U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Event

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Today's Topic:

Content of Human Factors Information in Medical Device Marketing Submissions, Final Guidance

July 22, 2026

Content of Human Factors Information in Medical Device Marketing Submissions, Final Guidance

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Final Guidance

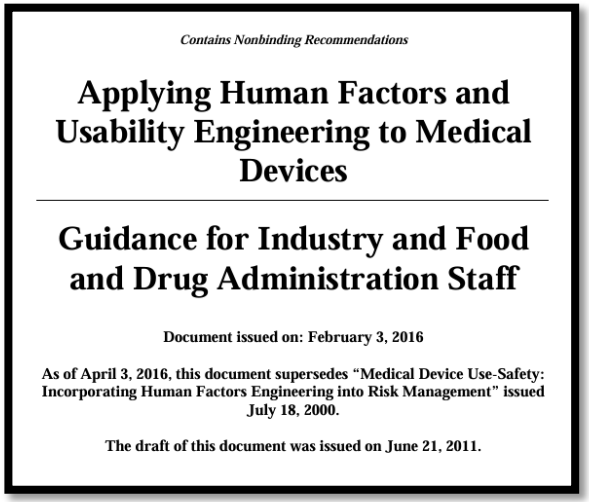
- **Content of Human Factors Information in Medical Device Marketing Submissions**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions

Learning Objectives

- Overview of two Human Factors Guidance documents “Content of Human Factors Information in Medical Device Marketing Submissions” which complements the current “Applying Human Factors and Usability Engineering to Medical Devices.”
- Describe the risk-based approach to help submitters determine what HF information they should include in their marketing submission.
- An overview of the three Human Factor (HF) Submission Categories.
- Walk through the flowchart to identify the HF Submission Category.
- The HF Content Guidance does not replace nor eliminate the requirement for conducting risk management activities, but provides guidance on how to communicate HF information to FDA.
- Updates to eSTAR reflect the new guidance and how to describe each categorization for a submission.

Human Factors Guidance Overview

Two Complimentary Guidance Documents



Contains Nonbinding Recommendations

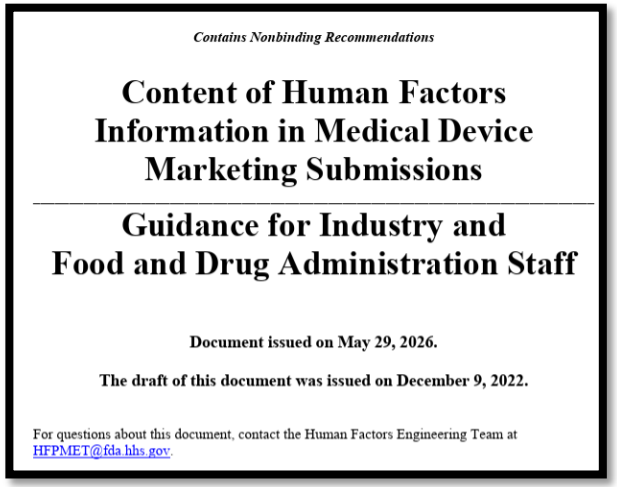
Applying Human Factors and Usability Engineering to Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on: February 3, 2016

As of April 3, 2016, this document supersedes "Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management" issued July 18, 2000.

The draft of this document was issued on June 21, 2011.



Contains Nonbinding Recommendations

Content of Human Factors Information in Medical Device Marketing Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on May 29, 2026.

The draft of this document was issued on December 9, 2022.

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

The HF Guidance (left) provides FDA's recommendations to assist industry in following appropriate human factors and usability engineering processes to maximize the likelihood that new medical devices will be safe and effective for the intended users, uses and use environments.

The HF Content Guidance (right) provides FDA's risk-based approach for what human factors information should be provided in marketing submissions and applies to 510(k)s, De Novo requests, PMAs, and HDEs.

- The HF Content Guidance does not replace nor eliminate the requirement for conducting risk management activities, but provides guidance on how to determine what documentation of human factors information should be provided in a marketing submission provided to FDA.

