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Content of Human Factors Information in Medical Device Marketing Submissions

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document, contact the Human Factors Engineering Team at HFPMET@fda.hhs.gov.



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

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2015-D-4599. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Content of Human Factors Information in Medical Device Marketing Submissions

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 is committed to fostering the development of and patient access to innovative medical devices while weighing their benefits and risks. An important consideration for medical devices is the critical impact the device user interface design has on the safe and effective use of the device. Manufacturers routinely perform human factors assessments of the device user interface during device development. The purpose of this guidance is to provide a risk-based framework to guide manufacturers and FDA staff on the human factors information that should be included in a marketing submission[1] to CDRH to facilitate efficiency of the FDA review process.

The goal of the human factors assessment is to ensure that the device user interface has been designed such that use errors that occur during use of the device that could cause harm or degrade medical treatment are either eliminated or reduced to the extent possible. The main factors to consider in a risk-based approach to human factors assessment, as described in this guidance, include the identification of (i.e., presence of or modification to) critical tasks and the elimination or reduction of use-related risks. While FDA believes that it is optimal to minimize use-related risks as far as possible, it may not be necessary, or practical, to eliminate all use-related device risks.

[1] For purposes of this guidance, the term "marketing submission" is a submission for a device submitted to the Center for Devices and Radiological Health (CDRH) and includes premarket approval applications (PMA), premarket notifications [510(k) submissions], De Novo Classification requests, and Humanitarian Device Exemption (HDE) applications.

This guidance includes recommendations for the content of human factors engineering and usability engineering (HFE/UE)[2] information included in marketing submissions. FDA's decision on a medical device marketing submission is based on the applicable statutory and regulatory criteria (e.g., substantial equivalence for premarket notification (510(k)) submissions, reasonable assurance of safety and effectiveness for premarket approval applications (PMAs) or De Novo classification requests (De Novo requests), evidence that the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from use of the device outweighs the risk of injury or illness from its use, among other criteria, for HDE applications). Human factors information, to the extent relevant, constitutes just one component of FDA's assessment.

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 safe and effective for the intended users, uses, and use environments. Marketing submissions should include, where appropriate and based on the recommendations in this guidance, 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. Including appropriate human factors information may improve the efficiency of FDA review by reducing the number of requests for additional information.

This guidance is intended to be used to complement the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" (hereafter referred to as the Human Factors Guidance). The purpose of the Human Factors Guidance is to recommend and guide manufacturers through HFE/UE processes during the development of new medical devices, focusing specifically on the user interface. The Human Factors Guidance provides relevant human factors definitions and recommends useful preliminary analysis and evaluation tools to support human factors validation testing that will enable manufacturers to assess and reduce risks associated with medical device use. The purpose of the current guidance is to help manufacturers apply a risk-based approach when considering what human factors information to include in a marketing submission. The current guidance provides a recommended structure for reporting human factors information, with samples illustrating the types of information that should be included in a human factors report and/or outlines of the report content provided in Appendix A, Appendix B, and Appendix C.

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

FDA recognizes and anticipates that the Agency and industry may need a minimum of 60 days to perform activities to operationalize the policies within this guidance. For regulatory submissions that are currently pending with FDA after publication of the guidance, as well as those

[2] In the United States, the term "human factors engineering" (HFE) is predominant but in other parts of the world, "usability engineering" (UE) is preferred. For the purposes of this document, the two terms are considered interchangeable.

submissions received before August 1, 2026, FDA generally does not anticipate that manufacturers will be ready to include the newly recommended information outlined in the guidance in their submission. FDA, however, intends to review any such information if submitted at any time.

In general, FDA's guidance documents 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.

II. Scope

This guidance is intended to help submitters and FDA staff determine what human factors information should be included in marketing submissions for medical devices, including 510(k)s, De Novo requests, PMAs, and HDE applications. Note that combination products[3] can have additional risks and considerations and are not addressed in this guidance document.[4] FDA encourages submitters to contact the appropriate Center and review division to discuss combination product-specific human factors concerns, as appropriate.[5]

The recommendations in this guidance are intended to be generally applicable for all medical devices reviewed by CDRH. If there are device-specific guidances or requirements, the applicable recommendations should, and applicable requirements must, be followed. This guidance is not intended to supersede other device-specific guidances.

This guidance is not intended to inform manufacturers about how to perform a human factors evaluation. This guidance is also not intended to describe when a marketing submission must be submitted for a new or modified device.

III. Definitions

The following definitions[6] apply for the purposes of this guidance:

[3] Refer to 21 CFR 3.2(e) for the definition of a combination product.
[4] For more information on the human factors evaluation of combination products, see the FDA guidance document "Application of Human Factors Engineering Principles for Combination Products: Questions and Answers."
[5] For more information regarding combination products, see the FDA combination products website. For additional information regarding ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics, see the guidance "Requesting FDA Feedback on Combination Products."
[6] The definitions provided in this section are informed by, but not necessarily identical to, the definitions found in the sources that are cited.

- **Abnormal use**: Conscious, deliberate act or deliberate omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer.[7]
- **Critical task**: A user task which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.
- **Formative evaluation**: User interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated use errors.[8]
- **Harm:** Injury or damage to the health of people, or damage to property or the environment.[9]
- **Hazard**: Potential source of harm.[10]
- **Hazardous situation**: Circumstance in which people, property or the environment is/are exposed to one or more hazards.[11]
- **Human factors engineering**[12]: Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of medical devices (including software), systems and tasks to achieve adequate usability.[13]
- **Human factors validation testing**[14]: Testing conducted at the end of the device development process to assess user interactions with a device user interface to identify use errors that would or could result in serious harm to the patient or user. Human factors validation testing is also used to assess the effectiveness of risk control measures. Human factors validation testing represents one portion of design validation.
- **Normal use**: Operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use.[15]
- **Residual risk**: Risk remaining after risk control measures have been implemented.[16]
- **Serious harm**: Includes both serious injury and/or death.

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[7] ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices.*
[8] *Id*.
[9] ANSI/AAMI/ISO 14971 Third Edition 2019-12 *Medical devices—Application of risk management to medical devices*.
[10] *Id.*
[11] *Id.*
[12] See footnote 2.
[13] See footnote 7.
[14] Human factors validation testing is sometimes referred to as "summative testing." However, summative testing can be defined differently and some definitions omit essential components of human factors validation testing as described in this guidance document.
[15] See footnote 7.
[16] See footnote 9.

- **Serious injury**: An injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure, or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.[17]
- **Task**: One or more user interactions with a medical device to achieve a desired result.[18]
- **Use environment**: Actual conditions and setting in which users interact with the medical device.[19]
- **Use error**: User action or lack of action that was different from that expected by the manufacturer and caused a result that (1) was different from the result expected by the user, (2) was not caused solely by device failure, and (3) did or could result in harm.
- **Use safety**: Freedom from unacceptable use-related risk.
- **User**: Person interacting with (i.e., operating or handling) the medical device.[20]
- **User interface**: Means by which the user and the medical device interact.[21] [Note: Examples include packaging, labeling,[22] training materials, physical controls, display elements, alarms, and logic of operation of each device component.]
- **Use-related risk analysis (URRA)**: Systematic use of available information to identify use-related hazards and to estimate the use-related risk.

IV. Risk-based approach to human factors information in marketing submissions

The purpose of including human factors information in a marketing submission is to help the manufacturer meet the applicable statutory and regulatory criteria by demonstrating that the user interface of the device is appropriate for the intended users, uses, and use environments. This section uses flowcharts, tables, and text to guide submitters through a risk-based approach to help submitters determine what human factors information they should include in their marketing submission.

FDA refers to this risk-based approach as the Human Factors (HF) Submission Category. Submitters should use the flowchart in Figure 1 and use its companion text to answer the questions posed at each decision point to determine which HF Submission Category is

[17] *See* 21 CFR 803.3(w).
[18] See footnote 7.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." Section 201(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 321(m).

appropriate to support their marketing submission. The flowchart is based on the device's indications for use and the URRA in the context of new devices or modifications to devices for which FDA has already granted marketing authorization.[23]

FDA based the HF Submission Categories on the identification of critical tasks, considering the types of changes that can affect the human factors assessment and risk-based factors such as user interface history of use, complexity, and existing risk control measures. Submitters should use the URRA and the decision points described below to help determine the HF Submission Category for their marketing submission. Submitters should identify one HF Submission Category per marketing submission. If a marketing submission for a modified device includes multiple modifications, the submitter should consider the modifications collectively when determining the HF Submission Category. Submitters should also reference Table 1 for FDA's recommended human factors information to provide in a marketing submission after they determine which HF Submission Category their submission falls under using Figure 1.

[23] This guidance generally references modifications to devices for which FDA has already granted marketing authorization, and not to 510(k)-exempt devices. The recommendations in the guidance, however, also apply to modifications of 510(k)-exempt devices that require premarket authorization.

