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Content of Human Factors Information in Medical Device Marketing Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on December 9, 2022.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments 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. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document, contact OHT3: Office of Gastro-Renal, ObGyn, General Hospital, and Urology Devices/DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors at (301) 796-5580.

When final, this guidance is intended to be used to complement the FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices,” issued February 3, 2016. After reviewing public comment on this draft guidance and upon its finalization, FDA intends to concurrently revise the “Applying Human Factors and Usability Engineering to Medical Devices” guidance, as described herein.



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

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Preface

Additional Copies

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 1500052 and complete title of the guidance in the request.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. Introduction¹

FDA is committed to fostering the development of and patient access to innovative medical devices while balancing their benefits and risks. A unique aspect of medical devices is the critical role of device-user interface interactions for their safe use. Manufacturers routinely perform human factors assessments of the human-device interface during device development. This guidance provides a risk-based framework to guide manufacturers and FDA staff on the human factors information that should be included in a marketing submission to the Center for Devices and Radiological Health (CDRH) to facilitate the 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 draft guidance, include the identification of (i.e., presence of or modification to) critical tasks and the elimination or reduction of use-related hazards.

This guidance includes recommendations for the content of human factors and usability engineering information to be included in marketing submissions.² FDA’s decision on a medical

¹ This guidance has been prepared by the Center for Devices and Radiological Health in cooperation with the Office of Combination Products at the Food and Drug Administration.

² In the United States, the term “human factors engineering” is predominant but in other parts of the world, “usability engineering” is preferred. For the purposes of this document, the two terms are considered interchangeable.

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32 device marketing submission is based on the applicable statutory and regulatory criteria (e.g.,
33 substantial equivalence for premarket notification (510(k)) submissions, reasonable assurance of
34 safety and effectiveness for premarket approval applications (PMAs) or De Novo classification
35 requests (De Novo requests)). Human factors, to the extent relevant, constitute just one
36 component of FDA’s assessment. While FDA believes that it is optimal to minimize use-related
37 risks, it may not be necessary, nor practical, to eliminate all use-related device risks.
38

39 The marketing submission should, where appropriate, demonstrate that the needs of the intended
40 users were considered in the device design and that the device is safe and effective for the
41 intended users, uses, and use environments. Thus, marketing submissions should include, where
42 appropriate, information that explains the presence or absence of critical tasks, validation testing
43 for risk mitigation strategies, and a description of residual risks. Including appropriate human
44 factors information may improve the efficiency of FDA review by reducing the number of
45 requests for additional information.
46

47 After considering stakeholder feedback on the draft guidance “[List of Highest Priority Devices
48 for Human Factors Review](#),”³ FDA has decided that it should issue another draft guidance
49 regarding submission of human factors information for the purposes of premarket review, which
50 will supersede the draft guidance “List of Highest Priority Devices for Human Factors Review.”
51

52 When finalized, this draft guidance is intended to be used to complement the FDA guidance
53 “[Applying Human Factors and Usability Engineering to Medical Devices](#)”⁴ (hereafter referred to
54 as the Human Factors Guidance). The purpose of the Human Factors Guidance is to recommend
55 and guide manufacturers through human factors engineering processes during the development
56 of new medical devices, focusing specifically on the user interface. That guidance provides
57 relevant human factors definitions and recommends useful preliminary analysis and evaluation
58 tools and validation testing that will enable manufacturers to assess and reduce risks associated
59 with medical device use. The purpose of the current guidance is to help manufacturers apply a
60 risk-based approach when considering what human factors information to include in a marketing
61 submission.
62

63 After reviewing public comment on this draft guidance and upon its finalization, FDA intends to
64 concurrently revise the Human Factors Guidance to incorporate the definitions included in this
65 guidance, superseding the definitions in Section 3 of the Human Factors Guidance. FDA also
66 intends to concurrently revise the Human Factors Guidance by replacing Section 9
67 “Documentation” and Appendix A “Human Factors and Usability Engineering Report” of the
68 Human Factors Guidance with cross-references to Section V of this guidance, and by making
69 any other revisions to the Human Factors Guidance as appropriate.
70

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/list-highest-priority-devices-human-factors-review>.

⁴ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>.

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71 For the current edition of the FDA-recognized consensus standard(s) referenced in this
72 document, see the [FDA Recognized Consensus Standards Database](#).⁵ For more information
73 regarding use of consensus standards in regulatory submissions, please refer to the FDA
74 guidance titled “[Appropriate Use of Voluntary Consensus Standards in Premarket Submissions](#)
75 [for Medical Devices](#).”⁶

76
77 FDA recognizes and anticipates that the Agency and industry may need up to 60 days to perform
78 activities to operationalize the policies within this guidance. If new information regarding the
79 content of human factors information for marketing submissions is not included in a marketing
80 submission received by FDA before or up to 60 days after the publication of the final guidance,
81 CDRH staff does not generally intend to request such information during the review of the
82 submission. CDRH does, however, intend to review any such information, if submitted.