Risk-Based Approach to HF Information in Marketing Submissions and an Overview of the HF Submission Categories

Use-Related Risk Analysis

Use-Related Risk Analysis (URRA)								
Task ID #	User Task	Possible use error	Hazardous situation	Potential harm to patient/ operator	Severity of harm	Critical Task* (Y/N)	Risk Control Measure(s)	Validation method for effectiveness of risk control measure
2A	A specific task involving a medical device	The predicted wrong actions the user can take or not perform	Circumstance in which people, property or the environment are exposed to 1 or more hazards.	The specific harm to the user/patient. e.g., sepsis, asphyxiation, fluid overload	Typically defined on a scale provided by the sponsor	Yes or No	Device design choices such as interlocks, fail safes, or software/firmware. Text and user interface design choices. Labeling or instructions for use	Scenario 1, Simulated Testing Scenario KT3, Knowledge task
*A critical task is a user task that, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user. This is a fundamental consideration in human factors reviews.								

- A Use-Related Risk Analysis (Table 2; HF Content Guidance) and comparative URRA (table 3; HF Content Guidance) are intended to be living documents; updates should be made to identified risks and hazards throughout the device design process.
- These tables may be critical or important during device design and development activities, in particular those for HF Submission Category 3

Human Factors Content Guidance Categories

- This new guidance is intended to help manufacturers decide what level of human factors information to include in a marketing submission using a risk-based approach.
- Flowchart, Appendices, tables, and examples provided to guide submitters through a risk-based approach to help submitters determine what HF information to include in their marketing submission - referred to as the Human Factors (HF) Submission Category.
  - **HF Submission Category 1:** Conclusion and high-level summary of HF evaluation
  - **HF Submission Category 2:** Detailed rationale for why HF validation should not be submitted based on analysis of critical tasks, user interface, and existing risk control measures.
  - **HF Submission Category 3:** Human Factors Engineering Report with HF validation testing

Flowchart and HF Categorization

Modification to an Existing Device

Decision Point A: Modification to Existing Device?

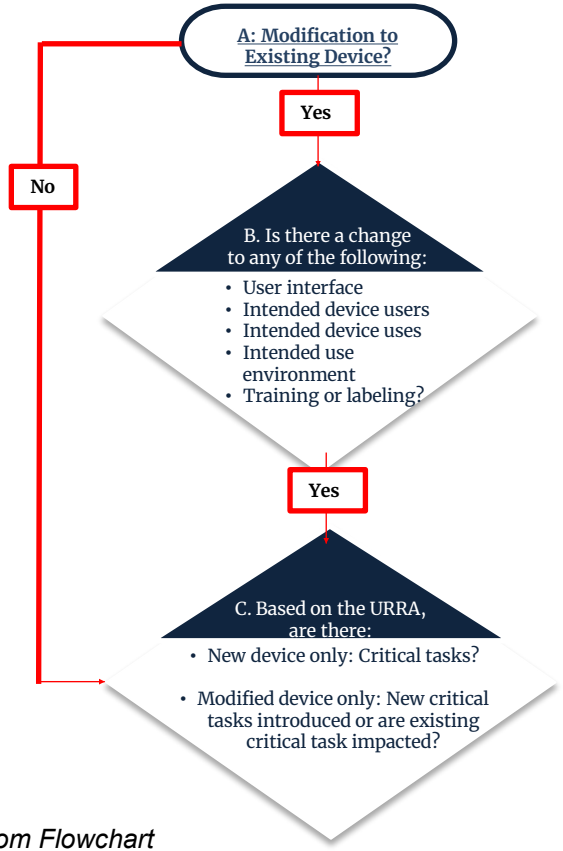
Answer "Yes" if:

- Change to device with existing FDA marketing authorization (510(k), PMA, HDE, De Novo)
- New device with same/similar user interface as a prior legally marketed device and leveraging HF information from prior legally marketed device

Answer "No" if:

- Completely new device without prior FDA authorization
- No legally marketed device of your own with similar interface to leverage HF information