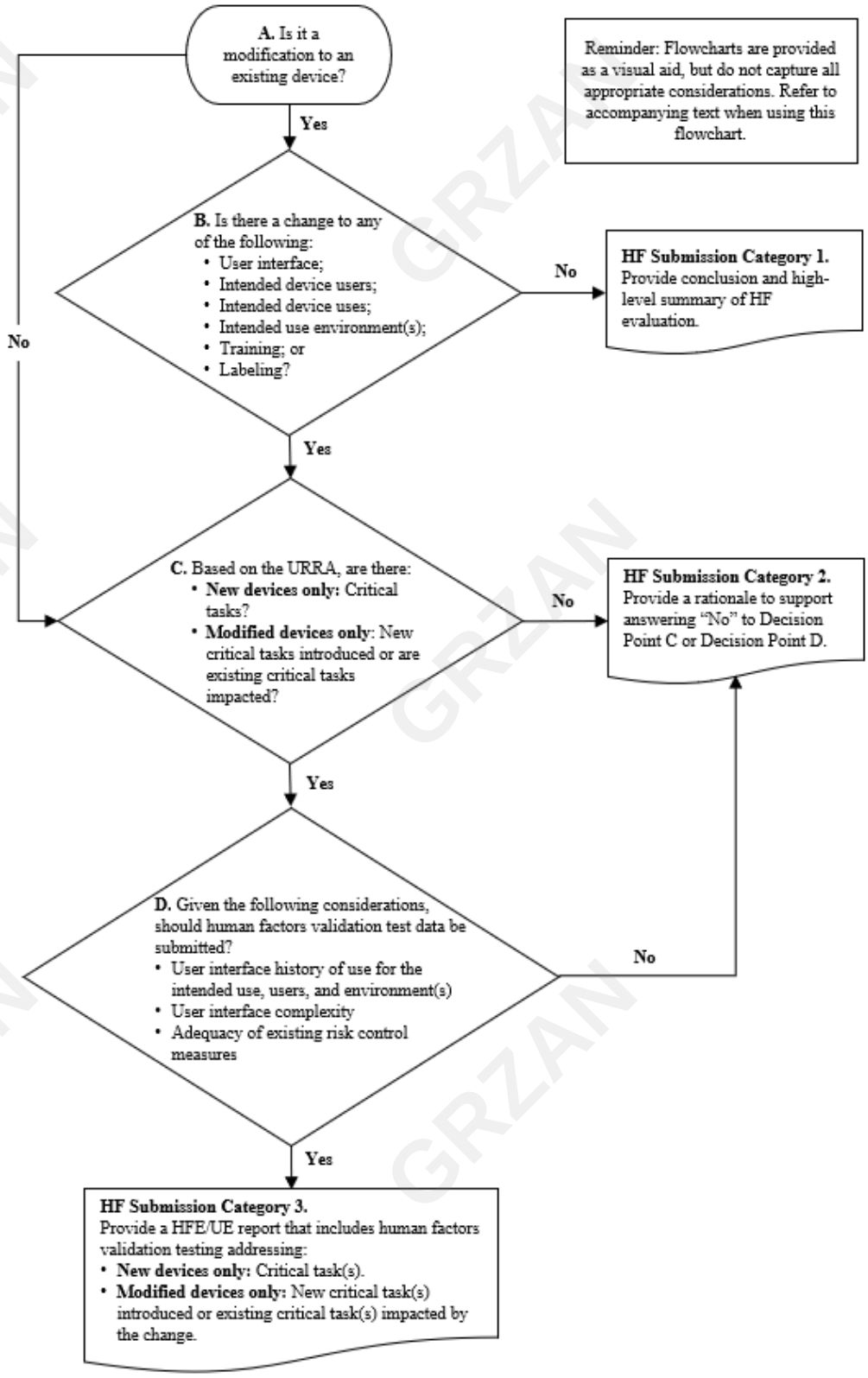


Figure 1. Flowchart illustrating a risk-based approach to determine the HF Submission Category. [24]

A. How to determine HF Submission Category

Decision Point A: Is it a modification to an existing device?[25]
Submitters should answer "Yes" to this question and proceed to Decision Point B when their submission is for a change to a device that has already received marketing authorization from FDA through a 510(k), PMA, HDE application, or De Novo request. Submitters should generally answer "No" and proceed to Decision Point C if their device is a completely new device that has not received marketing authorization from FDA.

Submitters may be able to answer "Yes" to this question for a new device when the new device has the same or similar user interface as one of their own legally marketed devices and they are leveraging human factors information from this legally marketed device for the new device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Decision Point B is intended to assess whether there have been any proposed changes that affect the human factors assessment. If the answer to this question is "No," then the level of information would fall into HF Submission Category 1; however, if the answer is "Yes," then the submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only:** Critical tasks?[26]
- **Modified devices only:** New critical tasks introduced or are existing critical tasks impacted?

The URRA incorporating risk analysis approaches such as Failure Mode and Effects Analysis (FMEA), analysis of known use problems, and formative evaluation should be referenced to

[24] Please note that, for the purposes of this flowchart, labeling and training have been separated out from user interface in Decision Point B to ensure that these important aspects of the user interface are considered during the decision-making process. As stated previously, this guidance's definition of user interface aligns with that of ANSI/AAMI/IEC 62366-1 which includes labeling and training as subsets of the user interface.
[25] See the following FDA guidances for additional information about modifications to existing devices, "Deciding When to Submit a 510(k) for a Change to an Existing Device," "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," and "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process." See also 21 CFR 807.81(a)(3), 21 CFR 814.108, and 21 CFR 814.39.
[26] For more information on how FDA recommends identifying and categorizing user tasks, leading to a list of critical tasks, see the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices."

answer this question.[27] The URRA should include all user tasks and identify those considered to be critical tasks (see Table 2 and Table 3 in Section IV.B of this guidance).

For modified devices, FDA recommends that submitters consider the URRA on the final finished device and not just modifications to the device. This recommendation is intended to provide a holistic assessment of any critical tasks that could be impacted upstream or downstream from the change(s) identified in Decision Point B. When determining if a critical task has been impacted by a change, FDA recommends considering if those changes influence the user's perception and/or cognition, or the user's physical interaction with the device. A reduction or increase in the steps to execute a critical task may be considered as impacting the critical task. If a marketing submission includes more than one change, the submitter should also consider whether there is an impact based on the cumulative changes.

If there are no critical tasks for a new device, or no new critical tasks introduced, and no impacted critical tasks for a modified device based on the URRA, the answer to this question is "No," and the level of information would fall into HF Submission Category 2.

If the answer is "Yes," then the submitter should proceed to Decision Point D.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **Device user interface complexity**
- **Adequacy of existing risk control measures**

Decision Point D is intended to help submitters determine whether data from human factors validation testing should be submitted in a marketing submission.[28] Submitters should assess the URRA when answering this question, and examine multiple considerations, including but not limited to intended user, uses, technological characteristics, user familiarity and experience with device user interface, user characteristics, clinical impact of use errors, and use environment. For example, a marketing submission for a device with user interface design features that are not complex and have an established history of safe use for the intended use, by the intended users, and in the intended use environment(s) may not need to submit human factors validation testing to support marketing authorization. It may be useful to conduct comparative analyses to similar legally marketed devices (e.g., labeling comparison, comparative task analysis, physical comparison) for the purposes of identifying what differences exist between the device user interfaces and where the same or similar risks may apply to the subject device.

[27] For more information on how FDA recommends using risk analysis approaches, analysis of use problems, and formative evaluation, see the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices."

[28] The Quality Management System Regulation (21 CFR part 820) requires that manufacturers of certain finished devices verify and validate device design, review and approve changes to device design, and document changes and approvals in the design and development file (21 CFR 820.10(c); ISO 13485:2016 Subclause 7.3). FDA recommends that human factors information be maintained by the manufacturer regardless of whether it is submitted to FDA.

For modified devices where critical tasks are impacted by the modification but existing risk control measures remain effective at eliminating or reducing the risk, submitters can consider providing a rationale in lieu of submitting new human factors validation testing. Such rationale should include objective evidence that the risk controls remain effective.

Human factors validation test data are likely needed to support marketing authorization for devices with complex user interfaces (e.g., devices that involve management such as programming, monitoring, and/or maintenance, systems with many steps such as connections, disconnections, and/or selections that influence how the device operates) and/or if the device type historically has been associated with known use error issues (e.g., infusion pumps)[29]. FDA may also determine that human factors validation test data are needed in a specific marketing submission to support authorization, even if human factors validation test data have not been submitted historically for that device type, under circumstances such as, but not limited to, the following:

- There is a significant difference in the subject device compared to similar legally marketed devices that affects its use (e.g., novel technological feature, new indications for use of the device, change in use environment, new user groups).
- New information (e.g., recalls, adverse events, problem reports, complaints) identifies a safety signal for which the cause has been attributed to use error.
- The severity of possible harm resulting from use error has increased.

If a rationale based on the considerations discussed above can be provided in the marketing submission in lieu of human factors validation testing the answer to this question is "No," and the level of information would fall into HF Submission Category 2. If the answer is "Yes," then the level of information would fall into HF Submission Category 3.