83
84 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
85 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
86 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
87 the word *should* in Agency guidance means that something is suggested or recommended, but
88 not required.

89

90 **II. Scope**

91 This guidance is intended to help submitters and FDA staff determine what human factors
92 evaluation information should be included in marketing submissions for medical devices,
93 including 510(k)s, De Novo requests, PMAs, including PMA supplements, and humanitarian
94 device exemption (HDE) applications.⁷

95

96 The guidance is not intended to inform manufacturers about how to perform a human factors
97 evaluation. This guidance is also not intended to describe when a marketing submission should
98 be submitted to legally market a new or modified device.

99

100 **III. Definitions**

101 The following definitions⁸ apply for the purposes of this guidance:

⁵ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

⁶ Available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>.

⁷ For more information on the human factors evaluation of combination products, see the FDA draft guidance document “[Human Factors Studies and Related Clinical Study Considerations in Combination Product Design and Development](#),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/human-factors-studies-and-related-clinical-study-considerations-combination-product-design-and>. When final, that guidance will represent FDA’s current thinking on the topic thereof.

⁸ The definitions provided in this section are informed by, but not necessarily identical to, the definitions found in the sources that are cited.

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- **Abnormal use:** An intentional act or intentional omission of an act that reflects violative or reckless use or sabotage beyond reasonable means of risk mitigation or control through design of the user interface.
 - **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.⁹
 - **Harm:** Injury or damage to the health of people, or damage to property or the environment.¹⁰
 - **Hazard:** Potential source of harm.¹¹
 - **Hazardous situation:** Circumstance in which people, property or the environment is/are exposed to one or more hazards.¹²
 - **Human factors engineering:** 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:** 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 management 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.¹⁴
 - **Residual risk:** Risk remaining after risk control measures have been implemented.¹⁵
 - **Serious harm:** Includes both serious injury and death.
 - **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

⁹ ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices*. Formative evaluation is generally performed iteratively throughout the design and development process, but prior to summative evaluation, to guide user interface design as necessary.

¹⁰ ANSI/AAMI/ISO 14971 Third Edition 2019-12 *Medical devices—Application of risk management to medical devices*.

¹¹ ANSI/AAMI/ISO 14971 Third Edition 2019-12 *Medical devices—Application of risk management to medical devices*.

¹² ANSI/AAMI/ISO 14971 Third Edition 2019-12 *Medical devices—Application of risk management to medical devices*.

¹³ ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices*.

¹⁴ *Ibid.*

¹⁵ ANSI/AAMI/ISO 14971 Third Edition 2019-12 *Medical devices—Application of risk management to medical devices*.

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- 133 irreversible impairment or damage to a body structure or function, excluding trivial
134 impairment or damage.¹⁶
- 135 • **Task:** One or more user interactions with a medical device to achieve a desired
136 result.¹⁷
 - 137 • **Use environment:** Actual conditions and setting in which users interact with the
138 medical device.¹⁸
 - 139 • **Use error:** User action or lack of action that was different from that expected by the
140 manufacturer and caused a result that (1) was different from the result expected by the
141 user and (2) was not caused solely by device failure and (3) did or could result in
142 harm.
 - 143 • **Use safety:** How safe a device is when used or the extent to which risks of harm
144 resulting from use error for medical devices have been either reduced to an acceptable
145 level or eliminated completely.
 - 146 • **User:** Person interacting with (i.e., operating or handling) the medical device.¹⁹
 - 147 • **User interface:** Means by which the user and the medical device interact.²⁰
 - 148 • **Use-related risk:** Combined probability, occurrence, and severity of harm for a given
149 aspect of device use or for the overall use of a device.²¹
 - 150 • **Use-related risk analysis:** Systematic use of available information to identify use-
151 related hazards and to estimate the use-related risk.
- 152

153 IV. Risk-based approach to human factors engineering 154 information in marketing submissions

155 The purpose of including human factors engineering information in a marketing submission is to
156 help the manufacturer meet the applicable legal standard by demonstrating that the user interface
157 of the device is appropriate for the intended users, uses, and use environments. This section uses
158 flowcharts, tables, and text to guide submitters through a risk-based approach to recommend
159 what human factors engineering information a submitter should include in their marketing
160 submission.

161
162 FDA refers to this risk-based approach as the Human Factors (HF) Submission Category.
163 Submitters should use the flowchart in
164 **Figure 1** and use its companion text to answer the questions posed at each decision point to
165 determine which HF Submission Category is appropriate to support their marketing submission.

¹⁶ See 21 CFR 803.3(w).

¹⁷ ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices*.

¹⁸ *Ibid.*

¹⁹ ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices*.

²⁰ ANSI/AAMI/IEC 62366-1:2015+AMD1:2020 *Medical devices—Part 1: Application of usability engineering to medical devices*. Examples include packaging, labeling, training materials, physical controls, display elements, alarms, and logic of operation of each device component.