If Yes? Go to Decision Point B
If No? Go to Decision Point C



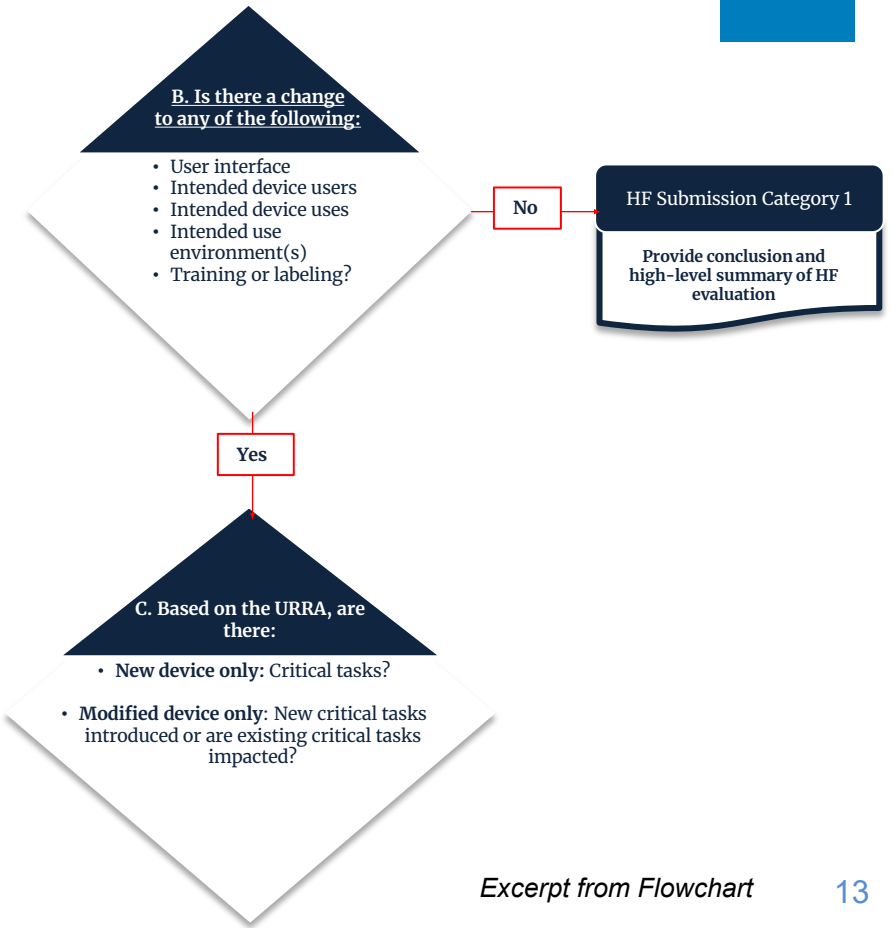
Excerpt from Flowchart

Risk Considerations Due to Device Changes?

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
- Labeling

If No? HF Submission Category 1
If Yes? Go to Decision Point C



Excerpt from Flowchart

New Use Risk Being Introduced?