See Section VI of this guidance for additional examples that illustrate this decision-making on whether human factors validation testing should be submitted, as well as the other decision points. Submitters should seek feedback through a Pre-Submission if they are not sure whether a rationale would be appropriate for their specific marketing submission.[30]

B. What to include in a marketing submission based on HF Submission Category

Using the flowchart in Figure 1 and its companion text to determine the HF Submission Category, manufacturers should include the following human factors information in marketing submissions:

[29] See Section 6.2 of the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" for more information on identifying known use-related problems.

[30] For more information, see the FDA guidance document "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

HF Submission Category 1. Conclusion and high-level summary of HF evaluation: The submission should include a statement justifying that the device modifications do not affect the human factors considerations of the modified device. If previous HFE/UE evaluations are being leveraged, these should be described as part of the conclusion and high-level summary.[31] See Table 1 for the minimum suggested submission content for devices that fall into HF Submission Category 1. See Appendix A for a sample illustrating the types of information that should be included in a human factors report and an outline of the report content for HF Submission Category 1.

HF Submission Category 2. Rationale in submission for why the answer to Decision Point C or Decision Point D is "No": If the answer is "No" to Decision Point C, the submitter should submit a rationale that clearly describes the basis of their decision that there are no critical tasks (for a new device), or no new critical tasks introduced and no impacted critical tasks (for a modified device). If the answer is "No" to Decision Point D, the submitter should submit a rationale that clearly describes the basis of their decision to not submit human factors validation in the marketing submission. These rationales should be based on the decision-making noted in Section IV.A that takes the submitter through each decision point. See Table 1 for the suggested minimum submission content for devices that fall into HF Submission Category 2. See Appendix B for samples illustrating the types of information that should be included in a human factors report and an outline of the report content for HF Submission Category 2.

HF Submission Category 3. A HFE/UE report that includes human factors validation testing: A comprehensive HFE/UE report that includes all elements of a HFE/UE report described in Section V of this guidance should be submitted to FDA for marketing submissions in HF Submission Category 3. See Appendix C for an outline of the content that should be included in a human factors report for HF Submission Category 3.

Table 1. Recommended minimum human factors information that should be provided for a marketing submission based on HF Submission Category

Recommended information (Report section numbers from Section V below)	**HF Submission Category**		
	1	**2**	**3**
Conclusion and high-level summary (Section 1)	✓	✓	✓
Descriptions of: • Intended device users, uses, use environments, and training (Section 2) • Device user interface (Section 3) • Summary of known use problems (Section 4)		✓	✓
Preliminary activities • Summary of preliminary HFE/UE analyses and evaluations (Section 5)			✓
URRA			✓

[31] FDA is not recommending resubmission of prior HFE/UE evaluations or materials which have been previously reviewed in prior marketing submissions; however, a cross-reference to such marketing submissions may be helpful.

• Analysis of hazards and risks associated with use of the device (Section 6) • Identification and description of critical tasks (Section 7)			
Details of human factors validation testing of final design (Section 8)			✓

Table 2. Example tabular format for the URRA[32]

Task ID #[33]	User Task [34]	Possible use error(s)	Hazardous situation	Potential harm to patient/ operator	Severity of harm	Critical Task (Y/N)	Risk Control Measure(s) [35]	Validation method for effectiveness of risk control measure[36]
Task #1								
Task #2								

[32] This is one possible option for formatting a URRA and is not intended to represent the only acceptable option. Submitters can modify the table content and formatting as needed.
[33] The Task ID # should provide traceability of the task with respect to other human factors documentation elements (e.g., risk management file, human factors validation testing).
[34] Note that information provided here should describe both knowledge tasks and performance tasks.
[35] Such risk control measures could include user interface design features, such as the design of the device itself, labels, instructions for use, or training. For example, if the risk control measure is the labeling (e.g., instructions for use, user manual, etc.) submitters could specify the relevant page or section in the labeling.
[36] For example, submitters could specify which use scenario(s)/knowledge-based task(s) trace to the relevant task/risk control.

Table 3. Example tabular format for the comparative URRA[37]

Existing Device							Modified Device			Submitter's comparison comments
Task ID #[38]	User Task[39]	Possible use error(s)	Hazardous situation	Potential harm to patient/ operator	Severity of harm	Critical task (Y/N)	Comparison of user task description to existing device	Comparison of device user interface, intended device users, intended devices uses, intended device use environments(s), training, labeling	Comparison of proposed risk control measure to existing device	
Task #1										
Task #2										

V. Recommended content of human factors information in marketing submissions

A manufacturer's internal documentation of risk management, human factors engineering, and design optimization processes can help provide evidence, where appropriate, that the needs of the intended users were considered in the design and that the device is safe and effective for the intended users, uses, and use environments. The Quality Management System Regulation (21 CFR part 820) requires that manufacturers of certain finished devices verify and validate device design, review and approve changes to device design, and document changes and approvals in the design and development files (21 CFR 820.10(c); ISO 13485:2016 Subclause 7.3).[40] FDA recommends that human factors information be maintained by the manufacturer regardless of

[37] This is one possible option for formatting a comparative URRA and is not intended to represent the only acceptable option. Submitters can modify the table content and formatting as needed.

[38] The Task ID # should provide traceability of the task with respect to other human factors documentation elements (e.g., risk management file, human factors validation testing).

[39] Note that information provided here should describe both knowledge tasks and performance tasks.

[40] See 89 FR 7496. FDA issued a final rule amending the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation (21 CFR Part 820) to harmonize and modernize the regulation. FDA harmonized to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (i.e., other countries). This revised Part 820 is referred to as the Quality Management System Regulation (QMSR). This final rule took effect on February 2, 2026, and removes the majority of the requirements previously in Part 820 and instead 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. The QMSR incorporates by reference the 2016 edition of ISO 13485. By incorporating ISO 13485 by reference, we are explicitly requiring current internationally recognized regulatory expectations for QMS for devices subject to FDA's jurisdiction. All references to ISO 13485 in this guidance are to ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*.

whether it is submitted to FDA. Manufacturers must keep records to the extent required under applicable law, including the Quality Management System Regulation (for example, by reference, ISO 13485:2016 Subclause 7.3.10), and these (and other) records must generally be made available to an FDA investigator upon request (see section 704(e) of the Federal Food, Drug, and Cosmetic Act).

This section describes the human factors information that may be appropriate for submission to FDA in a marketing submission when one is required.[41] This human factors information describes how the HFE/UE process was applied during the development of a medical device. Human factors information should summarize the evaluations performed. Such information does not typically include all raw data from a human factors validation test. The information should discuss the safety-related HFE/UE considerations, processes, issues, resolutions, and conclusions. The information should describe the identification, evaluation, and final assessment of all use-related hazards from using the device.

Documents or analyses that are part of the HFE/UE process should be included in the human factors information provided in a marketing submission. This includes portions of risk analyses focusing on user interactions with the device and specific HFE/UE processes, results, and conclusions. Such information can also reference materials relevant to the HFE/UE process in other parts of the submission. A recommended structure for reporting this human factors information is further described below. Samples of the HFE/UE report content and/or outlines are provided in Appendix A for HF Submission Category 1, Appendix B for HF Submission Category 2, and Appendix C for HF Submission Category 3.

Section 1: Conclusion and high-level summary

For all HF Submission Categories, submitters should begin with a conclusion stating the following:

- Whether the user interface of the device has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses under the expected conditions, and
- The identified HF Submission Category. Submitters should include applicable rationales to support their determination of the HF Submission Category and level of human factors information provided, as discussed in Section IV.

FDA recommends that submitters follow the conclusion with a high-level summary of the HFE/UE assessment, and a summary of the HFE/UE processes conducted (e.g., HFE/UE analyses and evaluations, design modifications, human factors validation testing) and analysis of the results.

[41] This guidance is not intended to address whether or not a 510(k), an HDE supplement or a PMA supplement is required for changes that may involve a HFE/UE analysis. Manufacturers should apply the applicable regulatory criteria in 21 CFR 807.81, 21 CFR 814.108 or 21 CFR 814.39 to determine whether a 510(k), HDE supplement or PMA supplement should be submitted. For more information, see the FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device," "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," "Humanitarian Device Exemption (HDE) Program" or "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process."

When applicable, this section should discuss any remaining use-related residual risks after human factors validation testing. Submitters should describe why further risk control is not possible or not practicable based on a benefit-risk analysis[42] for the device.

Section 2: Descriptions of intended device users, uses, use environments, and training
This section, which applies to HF Submission Categories 2 and 3, should include:

- A description of the intended user population. If there is more than one distinct user population, each population should be described. The description should include meaningful differences in capabilities or use responsibilities between user populations that could affect their interactions with the device. This includes lay and healthcare professional users who might use the same device to perform different tasks or different types of professionals who might perform different tasks on the device;
- A summary of the device's intended use;
- A summary of the device's operational context of use and critical aspects of device operation, including:
  - Whether users should or must be trained prior to device use;
  - How the device is used across clinical applications; and
  - Set up, maintenance, cleaning, and reprocessing information.
- A summary of the intended use environments (e.g., hospital, medevac vehicle, home) and the characteristics of those environments (e.g., glare, vibration, ambient noise, high levels of activity) that could affect user interactions with the device; and
- A description of any training users would receive. A sample of the training materials such as a video, presentation slides, or a pamphlet may be appended.
- For modified devices, a comparison of the subject device intended users, uses, use environments, and training to that of the existing device.