²¹ ANSI/AAMI HE75:2009/(R)2018: *Human factors engineering - Design of medical devices*.

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166 This flowchart is based on the device’s indications for use and the use-related risk analysis in the
167 context of new devices and devices for which FDA has granted marketing authorization.

168

169 FDA based the HF Submission Categories on the presence of or modification to critical tasks,
170 considering changes to technological characteristics or the indications for use, if relevant.

171 Submitters should use the use-related risk analysis and the decision points described below to
172 help determine the HF Submission Category for their marketing submission. Submitters should

173 also reference Table 1 for FDA’s recommended human factors engineering information to
174 provide in a marketing submission after they determine which HF Submission Category their

175 submission falls under using

176 **Figure 1.**

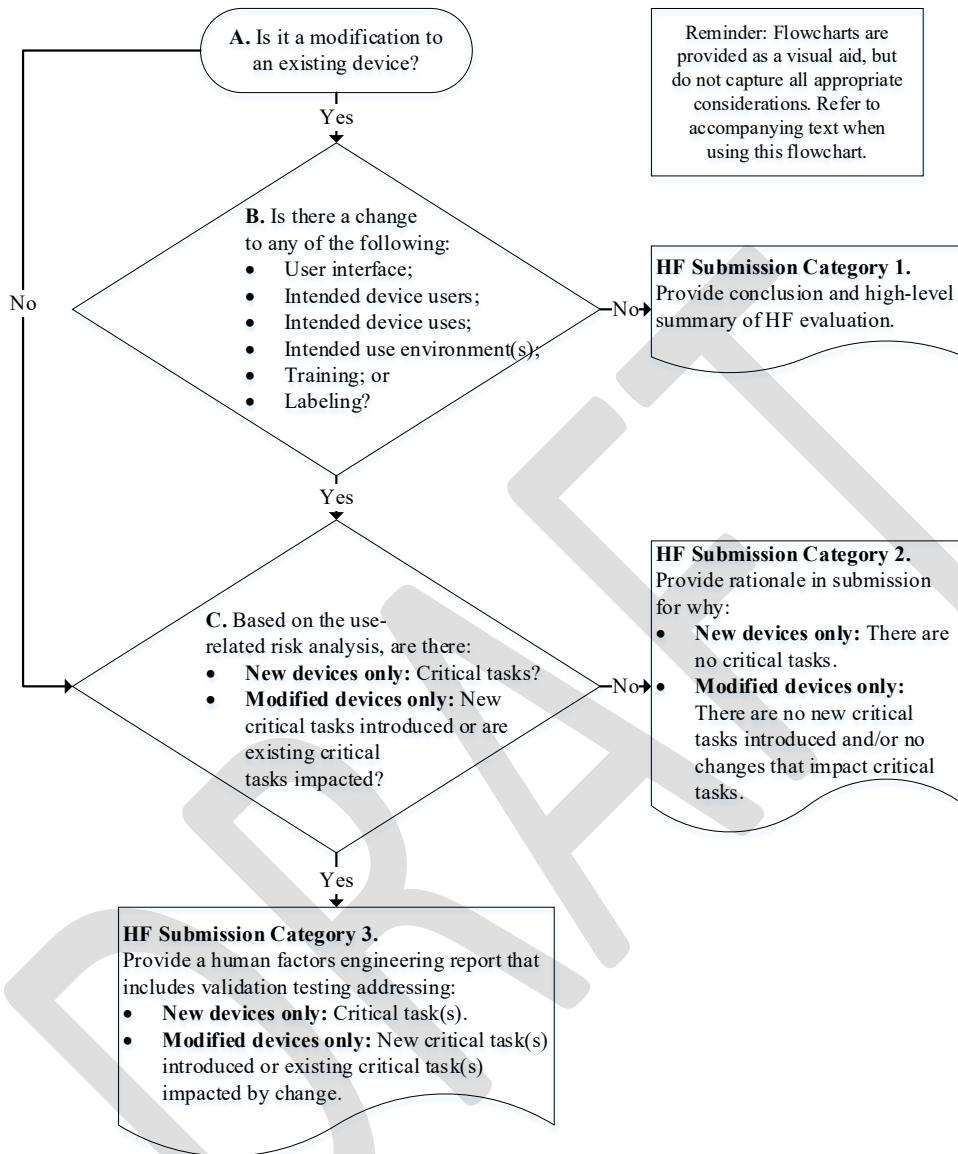
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Figure 1. Flowchart illustrating a risk-based approach to determine the HF Submission Category.²²

²² 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.

183 **A. How to determine HF Submission Category**

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

185 Submitters should answer “Yes” to this question when their submission is for a change to a
186 device that has already received marketing authorization from FDA through a 510(k), PMA,
187 HDE application, or De Novo request. Submitters should generally answer “No” if their device is
188 a completely new device that has not received marketing authorization from FDA. Depending on
189 specific facts and circumstances, submitters may be able to answer “Yes” to this question when
190 they are proposing to apply human factors information from one of their own legally marketed
191 devices to a subject device that has the same or a similar user interface.