Decision Point C: Risk Assessment

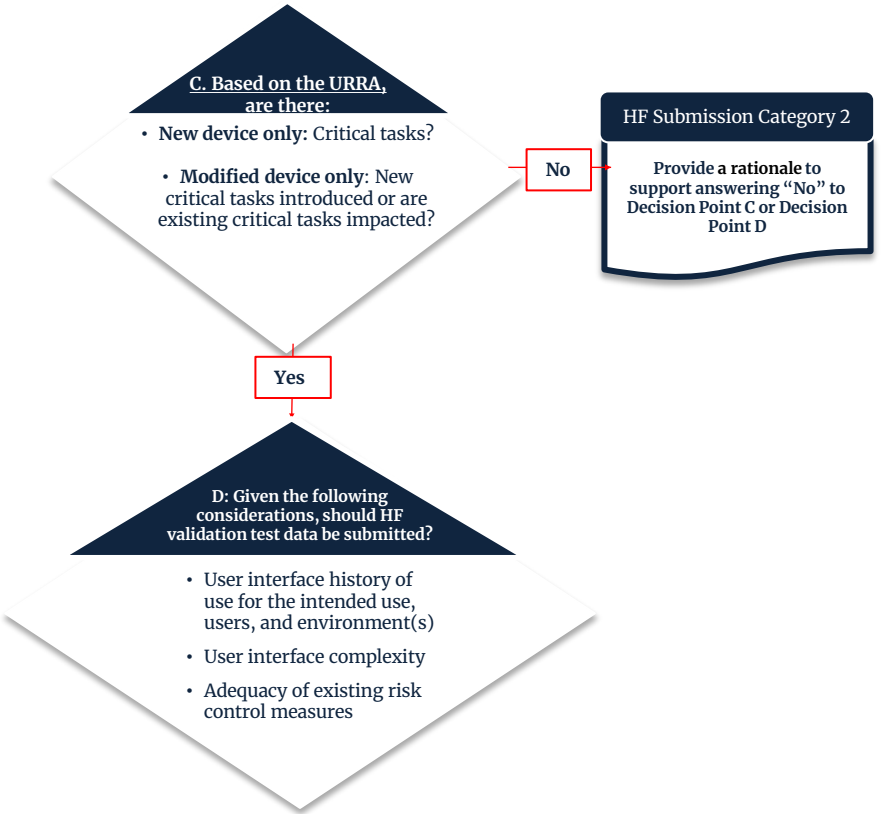
For New Devices:

- Based on the URRA, of the user tasks, are any considered to be critical tasks?

For Modified Devices:

- Are new critical tasks introduced?
- Are existing critical tasks impacted?

If No? HF Submission Category 2
If Yes? Go to Decision Point D



Excerpt from Flowchart

Risk of Complexity or Historical Experience

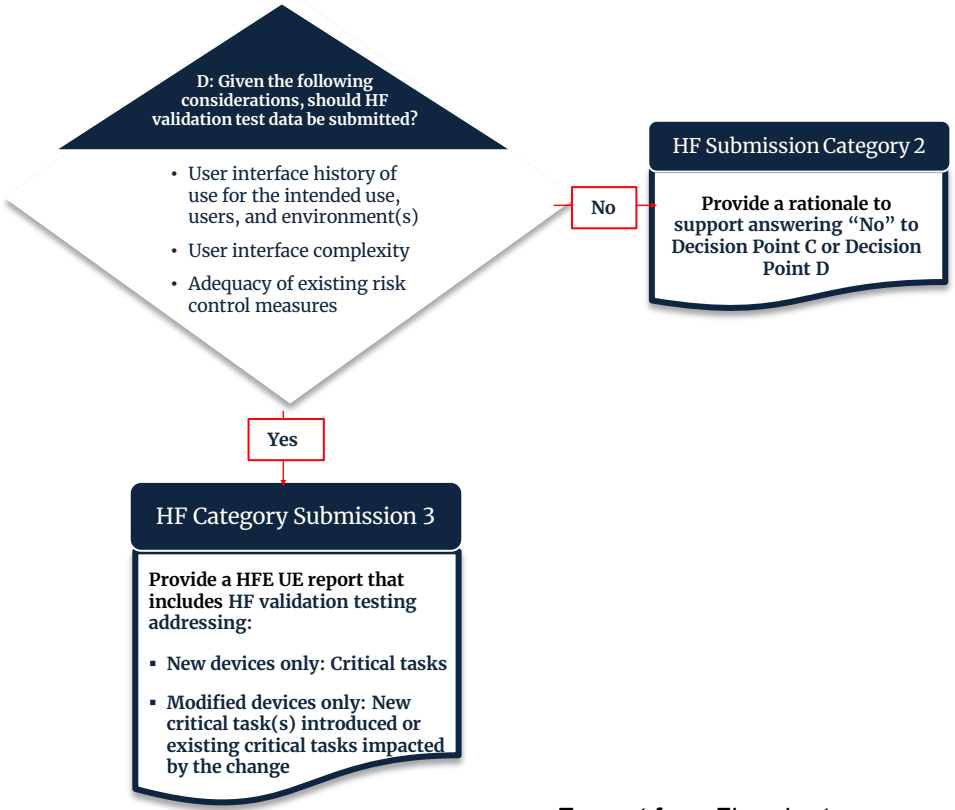
Decision Point D: Should HF validation test data be submitted?