In many cases, this information may be found in the device description or elsewhere within the submission. If that is the case, a simple reference to the relevant section is adequate to address this section. Information found elsewhere within the submission does not need to be repeated in the human factors report, but can be repeated if the submitter believes that its inclusion provides useful context to the report.

Section 3: Description of device user interface
When applicable, this section should include:

- A graphical representation (e.g., photographs, illustrations, line drawings) of the device and its user interface. This should depict the overall device and all components of the user interface with which the user will interact (e.g., display and function screens, alarm speakers, controls, keypads, buttons, doors, components to be connected, retaining clips);
- A written description of the device-user interface;

[42] For the purposes of this guidance, FDA uses the term "benefit-risk analysis" consistent with ANSI/AAMI/ISO 14971: 2019 *Medical devices—Application of risk management to medical devices*.

- A copy of the labeling that will be provided to the user with the device (e.g., instructions for use, user manual, quick-start guides, packaging);
- An overview of the operational sequence of the device and the user's expected interactions with the user interface. This should include the sequence of user actions performed to use the device and resulting device responses, when appropriate; and
- For modified devices, a comparison of the subject device user interface to that of the existing device (see Table 4 for an example format). FDA recommends identifying the elements of the device user interface components, including labeling, that were modified.

Similar to the information in Section 2, this information may already be found in the submission in other sections, such as the device description or the labeling section. If that is the case, the information for this section can simply be referenced. Information found elsewhere within the submission does not need to be repeated in the human factors report, but can be repeated if the submitter believes that its inclusion provides useful context to the report.

Table 4. Example tabular format for the comparison of the modified device user interface to the existing device[43]

Modification identifier	Image of existing device user interface component	Image of modified device user interface component	Description of the modification made to the modified device
Modification #1			
Modification #2			

Section 4: Summary of known use problems

This section, which applies to HF Submission Categories 2 and 3, should describe all known use problems for previous models of the same device (as applicable) or with similar types of devices (e.g., predicate devices). FDA recommends that submitters state that there are no known use problems, if applicable. For a device that has been modified specifically in response to use problems in the field, this section should discuss those problems and the device modifications implemented to address the problems.

Section 5: Summary of preliminary HFE/UE analyses and evaluations

This section, which applies to HF Submission Category 3, should identify the preliminary HFE/UE analysis and evaluation methods used (e.g., specific analysis techniques, formative evaluations), summarize the key results of those analyses and evaluations, describe modifications made to the user interface design in response, and discuss the key findings that informed the protocol development for the human factors validation test.

Section 6: Analysis of hazards and risks associated with use of the device

The Human Factors Guidance provides detailed recommendations on methodologies and tools to aid in performing analyses of hazards and risks.

[43] This is one possible option for formatting a comparison and is not intended to represent the only acceptable option. Submitters can modify the table content and formatting as needed.

This section, which applies to HF Submission Category 3, should include the URRA document.[44] This is typically an excerpt from the comprehensive risk analysis that includes all use-related hazards and risks identified through the preliminary analyses and evaluations, including those associated with potential use errors. The URRA document is intended to be a living document; updates should be made to identified risks and hazards throughout the device design process. FDA believes it can be useful to organize this information in a tabular format. An example tabular format is provided in Table 2. This example provides the recommended minimum information to evaluate the use-related risks associated with your device.

For modified devices, the submitter should provide a comparative URRA (see example tabular format in Table 3) comparing the modified device URRA with the existing device URRA. At a minimum, the comparative URRA should include all tasks associated with the use scenarios relevant to the modifications. Submitters should also discuss whether the risk associated with the modification is acceptable and assess whether the proposed changes warranted human factors validation testing. If the submitter determines that a device change resulting in a modification to any task, associated harm, and/or risk control measure does not merit new human factors validation test data to support the device's use safety, a rationale should be provided.

Section 7: Identification and description of critical tasks
This section, which applies to HF Submission Category 3, should:

- Explain the process followed to identify the critical tasks based on the URRA. Since critical tasks are determined by the severity of the potential harm, FDA recommends that the submitter describe the levels of severity being used and use a reference when appropriate. For example, if the submitter is using a qualitative five-level severity rating from a voluntary consensus standard (e.g., ISO 14971[45]), this section should include a table of severity levels with descriptions of each level and reference the applicable standard; and
- List and describe the critical tasks. For modified devices, FDA recommends providing a list of the new and/or impacted critical tasks. If critical tasks are introduced and/or impacted for a modified device, but existing risk control measures remain acceptable, the submitter should provide a rationale for why the task does not merit new human factors validation test data to support the device's use safety. The submitter should also describe each use scenario included in the human factors validation testing and list the critical and non-critical tasks that constitute each use scenario.

Section 8: Details of human factors validation testing of final design
This section, which applies to HF Submission Category 3, should summarize all human factors validation activities conducted. For modified devices, as stated in the Human Factors Guidance,

[44] The URRA can be provided as a separate document or appendix to the HFE/UE report.
[45] ANSI/AAMI/ISO 14971: *Medical devices—Application of risk management to medical devices* and AAMI/ISO TIR24971: *Medical devices - Guidance on the application of ISO 14971*.

the validation test may be limited to assessment of those aspects of users' interactions and tasks that were affected by the design modifications. This section should provide:

- A rationale for the test type selected (i.e., simulated use, actual use, or clinical study)
- Descriptions of the following:
  - the test environment and conditions of use
  - number and type of test participants
  - training provided to test participants and how the training corresponded to real-world training levels
  - critical tasks and use scenarios included in testing
  - definition of successful performance of each test task
  - data to be collected and methods for documenting observations and interview responses
- The test results, including:
  - observations of task performance and occurrences of use errors, close calls, and use problems
  - feedback from interviews with test participants regarding device use, critical tasks, use errors, and problems (as applicable)
- A comprehensive analysis of all use errors and problems that occurred that could have resulted in harm in real-world use
- A description of all design modifications made to the user interface in response to the test results
- A benefit-risk discussion (based on residual use-related risks)
- A full test protocol and a sample of all scripts and forms used in the testing should be appended

Submitters should also provide a residual risk analysis and the rationale for why implemented controls are acceptable. While elimination of all residual use-related risks may not be possible or practicable, submitters should have evidence of a systematic analysis of use errors and controls of use-related risks.[46] Submitters should reevaluate risk control measures to identify other means to reduce risk when it is determined that the residual use-related risks are unacceptable.

VI. Examples

The following are hypothetical examples of scenarios intended to illustrate FDA's risk-based approach to determine the HF Submission Category using the flowchart in Figure 1[47] and its companion text. Based on the HF Submission Category, FDA's recommended human factors information to support the marketing submission is outlined for each scenario. These examples do not account for every submission type nor the human factors information that may be appropriate for every situation. Additionally, the examples are based on an assumption that a manufacturer has already determined that it needs to submit a new marketing submission for the

[46] For example, see the Appendix of "Applying Human Factors and Usability Engineering to Medical Devices."
[47] Refer to footnote 23 for clarification on why labeling and training are listed separately from user interface for the purposes of this flowchart.

new or modified device.[48] Therefore, these examples are not intended to interpret when a marketing submission is required. In addition, these examples are not intended to comprehensively represent what should be included in a marketing submission for a new device or modification to an existing device.

A. Modification to an existing 510(k)-cleared device

Example A.1.

Scenario: A submitter currently has a cleared 510(k) for a gastrointestinal lesion software detection system. The device is a computer-assisted detection device used in conjunction with endoscopy for the detection of abnormal lesions in the gastrointestinal tract. The submitter has proposed to modify the computer-assisted detection algorithm and submitted a new 510(k). The algorithm modifications improve the system's ability to assist in detection of lesions and do not change any aspects of the device user interface.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

No. The changes to the algorithm do not impact any aspect of the device user interface. The intended users, uses, and use environments remain the same and in this instance, changes to the algorithm do not include modifications to the labeling or training programs.

Analysis: The recommended HF information for this marketing submission is defined by **HF Submission Category 1**. The submitter provides a statement justifying that the device modifications do not affect the human factors considerations of the modified device and the conclusion and high-level summary of HF evaluation referenced in Table 1.[49]

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[48] This guidance is not intended to address whether or not a 510(k), an HDE supplement or PMA supplement is required for changes that may involve a HFE/UE analysis. Manufacturers should apply the applicable regulatory criteria in 21 CFR 807.81, 21 CFR 814.108 or 21 CFR 814.39 to determine whether a 510(k), HDE supplement or PMA supplement should be submitted. For more information, see the FDA guidances "Deciding When to Submit a 510(k) for a Change to an Existing Device," "Deciding When to Submit a 510(k) for a Software Change to an Existing Device," "Humanitarian Device Exemption (HDE) Program" or "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process."

