode – The conductive portion of the electrosurgical device that delivers high density electrical current to the patient at the surgical site. This may or may not be removable from the active handle.

Argon beam coagulator – An electrosurgical device that combines the uses of argon gas with RF current to form a plasma at the surgical site to effect hemostasis in bleeding tissue. Besides argon gas, other gases (e.g., nitrogen) have been used.

Bipolar – An electrosurgical device in which the current flows between two active electrodes placed in close proximity.

Coagulation – The change of a liquid, especially blood, to a solid. This is considered separate from coagulation necrosis.

Coagulation necrosis – Necrosis in which the affected cells or tissue are converted into a dry, opaque, fairly homogenous eosinophilic mass as a result of the coagulation of protein.

Contact quality monitor (CQM) – A component of a monopolar electrosurgical system that monitors the contact between the neutral electrode and the patient. The CQM produces an alarm if the contact becomes insufficient and the patient is at risk for burns.

Continuity monitor – A component of a monopolar electrosurgical system that monitors the connection between the neutral electrode and the generator. The continuity monitor produces an alarm if the connection is lost, but it cannot detect if there may be a high current density through the neutral electrode.

Electrocautery – The use of electric current to heat an instrument, which is applied to tissue to create an effect. The current passes through the instrument only and not through the patient's tissue.

NOTE: The term electrocautery is often used incorrectly to refer to electrosurgical devices. To prevent confusion, FDA recommends that you avoid misuse of this term.

Electrosurgical device – A device that passes high-frequency electrical current through soft tissues for the purpose of removing tissue or controlling bleeding.

Electrosurgical system – A complete electrosurgical system includes the ESU, active accessories, neutral electrodes (if applicable), and miscellaneous accessories.

ESU – Abbreviation for electrosurgical unit. This term refers to the generator and control console.

Generator – The component of the electrosurgical system that produces the high-frequency current waveform that is delivered to tissues via the connecting cable(s), instrument(s), and electrode(s).

Hyfrecator – A type of monopolar electrosurgical device in which the current flows from a single active electrode at the surgical site and returns to earth (ground) through the patient's own body capacitance.

Instrument – The component of the electrosurgical system that is manipulated by the operator and applied to the surgical site, generally consisting of the handle and active electrode.

Monopolar – An electrosurgical technique in which the current flows from a single active electrode at the surgical site, through the patient, to a relatively distant neutral electrode.

Neutral electrode – An electrode connected to the patient, in an anatomical location away from the surgical site, to provide a return path for the high-frequency current. The neutral electrode has a large area relative to the active electrode in order to provide a low current density. Also known as: patient plate, ground pad, return electrode, dispersive electrode, inactive electrode, passive electrode, indifferent electrode, etc.

Radiofrequency (RF) – Generally refers to frequencies ranging from 100 kHz to 5 MHz. This is intended to exclude other frequencies (e.g., microwave ablation devices) that may technically fall within the radiofrequency portion of the electromagnetic spectrum but operate in a fundamentally different manner.

Vessel sealer – An electrosurgical device intended to seal isolated blood and lymphatic vessels for hemostasis, as an alternative to ties. Usually bipolar.