- History of safe use or of known use errors?
- Is the device-user interface complex?
- Existing risk control measures remain effective or is there new risk information to consider?

HF validation likely needed for submissions of:

- Complex user interfaces (programming, monitoring, changing settings)
- Device types with known use error issues
- Risk has changed compared to historical devices, new risk information has emerged, or severity of harm has increased

If No? HF Submission Category 2
If Yes? HF Submission Category 3



Excerpt from Flowchart

What To Provide For Each HF Submission Category and Documenting in eSTAR

Documents for Each HF Submission Category

HF Submission Category 1

- Conclusion & high-level summary

HF Submission Category 2

- Conclusion & high-level summary
- Description of intended device users, uses, use environments, and training
- Description of device user interface
- Summary of known use problems (post market)

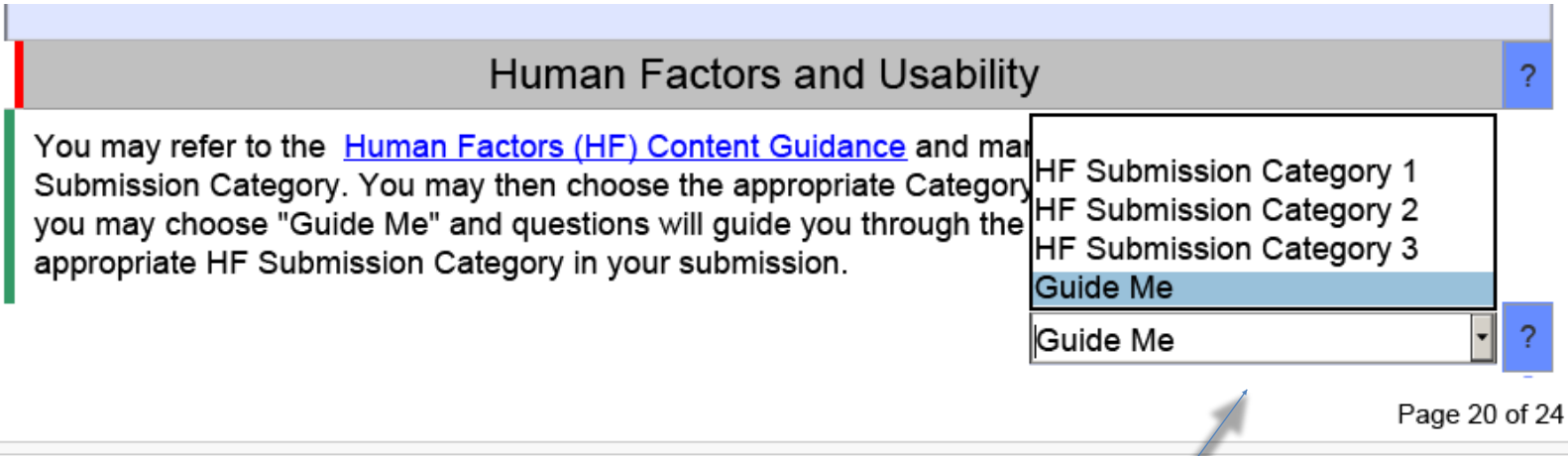
HF Submission Category 3

- Conclusion & high-level summary
- Description of intended device users, uses, use environments, and training
- Description of device user interface
- Summary of known use problems
- Summary of preliminary HFE/UE analyses and evaluations
- Use-related risk analysis (URRA), which includes:
  - Analysis of hazards and risks associated with use of the device
  - Identification and description of critical tasks
- Details of human factors validation testing of final design

FDA provides expectations on HF submission category documentation in Section V as well as:

- Appendix A: HF Submission Category 1
- Appendix B: HF Submission Category 2
- Appendix C: HF Submission Category 3

Guide Me or Choose a Category in eSTAR



The eSTAR document when selected for “Guide Me” will prompt sponsors to consider the questions from the flowchart and can assist sponsors in making a categorization.