[49] See 21 CFR 876.1520. This device type is subject to special controls, which include a usability assessment (21 CFR 876.1520(b)(3)). In this example, the device modifications made by the submitter to their predicate device do not impact the human factors considerations. The usability assessment previously submitted by the same manufacturer of the predicate device can be leveraged to help demonstrate compliance with the special controls for the modified device.

Sample language for the report of HF information in this scenario is shown in Appendix A.

Example A.2.

Scenario: A submitter currently has a cleared 510(k) for a gas machine for anesthesia. The gas machine for anesthesia is intended for use in the hospital environment and includes a touch screen graphical user interface (GUI) and control knobs to regulate gas flow. The submitter submits a new 510(k) for a modification to the internal gas valving system and, included in the 510(k), labeling changes to reflect the modification. There are no changes to the apparent flow settings from this internal change. Any modifications regarding calculated flow rates are made in software settings.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The labeling (instructions for use, in this example) was changed to describe the modification to the internal gas valving system. This change does not impact any external user interface component on the device itself. There are no changes to the intended device users, uses, intended use environment, or training because there are no such changes to the indications for use.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

No. Even though the labeling (instructions for use, in this example) has changed, this change does not impact how the intended user is expected to interact with the device because the user is not intended to directly interact with the gas valving system, since it is an internal component. There are no changes that influence the user's perception and/or cognition, or the user's physical interaction with the device. Therefore, there are no new critical tasks introduced, nor are existing critical tasks impacted.

Analysis: The recommended HF information for this marketing submission is defined by **HF Submission Category 2**. The submitter provides a rationale that clearly describes the basis of the decision that there are no new critical tasks introduced, and no impacted critical tasks for their modified device, along with the information referenced in Table 1.

Example A.3.

Scenario: In an alternate scenario to Example A.2, in addition to the change described in 0, the submitter is also changing the font size from 12 to 14 point on the text displayed on the graphical user interface (GUI) of the gas machine for anesthesia, along with a proportional increase in the screen's physical size. The submitter is also making associated software changes to address the proposed change in the font size. The GUI menu does not change in terms of selection layout and contains the same icons representing identical actions to those of the existing 510(k)-cleared device.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. There are changes to the user interface from the software changes because the user is intended to directly interact visually with the words on the touch screen GUI, which the submitter states is the only part of the device being modified. There are no changes to the intended device users, uses, intended use environment, training, or labeling.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

No. Even though the user interface (GUI) was changed to include larger text font and a larger screen display, this change does not impact how the intended user is expected to interact with the device because the same textual information is being presented in the same layout and format. The text size change was assessed to introduce no negative influence on the user's perception and/or cognition, or the user's physical interaction with the device. Therefore, there are no new critical tasks introduced, nor are existing critical tasks impacted.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 2**. The submitter provides a rationale (e.g., analysis of formative evaluation data) that clearly describes the basis of the decision that there are no new critical tasks introduced, and no impacted critical tasks for their modified device, along with the information referenced in Table 1.

Example A.4.

Scenario: The submitter submits a new 510(k) to change the GUI of the gas machine for anesthesia described in 0. The proposed changes consist of changing textual menu selection items to icons (i.e., graphics). In addition, the submitter is changing from a physical knob

interface with discrete values for gas flow control to a digital slider with continuous values within a pre-specified range that became an added feature to the touch screen GUI. Based on these changes, the submitter updated the labeling, including the user manual and instructions for use, and training.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. There are changes to the user interface because the user directly interacts visually with the icons and controls on the touch screen GUI. There is also a change in the way the user controls the gas flow. There are no changes to the intended device users, uses, or intended use environment. Both the submitter's training and labeling have changed based on the changes to the touch screen GUI.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. There are several critical tasks associated with the main touch screen GUI of the gas machine for anesthesia, such as setting the ventilation mode, setting tidal volume and inspiratory pressure, and setting alarms. Changing the GUI to include only icons instead of text for menu selections may impact the understandability of the device screen. There are also critical tasks associated with setting and controlling the gas flow to the patient. The interface for gas flow control changed from a physical knob to a digital slider on the touch screen interface, which impacts the physical interaction the user will have with the gas flow control. Although the same information is being conveyed, it is displayed in a different layout and format compared to the predicate.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. The device user interface is complex, consisting of features such as buttons, touch screen panel, sliders, assorted connections, and meters. While the intended user groups are unchanged, there are different types of users that interact with the user interface, including physician anesthesiologists, certified registered nurse anesthetists, certified anesthesiologist

assistants, nurses and anesthesia technicians, biomedical engineering technicians, and service engineers. Considering the complexity of the device user interface and the introduction of a different control mechanism that involves new training for users, human factors validation test data should be submitted.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3**. The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example A.5.

Scenario: A submitter currently has a cleared 510(k) for a duodenoscope. The duodenoscope is reusable and has validated reprocessing instructions. Investigation into reports of infections associated with the use of duodenoscopes determines the root cause is inadequate reprocessing from insufficient cleaning. The submitter is changing the reprocessing instructions for the device in response to the safety signal and has submitted a new 510(k).

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The labeling (instructions for use) was changed to describe the modified reprocessing instructions, which includes further reprocessing steps, such as additional channel brushing. The visual format of the reprocessing instructions in the labeling were also modified, such as color-coding and section headings.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. The submitter evaluated the existing critical tasks, and some were impacted. Reprocessing is impacted by the additional steps. The visual changes to the labeling could impact the user's understanding of the reprocessing instructions.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. Duodenoscope reprocessing is well-understood to be a complicated process. There is an established history of known use errors that can occur with duodenoscope reprocessing, resulting in serious harms.[50]

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3.** The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example A.6.

Scenario: A submitter currently has a cleared 510(k) for a stereotaxic navigation system. The system consists of a navigation camera, computer, 2D monitors, and navigated instruments. It is intended for precisely positioning instruments and implants during stereotactic orthopedic surgery when a rigid reference can be established relative to the patient's bony anatomy. The submitter submits a new 510(k) to introduce an augmented reality (AR) user interface that displays visual guidance to aid with intraoperative instrument positioning and alignment. The AR technology complements the existing 2D system monitors and computer interfaces by displaying exactly the same information as the monitors (without spatial registration on the patient) and does not introduce any new user interface functions.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. There are changes to the user interface from introducing the AR technology because the user is intended to directly interact with the AR user interface via voice, hand gestures, and eye movements. The change also impacts training and labeling (instructions for use, in this example). There are no changes to the intended device users, uses, or intended use environment.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. While no new critical tasks are introduced, existing critical tasks are impacted because the user now performs the tasks by interacting with the AR interface.

[50] See Section 6.2 of the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" for more information on identifying known use-related problems.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. The AR user interface can be controlled via voice, hand gestures, and eye movements. This user interface is more complex compared to the existing 2D user interfaces consisting of a monitor, touchscreen, and computer keyboard/mouse. The intended user group does not have a historical familiarity with the novel AR user interface. Further, the AR interface introduces additional complexity to the stereotactic orthopedic surgery system.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3.** The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example A.7.

Scenario: A submitter currently has a cleared 510(k) for an integrated continuous glucose monitoring system indicated for the management of diabetes in adults. The system consists of a transcutaneous glucose sensor that transmits glucose measurement data to digitally connected devices, including automated insulin dosing systems. The submitter submits a new 510(k) to expand the device indications to include pediatric patients, specifically age range of 2-21 years old.[51]

Decision Point A: Is it a modification to an existing device?

Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The change adds a new intended device user group.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**

[51] In section 520(m) of the FD&C Act, the term "pediatric patients" means patients who are 21 years of age or younger at the time of the diagnosis or treatment. FD&C Act sec. 520(m)(6)(E)(i); see 21 CFR 814.3(s). Section 515A(c) of the FD&C Act identifies, by reference to section 520(m)(6)(E)(ii) of the FD&C Act, several pediatric subpopulations: neonates, infants, children, and adolescents. Generally, FDA views the approximate age ranges for these pediatric subpopulations as follows: Neonates (from birth through the first 28 days of life); Infants (29 days to less than 2 years); Children (2 years to less than 12 years); and Adolescents (aged 12 through 21 (up to but not including the 22nd birthday)). See FDA's guidance document entitled "Providing Information about Pediatric Uses of Medical Devices."

- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. While no new critical tasks were introduced by the change, the existing critical tasks are impacted because, with this change, they are intended to be executed by an additional user group.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. Even though the device user interface has not changed, the addition of the pediatric user group introduces new risks and raises questions of the adequacy of existing risk control measures and user interface complexity. The pediatric user group involves multiple groups (e.g., those who are fully reliant on a caregiver versus those who are partially reliant on a caregiver for management of diabetes). There is also a range of pediatric users' overall experience with diabetes treatment, insulin pumps and automated insulin delivery systems, depending on when a Type 1 diabetes diagnosis has been made. Severity of possible harm from use errors is increased for pediatric users, who may not be able to communicate symptoms of severe hypoglycemia, hyperglycemia or diabetic ketoacidosis to their caregivers and could be at a higher risk of developing hypoglycemia unawareness.[52]

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3.** The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example A.8.