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

- 193 • User interface;
- 194 • Intended device users;
- 195 • Intended device uses;
- 196 • Intended use environment(s);
- 197 • Training; or
- 198 • Labeling?

199
200 This question applies to only modified devices and is intended to assess whether there have been
201 any proposed changes that affect the human factors assessment. If the answer to this question is
202 “No,” then the level of information would fall into HF Submission Category 1; however, if the
203 answer is “Yes,” then the submitter should proceed to Decision Point C.

204 **Decision Point C: Based on the use-related risk analysis, are there:**

- 205 • **New devices only:** Critical tasks?²³
- 206 • **Modified devices only:** New critical tasks introduced or are existing critical tasks
207 impacted?

208
209 The use-related risk analysis incorporating risk analysis approaches such as Failure Mode and
210 Effects Analysis (FMEA), analysis of known use problems, and formative evaluation should be
211 referenced to answer this question.²⁴ For modified devices, FDA recommends that submitters
212 consider the use-related risk analysis on the final finished device and not just modifications to
213 the device. This recommendation is intended to provide a holistic assessment of any critical tasks
214 that could be impacted upstream or downstream from the altered device-user interface
215 component.

216

²³ 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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>.

²⁴ 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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices),” available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>.

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217 Each identified critical task should be connected to the use-related risk analysis. When
218 determining if a critical task has been affected by a change to the device-user interface, we
219 recommend considering if those changes influence the cognitive and/or visual perception or the
220 physical interaction between the user and the device. A reduction or increase in the steps to
221 execute a critical task may be considered as affecting the critical task.

222
223 If there are no critical tasks for a new device, or no new critical tasks introduced, and no
224 impacted critical tasks for a modified device based on the use-related risk analysis, the answer to
225 this question is “No,” and the level of information would fall into HF Submission Category 2.

226
227 If the answer is “Yes,” then the level of information would fall into HF Submission Category 3.
228

229 **B. What to include in a marketing submission based on HF** 230 **Submission Category**

231 Using the flowchart in

232 **Figure 1** and its companion text to determine the HF Submission Category, manufacturers
233 should include the following human factors information in marketing submissions:
234

235 **HF Submission Category 1. Provide conclusion and high-level summary of HF evaluation:**
236 The submission should include a statement justifying that the device modifications do not affect
237 the human factors considerations of the modified device and leverage, if applicable, previous
238 human factors engineering evaluations to provide the conclusion and high level summary. See
239 Table 1 for the suggested submission content for devices that fall into HF Submission Category
240 1.
241

242 **HF Submission Category 2. Provide rationale in submission for why: there are no critical**
243 **tasks (new devices only); or there are no new critical tasks introduced and/or no changes**
244 **that impact critical tasks (modified devices only):** The submitter should submit a rationale that
245 clearly describes the basis of their decision that there are no critical tasks for a new device, or no
246 new critical tasks introduced, and no impacted critical tasks for a modified device. This rationale
247 should be based on the decision-making noted in Section IV.A that takes the submitter through
248 each decision point. See Table 1 for the suggested submission content for devices that fall into
249 HF Submission Category 2.
250

251 **HF Submission Category 3. Provide a human factors engineering report that includes**
252 **validation testing addressing: critical task(s) (new devices only; see Table 2); or new critical**
253 **task(s) introduced or existing critical task(s) impacted by change (modified devices only;**
254 **see Table 3):** A comprehensive human factors engineering report that includes all elements of a
255 human factors engineering report described in Section IV of this guidance should be submitted to
256 FDA for marketing submissions in HF Submission Category 3. Please note that if critical tasks
257 are impacted for a modified device, but existing risk control measures remain acceptable, you
258 should provide your rationale in your submission as part of the human factors information.

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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: <ul style="list-style-type: none"> • Intended device users, uses, use environments, and training (Section 2) • Device-user interface (Section 3) • Summary of known use problems (Section 4) 		✓	✓
Preliminary activities <ul style="list-style-type: none"> • Summary of preliminary analyses and evaluations (Section 5) 			✓
Use-related risk analysis <ul style="list-style-type: none"> • Analysis of hazards and risks associated with use of the device (Section 6) • Identification and description of critical tasks (Section 7) 			✓
Details of validation testing of final design (Section 8)			✓

262
263

Table 2. Example tabular format for the use-related risk analysis

Use-related risk analysis Task #	User Task	Possible use error(s)	Potential hazards and clinical harm	Severity of harm	Critical Task (Y/N)	Risk Mitigation Measure(s) ²⁵	Validation method for effectiveness of risk mitigation measure ²⁶
Task #1							
Task #2							

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²⁵ For example, such risk mitigation measures could include user interface design features, labels, instructions for use, or training.

²⁶ For example, such validation methods could include human factors testing or simulated use scenario.