Sponsors and manufacturers can decide to choose their own category too if they have already decided what is appropriate for their submission.

Support and Rationale in eSTAR

HF Submission Category 2: The Human Factors Engineering/Usability Engineering (HFE/UE) documentation below is recommended based on your response(s) above and corresponds with Sections 1 - 4 of the HFE/UE report in the HF Content Guidance. Documentation can be added to the bench testing/ analytical performance section, the clinical evidence section (if clinical evidence was provided), or elsewhere as you prefer.

Please specifically cite the attachment(s) and page number(s) where the following information is located. If information is already included under a different section of eSTAR (e.g., Device Description, Labeling), cite the attachment(s) and page number(s) from that section.

The HF Conclusion and High-Level Summary. See the help text for more information.	"HFE Summary.pdf" page 1	?
A description of the intended user population. Type "Indications for Use statement" if this is included in the Indications for Use statement.	"HFE Summary.pdf" page 2	?
A summary of the device's intended use. Type "Indications for Use statement" if this is included in the Indications for Use statement.	Indications for Use Statement	?
A summary of the device's operational context of use and critical aspects of device operation.	"HFE Summary.pdf" page 3	?

Category 2 Example:

Sponsor should provide documentation of the recommended HF information

- Report sections 1-4 (Section V of the guidance)
  - Conclusion and high-level summary (Section 1)
  - Descriptions of intended device uses, users, use environments and training; device user interface; and summary of known use problems (Sections 2-4)

The relevant information within the fillable eSTAR boxes may be contained within a single document or spread across different documents. The fillable boxes should tell review staff where to locate relevant information.

Category 3: HFE/UE Reports

For HF Submission Category 3, sponsors should provide full report documentation to support their HF validation efforts.

In addition to the information provided for HF Category 2 submissions (detailed in HF Content guidance, Section V):

- Summary of preliminary HFE/UE analyses and evaluations (Report Section 5)
- A use-related risk analysis (URRA)
  - Analysis of hazards and risks (Report Section 6)
  - Identification and description of critical tasks (Report Section 7)
- Details of the HF validation testing of final design (Report Section 8)

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Examples from the HF Content Guidance

HF Category 1 Example (A.1. in guidance)

A sponsor has a 510(k) cleared gastrointestinal lesion software detection system and the submission is for a modification to the device's detection algorithm's ability to detect a lesion, but does not change aspects of the user interface.

✓ **Decision Point A: Modification to existing Device**

✓ **Decision Point B: Changes do not impact user interface, users/uses, environment, training, or labeling**

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.

HF Category 1 Example: Sample Report Language

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.

HF Category 2 Example (B.1. in guidance)

An implantable infusion pump with a physician programmer has been approved through a PMA. A PMA supplement is submitted to expand the volume of the reservoir of the pump.

✓ **Decision Point A: Modification to existing Device**

There is a change to the device labeling and software to describe new volume.

✓ **Decision Point B: Changes to modified device include labeling**

Labeling was updated to specify the change in the reservoir volume, but no change to the medication concentration, dosing calculation or programming.

✓ **Decision Point C: No new critical tasks introduced or impacted by the device change**

HF Submission Category 2: Critical tasks present are not impacted by device design change.

HF Category 2 Example (C.4. in guidance)

A 510(k) for a new blood lancet intended for a single use to puncture the skin to obtain a drop of capillary blood. 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: Modification to existing Device?** No, new device
✓ **Decision Point C: Based on the URRA there are critical tasks?** Yes
✓ **Decision Point D: Should HF validation test data be submitted?** No

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.

HF Submission Category 2: Low complexity, existing risk controls are sufficient, and there is no major difference in the existing technology.

HF Category 3 Example (B.2. in guidance)

An implantable infusion pump with a physician programmer has been approved as a standalone device through the PMA process as in Example B.1. The submitter requests approval in a PMA Supplement for a modification to the physician programmer from the approved monochrome UI to a mini-tablet computer with a touch screen user interface and includes full color and new icons for menu functions.