Scenario: A submitter currently has a cleared 510(k) for an interoperable automated glycemic controller for use in the management of type 1 diabetes mellitus. The device works with an integrated continuous glucose monitor to measure glucose levels and increases or reduces insulin infusion from an alternate controller enabled insulin pump. The submitter submits a 510(k) to expand the device indications for use to include adults with type 2 diabetes mellitus. There are no changes to the device design.

Decision Point A: Is it a modification to an existing device?

Yes. The submitter is modifying their own existing 510(k)-cleared device and using that device as the predicate device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**

[52] See 21 CFR 862.1355. This device type is subject to special controls, which require a usability study that demonstrates that the intended user can use the device safely and obtain the expected glucose measurement accuracy (21 CFR 862.1355(b)(6)). The submitter conducted HF testing to comply with the special controls.

- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The change adds a new intended device user group.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. While no new critical tasks were introduced by the expanded indications for use, the existing critical tasks are impacted because, with this change, they are intended to be executed by an additional user group.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. The type 2 diabetes population is larger than the current type 1 diabetes user population and more diverse. The type 2 diabetes population may include users with a range of familiarity and experience with using an insulin pump. Additionally, compared to the current type 1 diabetes user population, the type 2 diabetes population generally introduces users with different levels of diabetes disease experience and have generally been escalated through multiple medications and device interventions. People with type 2 diabetes may also have additional comorbidities due to disease progression later in life and who may have different disease related impairments (e.g., neuropathy, retinopathy). Considering these characteristics of the new type 2 diabetes population, it is not apparent whether the existing risk controls are still valid for this new population.[53]

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3.** The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

B. Modification to an existing PMA-approved device[54]

Example B.1.

Scenario: An implantable infusion pump with a physician programmer has been approved as a standalone device through the PMA process. The approved physician programmer is a

[53] See 21 CFR 862.1356. The device type is subject to special controls, which require a human factors study that demonstrates that an intended user can safely use the device for its intended use (21 CFR 862.1356(b)(1)(ii)). In this example, the human factors validation study was necessary to comply with the special controls for this device type.

[54] Although the statutory and regulatory criteria for an HDE are different from a PMA, FDA's review of HDE applications has similarities to the review of PMAs. For more information on HDEs, see the FDA guidance "Humanitarian Device Exemption (HDE) Program."

personal digital assistant (PDA) device, with a monochrome screen and physical buttons to control scrolling and menu selection. The submitter requests approval in a PMA Supplement for a modification to the reservoir volume of the infusion pump. This proposed change does not result in any change to medication concentration or dosing calculation. The software is being updated to allow for the proposed volume change. The proposed modifications, including the software changes, have no direct effect on the device with which a physician or patient directly interact.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing PMA-approved device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The labeling (instructions for use, in this example) was updated to specify the change in the reservoir volume.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

No. There are critical tasks that could in some circumstances have been impacted by a change in the reservoir volume, including medication concentration and the dosing that are related to drug delivery to the patient. In this case, the medication concentration and dosing remained the same, even with the change in reservoir volume. Therefore, no critical tasks were impacted by the change in reservoir volume.

Analysis*:* The recommended HF information for this marketing submission is **HF Submission Category 2**. The submitter provides a rationale (e.g., discussion of how the change in total reservoir volume does not impact critical tasks such as setting concentration or calculating dosage) that clearly describes the basis of the decision that there are no new critical tasks introduced, and no impacted critical tasks for their modified device, along with the information referenced in Table 1.

Example B.2.

Scenario: Like Example B.1, an implantable infusion pump with a physician programmer has been approved through the PMA process. The approved physician programmer is a PDA device, with a monochrome screen and physical buttons to control scrolling and menu selection. The submitter requests approval in a PMA Supplement for a modification to the physician programmer from the approved monochrome PDA to a mini-tablet computer with a touch screen user interface. The display on the tablet computer will feature a full color display and new icons for menu functions.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is modifying their own existing PMA-approved device.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

Yes. The introduction of new icons, color selection and display, and new menu orientation, has changed the user interface. Due to these changes, the submitter is also proposing to change the relevant training and labeling (instructions for use, in this example).

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. In this case, the submitter evaluated the existing critical tasks, and some were impacted. Dose calculation function is impacted by additional (new) icon access on new home screen for unit selection and confirmation. Additional steps and workflow with the new icon could cause user negative transfer of experience and lead to delay of therapy.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. The device user interface is complex, as the user navigates through sets of workflows on the touchscreen interface to program the pump, to which it wirelessly connects. Users experience audible and visual feedback while interacting with the device. Additionally, there is a history of known use errors associated with this device type.[55] Considering the complexity of the device user interface and history of known use errors for this device type, human factors validation test data should be submitted.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3.** The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example B.3.

Scenario: A submitter has an approved PMA for a stent with a balloon catheter delivery system. The submitter is requesting approval for a new stent for use in conjunction with an

[55] See Section 6.2 of the FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices" for more information on identifying known use-related problems.

existing balloon catheter delivery system under a new PMA. The new stent uses the same balloon catheter delivery system as the submitter's own PMA-approved stent. The submitter is proposing to leverage the previous human factors information for the balloon catheter delivery system.

Decision Point A: Is it a modification to an existing device?
Yes. The submitter is using their own existing PMA-approved balloon catheter delivery system with a new stent.

Decision Point B: Is there a change to any of the following:

- **User interface;**
- **Intended device users;**
- **Intended device uses;**
- **Intended use environment(s);**
- **Training; or**
- **Labeling?**

No. Even though the submitter has submitted a new PMA, in this case, the user interface of the balloon catheter delivery system is the same as that used in the approved PMA. The only changes to the device are the stent design and coating, which are not user-interfacing and are based on the submitter's approved PMA. The submitter evaluated the critical tasks, and none of them were impacted by the change in stent design and coating. The submitter can leverage the previous human factors information in their new PMA.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 1.** The submitter provides a statement justifying that the device modifications do not affect the human factors considerations of the modified device and the conclusion and high-level summary of HF evaluation referenced in Table 1.

C. New devices

Example C.1.

Scenario: In an alternate scenario to Example B.3, the submitter is proposing to introduce the new stent as described above, along with a new balloon catheter delivery system that has a different design from the PMA-approved system and submits a PMA.

Decision Point A: Is it a modification to an existing device?
No. The submitter is submitting a new PMA based on a new design of the catheter delivery system with a new stent. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. The submitter has determined based on the URRA that there are critical tasks associated with the subject device.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

No. The design of the balloon catheter delivery system does not contain any novel technological features, as it uses mechanisms for positioning, deployment, and retraction of the stent that are similar to those of other legally marketed devices with the same intended use. Device users are trained physicians and are familiar with operating these mechanisms. The submitter has provided results from a simulated use study conducted with the subject device that demonstrated safe and reliable delivery, deployment, and retraction of the stent.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 2.** The submitter provides a rationale that clearly describes the basis of the decision to not submit human factors validation test data in the marketing submission,[56] along with the information referenced in Table 1.

Example C.2.

Scenario: The submitter submits a 510(k) for a new portable fingertip oximeter intended for spot checking oxygen saturation of arterial hemoglobin of adult patients in professional healthcare facilities and the home. The device is indicated for prescription use only. This is the first portable oximeter device developed by the submitter. The submitter identified a device from a different manufacturer as the predicate device. The subject device does not include any alarms or additional information interpreting the oxygen saturation, nor is it intended for life supporting or life-sustaining functions. The user of the device places the sensor on a finger and then reads the oxygen saturation values calculated by the device. The submitter compares their device with the predicate device to show the indications for use, use environment, and users are the same between the two devices.

Decision Point A: Is it a modification to an existing device?

No. The submitter has manufactured a new device. For purposes of demonstrating substantial equivalence, the submitter has identified a device from another device manufacturer as the predicate device. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

No. The submitter determined through the URRA that the action of placing the sensor on a user's finger and reading the oxygen saturation values could not cause serious harm to the

[56] FDA recommends that human factors information be maintained by the manufacturer regardless of whether it is submitted to FDA. Manufacturers must keep records to the extent required under applicable law, including the Quality Management System Regulation (for example, by reference, ISO 13485:2016 Subclause 7.3.10), and these (and other) records must generally be made available to an FDA investigator upon request (see section 704(e) of the FD&C Act).

user/patient. The submitter further justifies this conclusion by stating the device is used as a spot-check and there are no alarms or additional information interpreting the results from the device.

Analysis: The recommended HF Submission Category in this marketing submission is **HF Submission Category 2**. The submitter provides a rationale for why there are no critical tasks, along with the information referenced in Table 1.

Example C.3.