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265 **Table 3. Example tabular format for the comparative use-related risk analysis**

Existing Device						Modified Device			Submitter's comparison comments
URRA Task #	User Task	Possible use error(s)	Potential hazards and clinical harm	Severity of harm	Critical task (Y/N)	Comparison of use task description to existing device	Labeling content and/or design change differences	Comparison of proposed risk mitigation measure to existing device	
Task #1									
Task #2									

266

267 **V. Recommended content of human factors information in**
268 **marketing submissions**

269 A manufacturer's internal documentation of risk management, human factors engineering testing
270 (when applicable), and design optimization processes can help provide evidence, where
271 appropriate, that the needs of the intended users were considered in the design and that the device
272 is safe and effective for the intended users, uses, and use environments. The Quality System
273 Regulation (21 CFR part 820) requires that manufacturers of certain finished devices verify and
274 validate device design, review and approve changes to device design, and document changes and
275 approvals in the design history file (21 CFR 820.30). FDA recommends that human factors
276 information be maintained by the manufacturer regardless of whether it is submitted to FDA.
277 Manufacturers must keep records to the extent required under applicable law, including the
278 Quality System Regulation (*e.g.*, 21 CFR 820.30(j)), and these (and other) records must generally
279 be made available to an FDA investigator upon request (see section 704(e) of the Federal Food,
280 Drug, and Cosmetic Act).

281
282 This section describes the HF information that may be appropriate for submission to FDA in a
283 marketing submission when one is required.²⁷ This human factors engineering information
284 describes how the human factors engineering process was applied during the development of a
285 medical device. Human factors engineering information should summarize the evaluations
286 performed. Such information does not typically include all raw data from a human factors

²⁷ This guidance is not intended to address whether or not a 510(k) or a PMA supplement is required for changes that may involve a human factors engineering analysis. Manufacturers should apply the applicable regulatory criteria in 21 CFR 807.81 or 21 CFR 814.39 to determine whether a 510(k) 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](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device)," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>, "[Deciding When to Submit a 510\(k\) for a Software Change to an Existing Device](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device)," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device>, or "[Modifications to Devices Subject to Premarket Approval \(PMA\) - The PMA Supplement Decision-Making Process](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process)," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process>.

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287 validation test. The information should discuss the safety-related human factors engineering
288 considerations, processes, issues, resolutions, and conclusions. The information should describe
289 the identification, evaluation, and final assessment of all use-related hazards from using the
290 device.

291
292 Documents or analyses that are part of the human factors engineering process should be included
293 in the human factors engineering information provided in a marketing submission. This includes
294 portions of risk analyses focusing on user interactions with the device and specific risk analysis
295 processes, results, and conclusions. Such information can also reference materials relevant to the
296 human factors engineering process in other parts of the submission. A recommended structure
297 for this human factors engineering information is further described below:

298

Section 1: Conclusion and high-level summary

299 Submitters should begin with a conclusion stating whether the user interface of the device has
300 been found to be adequately designed for the intended users, uses, and use environments and
301 whether new human factors testing was conducted to support this conclusion. FDA recommends
302 that submitters begin with a high-level summary of the human factors engineering assessment
303 (e.g., use-related risks), including the underlying rationale for conducting the assessment, and a
304 summary of the human factors engineering processes conducted (e.g., human factors engineering
305 analyses and evaluations, device-user interface modifications and validation testing) and analysis
306 of the results.
307

308 When applicable, this section should discuss any remaining residual use-related risks after
309 human factors validation testing. Submitters should describe why further risk mitigation is not
310 practicable based on a benefit-risk analysis²⁸ for the device.

311

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

312 This section should include:

- 313 • A description of the intended user population. If there is more than one distinct user
314 population, each population should be described. The description should include
315 meaningful differences in capabilities or use responsibilities between user populations
316 that could affect their interactions with the device. This includes lay and healthcare
317 professional users who might use the same device to perform different tasks or
318 different types of professionals who might perform different tasks on the device;
- 319 • A summary of the device's intended use;
- 320 • A summary of the device's operational context of use and critical aspects of device
321 operation, including:
 - 322 • Whether users should or must be trained by a healthcare professional prior to
323 device use;
 - 324 • How the device is used across clinical applications; and
 - 325 • Set up, maintenance, cleaning, and reprocessing information.
- 326

²⁸ 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*.

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- A summary of the intended use environments (e.g., hospital, medevac vehicle, home use) 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.

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, dedicated buttons, doors, components to be connected, retaining clips);
- A written description of the device user interface;
- 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, consider providing information comparing the subject and existing devices (see Table 4 for an example format).

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

Modification description	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 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.

Section 5: Summary of preliminary analyses and evaluations

This section should identify the preliminary 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.

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

366 This section should include the use-related risk analysis document and/or comparative task
367 analysis, as applicable. This is typically an excerpt from the comprehensive risk analysis that
368 contains all use-related hazards and risks identified through the preliminary analyses and
369 evaluations, including those associated with potential use errors. The use-related risk analysis
370 document is intended to be a living document; updates should be made to identified risks and
371 hazards throughout the device design process. FDA believes it can be useful to organize this
372 information in a tabular format. An example tabular format is provided in Table 2. This example
373 provides the recommended minimum information to evaluate the use-related risks associated
374 with your device. For modified devices in HF Submission Category 3, the submitter should
375 provide a comparative task analysis (see example tabular format in Table 3) comparing the
376 modified device use-related risk analysis with the existing device use-related risk analysis.