- ✓ **Decision Point A – Modified device**
- ✓ **Decision Pont B – Changes to the user interface, relevant training & labeling**
- ✓ **Decision Point C – Changes impact critical tasks**
- ✓ **Decision Point D – Complex interface with audible and visual feedback, history of known use errors**

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.

Implementation and Timeline

- HF Content Guidance published on May 29, 2026
- FDA indicated at least 60-day implementation period after final guidance publication.
  - New version of eSTAR is available (as of June 1, 2026)
  - Guidance will be implemented on August 1, 2026
- Submissions received before August 1, 2026:
  - Not expected to include the newly recommended information outlined in the HF Content guidance in their submission
  - Not expected to use new version of eSTAR
  - Intend to review newly recommended information if submitted at any time

Summary

- The Human Factors Guidance and Human Factors Content Guidance complement each other and are intended to be used for medical devices (not combination products).
- Use-Related Risk Analysis and comparative Use-Related Risk Analysis are described in tables 2 and 3 in the HF Content Guidance and are recommended for inclusion in submissions to support HF Submission Categories 3.
- The flowchart guides industry and FDA on how to identify the HF Submission Category and the recommended information to provide in submissions.
- Updates to eSTAR reflect the new HF Content Guidance and how to describe each categorization.
- Human Factors and Usability are aspects of a holistic medical device risk management process.


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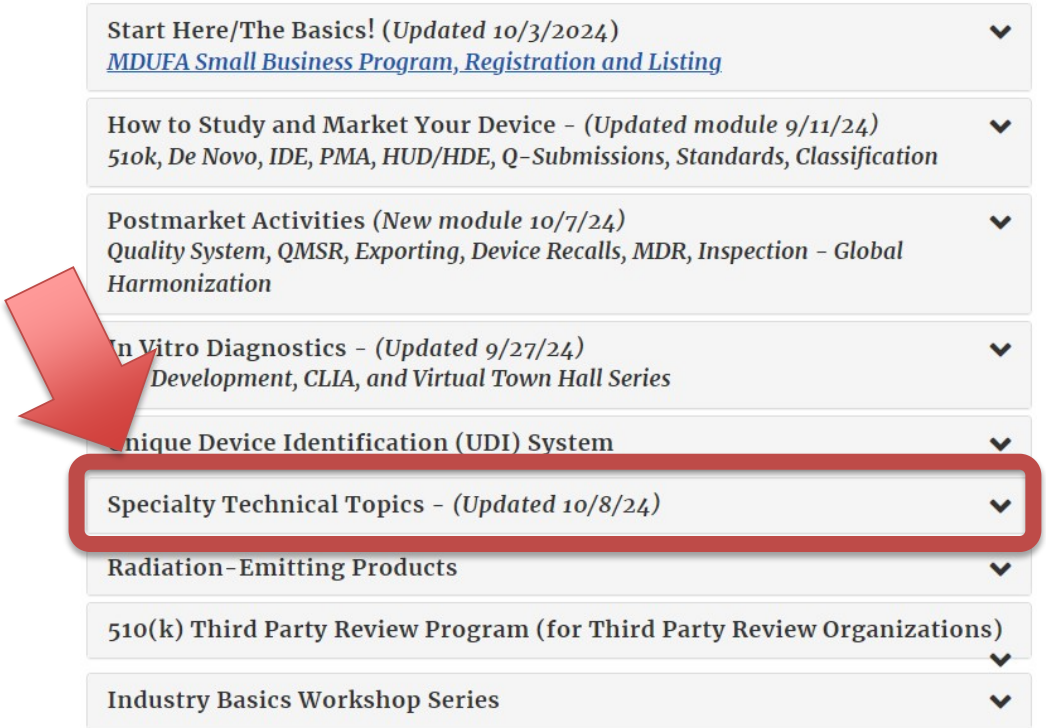
Previously Submitted Questions

Closing Remarks

Thanks for Joining Today!

- **Presentation, Slides and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's event**
  - Email: DICE@fda.hhs.gov
- **Upcoming CDRH Events**
  - www.fda.gov/CDRHEvents

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