Scenario: The submitter submits a 510(k) for an injection device intended for aspiration and injection. This is the first injection device developed by the submitter. The submitter uses a device from a different manufacturer as the predicate device. The subject device has a unique design feature incorporated into the user interface. The submitter compares their device with the predicate device to show the indications for use, use environment, and users are the same between the two devices.

Decision Point A: Is it a modification to an existing device?
No. The submitter has manufactured a new device. For the purposes of demonstrating substantial equivalence, the submitter has identified a device from another device manufacturer as the predicate device. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. The submitter has determined based on the URRA that there are critical tasks associated with the new user interface feature.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. Human factors validation test data should be submitted as a result of the subject device's novel user interface. The risk rating (probability of occurrence and severity of harm) associated with executing critical tasks using the subject device may be different than other legally marketed injection devices for the same intended use due to the subject device's unique user interface and resulting increased user complexity.

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3**. The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

Example C.4.

Scenario: The submitter submits a 510(k) for a new blood lancet intended for a single use to puncture the skin to obtain a drop of capillary blood. This is the first blood lancet device

developed by the submitter. The submitter uses a device from a different manufacturer as the predicate device. The device design includes an integral sharps injury prevention feature in the form of a spring-loaded auto-retracting blade, which allows the device to be used once and then renders it inoperable of further use. The submitter compares their device with the predicate device and demonstrates that the indications for use, use environment, and users are the same between the two devices.

Decision Point A: Is it a modification to an existing device?
No. The submitter has manufactured a new device. For the purposes of demonstrating substantial equivalence, the submitter has identified a device from another device manufacturer as the predicate device. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. The submitter has determined based on the URRA that there are critical tasks associated with the subject device, such as setting the penetration depth, actuating the device, and handling and disposal of contaminated parts.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

No. The subject device design incorporates user interface components that are of low complexity and similar to other legally marketed devices with the same intended use that have been marketed for many years. There are no major differences in the technology (e.g., safety features, principle of operation) compared to the predicate device. Like the predicate device, the subject device mitigates risk of known use problems by including an integral sharps injury prevention feature in the form of a spring-loaded auto-retracting blade, which allows the device to be used once and then renders it inoperable of further use. The intended device users, uses, and use environments are the same as the predicate device. The subject device labeling is comparable to that of the predicate device.

Analysis: The recommended HF Submission Category for this marketing submission is **HF Submission Category 2.** The submitter provides a rationale that clearly describes the basis of the decision to not include human factors validation test data in the marketing submission, along with the information referenced in Table 1.

Sample language for the report of HF information in this scenario is shown in Appendix B.

Example C.5.

Scenario: The submitter submits a 510(k) for a non-resorbable plate and screw system intended for fracture fixation of small bones of the hand and foot. This is the first plate and screw system developed by the submitter. The submitter uses a device from a different manufacturer as the predicate device. The subject device design includes titanium alloy bone

plates that are used in conjunction with compatible titanium alloy bone screws to create a stabilizing construct that promotes fracture healing. The system contains locking and nonlocking screws, and the screw design allows variable angle placement. The submitter compares their device with the predicate device to show the indications for use, use environment, and users are the same between the two devices.

Decision Point A: Is it a modification to an existing device?
No. The submitter has manufactured a new device. For the purposes of demonstrating substantial equivalence, the submitter has identified a device from another device manufacturer as the predicate device. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. The submitter has determined based on the URRA that there are critical tasks within various use scenarios/workflows, such as preoperative planning, size selection, and implantation, associated with the subject device.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

No. Planning and implantation of bone plates and screws are routine procedures familiar to the user group (surgeons). Orthopedic surgeons are highly trained users that are familiar with historically utilized bone plates and screws. The user interface's characteristics and risk control measures have been historically shown to have adequate risk controls and are correlated with positive patient outcomes. The subject device does not have any novel or complex user interface features.

Analysis: The recommended HF Submission Category for this marketing submission is **HF Submission Category 2.** The submitter provides a rationale that clearly describes the basis of the decision to not submit human factors validation test data in the marketing submission, along with the information referenced in Table 1.

Sample language for the report of HF information in this scenario is shown in Appendix B.

Example C.6.

Scenario: The submitter submits a 510(k) for a new guided ultrasound device intended to be used by expert users and non-expert users in a professional healthcare environment to obtain diagnostic ultrasound images.

Decision Point A: Is it a modification to an existing device?
No. The submitter has manufactured a new device. For purposes of demonstrating substantial equivalence, the submitter has identified a device from another device manufacturer as the predicate device. The submitter should proceed to Decision Point C.

Decision Point C: Based on the URRA, are there:

- **New devices only: Critical tasks?**
- **Modified devices only: New critical tasks introduced or are existing critical tasks impacted?**

Yes. Critical tasks have been identified by the submitter that if performed incorrectly or not performed at all, could impact patient safety by providing inadequate imaging which could prevent the detection of potentially life-threatening conditions.

Decision Point D: Given the following considerations, should human factors validation test data be submitted?

- **User interface history of use for the intended use, users, and environment(s)**
- **User interface complexity**
- **Adequacy of existing risk control measures**

Yes. The device provides feedback to the user on obtaining ultrasound image scans for diagnostic use. The device intended user groups include medical professionals that are not specifically trained to perform ultrasound scans. This non-expert user group does not have the same familiarity with the device user interface compared to the expert user group. The URRA indicated that human factors validation testing was necessary.[57]

Analysis: The recommended HF information for this marketing submission is **HF Submission Category 3**. The submitter provides test results and analysis from a new HF validation study for the subject device in an HFE/UE Report. The HFE/UE Report includes the information referenced in Table 1.

[57] See 21 CFR 892.2100. The device type is subject to special controls, which require a thorough discussion on use-related risk analysis/human factors data in the required report on the clinical performance testing and a report on usability testing demonstrating the effectiveness of the required training program on user performance (21 CFR 892.2100(B)(1)(iii)(E), (v)). In this example, the URRA and resultant human factors validation testing were necessary to comply with the special controls for this device type.

Appendix A – Sample HFE/UE Report Content: Category 1

This appendix provides some examples illustrating the types of information that should be included in a human factors report for HF Submission Category 1. However, the examples are not exhaustive, and are not intended to cover all possible details, risks, or considerations. Ultimately, decisions about the types of information to be included in each applicable section of the human factors report are generally fact-specific for each device.

Table A-1. Outline of HFE/UE Report for Category 1 Submissions

Sec.	Contents

1	**Conclusion and high-level summary**
	The <device> has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected conditions of use.
	• Rationale for HF Submission Category 1 determination based on assessment of device per Section IV, discussing, as applicable:
	  • HFE/UE assessments conducted
	  • HFE/UE processes conducted (e.g., HFE/UE analyses and evaluations, design modifications, human factors validation testing)
	  • Previous HFE/UE assessment(s) being leveraged to support the overall conclusion, with a reference to the location of the leveraged information by submission and section numbers
	  • Changes to the device and why they do not affect any of the following:
	  • User interface
	  • Intended device users
	  • Intended device uses
	  • Intended use environment(s)
	  • Training
	  • Labeling
	  • Analysis of results that support the overall conclusion
	• Discussion of any use-related residual risks (if applicable) and why further risk control is not possible or not practicable

Sample report language for example A.1 (HF Category 1).

Section 1: Conclusion and high-level summary

This submission falls under HF Submission Category 1. The [GI Lesion Software Detection System] has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected conditions.

The proposed device modifications to the algorithm were assessed, and the benefit-risk analysis identified that the changes to the algorithm do not impact the device-user interface, labeling, or training programs. Additionally, the intended users, uses, and use environments remain the same, and no additional risk-control measures are necessary. Consequently, no additional human factors test data is provided as part of the marketing submission.

Appendix B – Sample HFE/UE Report Content: Category 2

This appendix provides some examples illustrating the types of information that should be included in a human factors report for HF Submission Category 2.

The following outline identifies at a high level the information that should be considered for inclusion in each section of the HFE/UE Report, as applicable. In some cases, this report could be very brief. If the information is contained within another section of the submission, a reference to the applicable section is appropriate.