377
378 If you determine that a device change resulting in a modification to any task, associated harm,
379 and/or risk mitigation measure does not merit new HF validation test data to support the device's
380 use safety, please provide a rationale.

381 382 **Section 7: Identification and description of critical tasks**

383 This section should:

- 384 • Explain the process followed to identify the critical tasks based on the use-related risk
385 analysis document. Since critical tasks are determined by the severity of the potential
386 harm, FDA recommends that the submitter describe the levels of severity being used
387 and use a reference when appropriate. For example, if the submitter is using a
388 qualitative five-level severity rating from a voluntary consensus standard (e.g., ISO
389 14971²⁹), this section should include a table of severity levels with descriptions of
390 each level and reference the applicable standard; and
- 391 • List and describe the critical tasks. For HF Submission Category 3, the submitter
392 should provide a separate table highlighting the new critical tasks if relevant and
393 rationale for why the task does not merit new HF validation test data to support the
394 device's use safety. The submitter should also describe each use scenario included in
395 the human factors validation testing and list the critical and non-critical tasks that
396 constitute each use scenario.

397
398 When modifying an existing device, FDA recommends that submitters compare the new device
399 user interface to their own existing device in their marketing submission. FDA recommends
400 completing this comparison in a tabular format. An example tabular format is provided in Table
401 4. In addition to the use-related risk analysis document for the entire device, submitters should
402 include a subset of the use-related risk analysis that isolates tasks and risks associated with the
403 proposed modifications made to the device. FDA recommends including photographic images of
404 the device-user interface components that were modified, including modifications to labeling
405 such as warning statements in an instructional manual. Submitters should list any critical tasks
406 affected by the modification(s). Submitters should also discuss whether the risk associated with
407 the modification is acceptable and assess whether the proposed changes warranted human factors

²⁹ ANSI/AAMI/ISO 14971: *Medical devices—Application of risk management to medical devices*.

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408 validation testing. As stated in the [Human Factors Guidance](#),³⁰ the validation test may be limited
409 to assessment of those aspects of users' interactions and tasks that were affected by the design
410 modifications.

411

412 **Section 8: Details of HF validation testing of final design**

413 This section should summarize all HF validation activities conducted. In addition to test results,
414 this section should have a comprehensive analysis of all use errors and problems that occurred
415 that could have resulted in harm in real-world use, a description of all design modifications made
416 to the user interface in response to the test results, and a benefit-risk discussion. A full test
417 protocol and a sample of all scripts and forms used in the testing should be appended. Submitters
418 should provide a residual risk analysis and the rationale for why existing mitigation controls are
419 acceptable. While elimination of all residual risks may not be practicable, submitters should have
420 evidence of a systematic analysis of use errors and mitigations of use-related risks.³¹ Submitters
421 should reevaluate risk control and mitigation measures to identify other means to reduce risk
422 when it is determined that the residual risks are unacceptable.

423

424 **VI. Examples**

425 The following are hypothetical examples of scenarios intended to illustrate FDA's risk-based
426 approach to determine the HF Submission Category using the flowchart in
427 **Figure 1**³² and its companion text. Based on the HF Submission Category, FDA's recommended
428 HF information to support the marketing submission is outlined for each scenario. These
429 examples do not account for every submission type nor the human factors information that may
430 be appropriate for every situation. Additionally, the examples describing modifications to an
431 existing device are based on an assumption that a manufacturer has already determined that it
432 needs to submit a new marketing submission. Therefore, these examples are not intended to
433 interpret when a new marketing submission is required. In addition, these examples are not
434 intended to comprehensively represent what should be included in a marketing submission for a
435 new or modification to an existing device.

436

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

438 **Example A.1.**

439 **Scenario:** A submitter currently has marketing authorization for a gastrointestinal lesion
440 software detection system³³ in a cleared 510(k). The device is a computer-assisted detection
441 device used in conjunction with endoscopy for the detection of abnormal lesions in the

³⁰ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>.

³¹ For example, see Appendix C of "[Applying Human Factors and Usability Engineering to Medical Devices](#)."

³² Please refer to footnote 20 for clarification on why labeling and training are listed separately from user interface for the purposes of this flowchart.

³³ Gastrointestinal lesion software detection systems are classified under 21 CFR 876.1520 and are subject to the special controls established in the [reclassification order](#), available at https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200055.pdf. The publication of this classification in the Federal Register and codification in the Code of Federal Regulations is currently pending.

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442 gastrointestinal tract. The submitter has proposed to modify the computer-assisted detection
443 algorithm such that a new 510(k) was submitted. The algorithm modifications improve the
444 system's ability to assist in detection of lesions and does not change any aspects of the
445 device-user interface.