Table B-1. Outline of HFE/UE Report for Category 2 Submissions

Sec.	Contents

1	**Conclusion and high-level summary**
	The <device> has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected conditions of use.
	• High-level summary of HFE/UE assessment, HFE/UE processes conducted, and results that support this conclusion
	• Whether previous HFE/UE evaluations are being leveraged to support this conclusion, and, if so, provide a reference to the location of the leveraged information by submission and section numbers
	• Rationale for HF Submission Category 2 determination and not providing human factors validation test data based on assessment of device per Section IV, discussing, as applicable:
	  • How it was determined there are no critical tasks (for new devices), or no new/impacted critical tasks (for modified devices)
	  • Established history of safety and effectiveness of the device user interface *[Note: labeling comparisons, comparative task analyses, and/or physical device comparisons are examples of supplemental information which may be submitted to help support the conclusion]*
	  • User interface complexity (e.g., devices that involve management such as programming, monitoring, and/or maintenance, systems with many steps such as connections, disconnections, and/or selections that influence how the device operates) *[Note: Images or a graphical description of the UI, provided in Section 3 of the HFE/UE report, may be used to support the conclusion]*
	  • Adequacy of existing risk control measures *[Note: The summary of known use problem analysis, provided in Section 4 of the HFE/UE report, may be used to support the conclusion]*
	  • For modified devices with impacted critical tasks and unchanged risk control measures, the rationale should include evidence demonstrating the effectiveness of the existing risk controls
	• Discussion of any use-related residual risks (if applicable) and why further risk control is not possible or not practicable

2	**Descriptions of intended device users, uses, use environments, and training** • Intended user population(s) and meaningful differences in capabilities between multiple user populations that could affect user interactions with the device • Intended use • Operational contexts of use and critical aspects of device operation • Use environments and characteristics that could affect user interactions with the device • Training intended for users

Sec.	Contents
	• For modified devices, comparison of the subject device intended users, uses, use environments, and training to that of the existing device
3	**Description of device user interface** • Graphical representation of device and its user interface • Description of device user interface • Device labeling • Overview of operational sequence of device and expected user interactions with user interface • For modified devices, comparison of the subject device user interface to that of the existing device
4	**Summary of known use problems** • Known use problems with previous models of the subject device • Known use problems with similar devices (e.g., predicate devices, devices with similar user interface elements) • Design modifications implemented in response to post-market use error problems

Sample report language is provided below to illustrate the potential brevity of Category 2 reports for devices with critical tasks which have a known history of use, a simple (low complexity) user interface, and demonstrated adequacy of existing risk controls. These examples are not exhaustive, and are not intended to cover all possible details, risks, or considerations. Ultimately, decisions about the types of information to be included in each applicable section of the human factors report are generally fact-specific for each device.

Sample report language for example C.4. (HF Category 2).

Section 1: Conclusion and high-level summary

This submission falls under HF Submission Category 2. The [blood lancet device] has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected conditions.

The proposed blood lancet is a new device and is not a modification to a legally marketed blood lancet. A URRA was conducted and identified that there are multiple critical tasks associated with the new device, such as setting the penetration depth, actuating the device, and handling and disposal of contaminated parts. However, the device design incorporates user interface components that are of low complexity and are similar to other legally marketed devices with the same intended use that have been marketed for many years, providing comparable risk control measures for users (see Section 4 of this HFE/UE report). Like the predicate device, the proposed device design mitigates risk of known use problems by including an integral sharps injury prevention feature in the form of a spring-loaded auto-retracting blade, which allows the device to be used once and then renders it inoperable of further use. Additionally, the subject device labeling is comparable to that of the predicate device. The intended device users, uses, and use environments are the same as for the predicate device. For these reasons, it was determined that human factors validation test data would not be included in this marketing submission.

Section 2: Descriptions of intended device users, uses, use environments, and training

Please see the device description in Section xx of the submission for a detailed description of the intended device users, uses, use environments, and training.

Section 3: Description of device user interface

Please see the device description in Section xx of the submission for a description of the device user interface.

Section 4: Summary of known use problems

Known use problems with this type of device include bloodborne pathogen transmission from improper use/reuse, sharp object injuries, and local tissue infections. These risks have historically been associated with misuse/use errors, but have been mitigated through integral sharps injury prevention features. No additional risk control measures were necessary to address these known use problems.

Sample report language for example C.5. (HF Category 2).

Section 1: Conclusion and high-level summary

This submission falls under HF Submission Category 2. The [non-resorbable plate and screw system] has been designed for its intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, based upon an analysis of common user interface concepts that are historically recognized as clinically successful mitigations against known user problems for this device type.

Based on the URRA, critical tasks associated with the use of the subject device were identified within the following use scenarios: preoperative planning, component selection, and implantation. Planning, component selection, and implantation of bone plates and screws are routine procedures familiar to the intended user group (orthopedic surgeons). Orthopedic surgeons are highly trained users that are familiar with bone plates and screws. The user interface's characteristics and risk control measures have historically shown to have adequate risk controls against known use problems. The proposed user interface (implant and surgical instrumentation) and expected user interactions (planning, component selection, and implantation) do not differ from clinically common manual surgical techniques for component design selection, site preparation, and implementation as evidenced by comparison to the predicate device(s). This device does not have any novel or complex user features nor would users be expected to interact with this device in a manner which is not consistent with their established medical training and/or practice. Therefore, it was determined that human factors validation test data would not be included in this marketing submission. Note, post-market data will be reviewed on a periodic basis to support determinations of whether the device design and existing risk controls remain adequate.

Section 2: Descriptions of intended device users, uses, use environments, and training

Please see the device description in Section X of the submission for a detailed description of the intended device users, uses, use environments, and training program.

Section 3: Description of device user interface

Please see the device description/user interface section (Attachment X, Section Y) of the submission for a description of the device user interface, operational sequence of device use, and expected user interactions with the user interface.

Section 4: Summary of known use problems

In a Total Product Life Cycle (TPLC) report search of the MAUDE database for our identified product codes [HRS, HWC, NDJ] we found X (out of Y) reports which were attributed to use-related issues that led to serious harm(s) of patients. The identified known use problems have been adequately mitigated in our subject device which has been designed and tested in accordance with applicable standards and in alignment with relevant FDA guidances. No additional risk control measures are necessary to address these known use problems.

Appendix C – Outline of HFE/UE Report: Category 3

The following outline identifies at a high level the information that should be considered for inclusion in each section of the HFE/UE Report, as applicable. If the information is contained within another section of the submission, the applicable section can simply be referenced in the HFE/UE Report. Information found elsewhere within the submission does not need to be repeated in the human factors report, but can be repeated if the submitter believes that the inclusion provides useful context to the report.

Table C-1. Outline of HFE/UE Report for Category 3 Submissions

Sec.	Contents
1	**Conclusion and high-level summary** The <device> has been found to be adequately designed for the intended users, uses, and use environments, such that the device can be used by the intended users without serious use errors or problems, for the intended uses and under the expected conditions of use. • High-level summary of HFE/UE assessment, HFE/UE processes conducted, and results that support this conclusion • Discussion of any use-related residual risks (if applicable) and why further risk control is not possible or not practicable
2	**Descriptions of intended device users, uses, use environments, and training** • Intended user population(s) and meaningful differences in capabilities between multiple user populations that could affect user interactions with the device • Intended use • Operational contexts of use and critical aspects of device operation • Use environments and characteristics that could affect user interactions with the device • Training intended for users • For modified devices, comparison of the subject device intended users, uses, use environments, and training to that of the existing device
3	**Description of device user interface** • Graphical representation of device and its user interface • Description of device user interface • Device labeling • Overview of operational sequence of device and expected user interactions with user interface • For modified devices, comparison of the subject device user interface to that of the existing device
4	**Summary of known use problems** • Known use problems with previous models of the subject device • Known use problems with similar devices (e.g., predicate devices, devices with similar user interface elements) • Design modifications implemented in response to post-market use error problems
5	**Summary of preliminary HFE/UE analyses and evaluations** • Evaluation methods used • Key results and design modifications implemented in response • Key findings that informed the human factors validation test protocol

6	**Analysis of hazards and risks associated with use of the device**
	• The URRA document, identifying:
	  • Potential use errors
	  • Potential harm and severity of harm that could result from each use error

	• Risk management measures implemented to eliminate or reduce the risk • Evidence of effectiveness of each risk management measure • For modified devices, a comparative URRA, discussion of whether the risk associated with the modification is acceptable, and whether the proposed changes warranted human factors validation testing
7	**Identification and description of critical tasks** • Process used to identify critical tasks • List and descriptions of critical tasks • Categorization of critical tasks by severity of potential harm • Descriptions of use scenarios that include critical tasks

8	**Details of human factors validation testing of final design**
	• Rationale for test type selected (i.e., simulated use, actual use or clinical study)
	• Descriptions of the following:
	  • Test environment and conditions of use
	  • Number and type of test participants
	  • Training provided to test participants and how it corresponded to real-world training levels
	  • Critical tasks and use scenarios included in testing
	  • Definition of successful performance of each test task
	  • Data to be collected and methods for documenting observations and interview responses
	• Test results, including:
	  • Observations of task performance and occurrences of use errors, close calls, and use problems
	  • Feedback from interviews with test participants regarding device use, critical tasks, use errors, and problems (as applicable)
	• Comprehensive analysis of all use errors and problems that occurred that could have resulted in harm in real-world use
	• Description of all design modifications made to the user interface in response to the test results
	• Benefit-risk discussion (based on residual use-related risks)
	• Full test protocol and sample of all scripts and forms used in the testing (appended)
	• Residual risk analysis and rationale for why existing controls are acceptable

Guidance History*	Date	Description
Level 1 Final Guidance	May 2026	See Notice of Availability for more information.**
Revised Level 1 Draft Guidance	December 2022	See Notice of Availability for more information.**

*This table was implemented beginning February 2025 and previous guidance history may not be captured in totality.
**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.