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

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

449

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

- 451 • **User interface;**
- 452 • **Intended device users;**
- 453 • **Intended device uses;**
- 454 • **Intended use environment(s);**
- 455 • **Training; or**
- 456 • **Labeling?**

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

460

461 **Analysis:** The recommended HF information in this marketing submission is defined by **HF**
462 **Submission Category 1**. The submitter should include a statement justifying that the device
463 modifications do not affect the human factors considerations of the modified device and the
464 conclusion and high level summary of HF evaluation.

465

466 **Example A.2.**

467 **Scenario:** A submitter currently has marketing authorization for a gas machine for anesthesia
468 in a cleared stand-alone device 510(k) submission. The gas machine for anesthesia is
469 intended for use in the hospital environment and includes a touch screen graphical user
470 interface (GUI) and control knobs to regulate gas flow. The submitter requests 510(k)-
471 clearance for a modification to the internal gas valving system and included in their 510(k)
472 labeling changes to reflect the modification. There are no changes to the apparent flow
473 settings from this internal change. Any modifications regarding calculated flow rates are
474 made in software settings.

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

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

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

- 479 • **User interface;**
- 480 • **Intended device users;**
- 481 • **Intended device uses;**
- 482 • **Intended use environment(s);**
- 483 • **Training; or**

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484 • **Labeling?**

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

490 **Decision Point C: Based on the use-related risk analysis, are there:**

491 • **New devices only: Critical tasks?**

492 • **Modified devices only: New critical tasks introduced or are existing critical**
493 **tasks impacted?**

494 No. Even though the labeling (instructions manual) has changed, this change does not impact
495 how the intended user is expected to interact with the device because the user is not intended
496 to directly interact with the gas valving system, since it is an internal component. There are
497 no changes that influence the cognitive and/or visual perception or the physical interaction
498 between the user and the device. Therefore, there are no new critical tasks introduced, nor are
499 existing critical tasks impacted.

500

501 **Analysis:** The recommended HF information in this marketing submission is defined by **HF**
502 **Submission Category 2.** The submitter should provide a rationale that clearly describes the
503 basis of their decision that there are no new critical tasks introduced, and no impacted critical
504 tasks for their modified device.

505

506 **Example A.3.**

507 **Scenario:** In addition to the change described in Example A.2, the submitter also requests
508 510(k) clearance to change the font size from 12 to 14 point on the text displayed on the
509 graphical user interface (GUI) of the gas machine for anesthesia, along with a proportional
510 increase in the screen's physical size. The submitter is also making associated software
511 changes to address the proposed change in the font size. The GUI menu does not change in
512 terms of selection layout and contains the same icons representing different intended actions.

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

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

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

517 • **User interface;**

518 • **Intended device users;**

519 • **Intended device uses;**

520 • **Intended use environment(s);**

521 • **Training; or**

522 • **Labeling?**

523 Yes. There are changes to the user interface from the software changes because the user is
524 intended to directly interact visually with the words on the touch screen GUI, which the

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525 submitter states is the only part of the device being modified. There are no changes to the
526 intended device users, uses, intended use environment, training, or labeling.

527 **Decision Point C: Based on the use-related risk analysis, are there:**

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

531 No. Even though the user interface (GUI) was changed to include larger text font and a larger
532 screen display, this change does not impact how the intended user is expected to interact with
533 the device because the same textual information is being presented in the same layout and
534 format. The text size change was assessed to introduce no negative influence on the cognitive
535 and/or visual perception or the physical interaction between the user and the device. In this
536 case, the submitter can choose to provide formative data and/or literature supporting this
537 conclusion. Therefore, there are no new critical tasks introduced, nor are existing critical
538 tasks impacted.

539
540 **Analysis:** The recommended HF information in this marketing submission is **HF**
541 **Submission Category 2.** The submitter should provide a rationale (e.g., analysis of a
542 literature review for acceptable font size) that clearly describes the basis of their decision that
543 there are no new critical tasks introduced, and no impacted critical tasks for their modified
544 device.

545
546 **Example A.4.**

547 **Scenario:** The submitter requests to change the GUI of the gas machine for anesthesia
548 described in Example A.2. The proposed changes consist of changing textual menu selection
549 items to icons (i.e., graphics). In addition, the submitter requests a change from the physical
550 knob interface with discrete values for gas flow control to a digital slider with continuous
551 values within a pre-specified range that became an added feature to the touch screen GUI.
552 Based on these changes, the submitter updated the labeling, including the user manual and
553 instructions for use, and training.

554
555 **Decision Point A: Is it a modification to an existing device?**

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

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

- 559 • **User interface;**
- 560 • **Intended device users;**
- 561 • **Intended device uses;**
- 562 • **Intended use environment(s);**
- 563 • **Training; or**
- 564 • **Labeling?**

565 Yes. There are changes to the user interface because the user directly interacts visually with
566 the icons and controls on the touch screen GUI. There is also a change in the way the user
567 controls the gas flow. There are no changes to the intended device users, uses, or intended

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568 use environment. Both the submitter’s training and labeling have changed based on the
569 changes to the touch screen GUI.

570 **Decision Point C: Based on the use-related risk analysis, are there:**

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

574 Yes. There are several critical tasks associated with the main touch screen GUI of the gas
575 machine for anesthesia, such as setting the ventilation mode, setting tidal volume and
576 inspiratory pressure, and setting alarms. Changing the GUI to include only icons instead of
577 text for menu selections may impact the ability of the user to comprehend the correct
578 selection. There are also critical tasks associated with setting and controlling the gas flow to
579 the patient. The interface for gas flow control changed from a physical knob to a digital slider
580 on the touch screen interface, which impacts the physical interaction the user might have
581 with the gas flow control. Although the same information is being conveyed, it is displayed
582 in a different layout and format compared to the predicate.
583

584 **Analysis:** This requested change would be considered **HF Submission Category 3**. The
585 submitter should submit test results and analysis from a new HF validation study for the
586 subject device in an HF Report. The HF Report should include the use-related risk analysis,
587 along with the information referenced in Table 3.
588

589 **B. Modification to an existing PMA-approved device**

590 **Example B.1.**

591 **Scenario:** An implantable infusion pump has a physician programmer and both have been
592 approved as a standalone device through the PMA process. The approved physician
593 programmer is a personal digital assistant (PDA) device, with a monochrome screen and
594 physical buttons to control scrolling and menu selection. The submitter requests approval in a
595 PMA Supplement for a modification to the reservoir volume of the infusion pump. This
596 proposed change does not result in any change to medication concentration or dosing
597 calculation. The software is being updated to allow for the proposed volume change. The
598 proposed modifications, including the software changes, have no direct effect on the device
599 with which a physician or patient directly interact.

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

601 Yes. The submitter is modifying their own existing PMA-approved device.
602

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

- 604 • **User interface;**
- 605 • **Intended device users;**
- 606 • **Intended device uses;**
- 607 • **Intended use environment(s);**
- 608 • **Training; or**
- 609 • **Labeling?**

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610 Yes. The labeling (instructions manual) was updated to specify the change in the reservoir
611 volume.

612 **Decision Point C: Based on the use-related risk analysis, are there:**

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

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

621
622 **Analysis:** The recommended HF information in this marketing submission is **HF**
623 **Submission Category 2.** The submitter should provide a rationale (e.g., discussion of how
624 the change in total reservoir volume does not affect critical tasks such as setting
625 concentration or calculating dosage) that clearly describes the basis of their decision that
626 there are no new critical tasks introduced, and no impacted critical tasks for their modified
627 device.

628
629 **Example B.2.**

630 **Scenario:** Like 0, an implantable infusion pump has a physician programmer and both have
631 been approved through the PMA process. The approved physician programmer is a PDA
632 device, with a monochrome screen and physical buttons to control scrolling and menu
633 selection. The submitter requests approval in a PMA Supplement for a modification to the
634 physician programmer from the approved monochrome PDA to a mini-tablet computer with
635 a touch screen user interface. The display on the tablet computer will feature a full color
636 display and new icons for menu functions.

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

638 Yes. The submitter is modifying their own existing PMA-approved device.
639

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

- 641 • **User interface;**
- 642 • **Intended device users;**
- 643 • **Intended device uses;**
- 644 • **Intended use environment(s);**
- 645 • **Training; or**
- 646 • **Labeling?**

647 Yes. The introduction of new icons, color selection and display, and new menu orientation,
648 has changed the user interface. Due to these changes, the submitter is also proposing to
649 change the relevant training and labeling (instructions manual).
650

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651 **Decision Point C: Based on the use-related risk analysis, are there:**

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

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

659
660 **Analysis:** The recommended HF information in this marketing submission is **HF**
661 **Submission Category 3.** The submitter should submit test results and analysis from a new
662 HF validation study for the subject device in an HF Report. The HF Report should include
663 the use-related risk analysis, along with the information referenced in Table 3.

664
665 **Example B.3.**

666 **Scenario:** A submitter has an approved PMA for a stent with a balloon catheter delivery
667 system. The submitter is requesting approval for a new stent under a new PMA that has a
668 different stent design and coating. The new stent uses the same balloon catheter delivery
669 system as the submitter’s own PMA-approved stent. The submitter is proposing to leverage
670 the previous HF validation test results for the balloon catheter delivery system.

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

672 Yes. The submitter is using their own existing PMA-approved balloon catheter delivery
673 system with a new stent.

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

- 675 • **User interface;**
- 676 • **Intended device users;**
- 677 • **Intended device uses;**
- 678 • **Intended use environment(s);**
- 679 • **Training; or**
- 680 • **Labeling?**

681 No. Even though the submitter has submitted a new PMA, in this case, the user-interface of
682 the balloon catheter delivery system is the same as that used in the approved PMA. The only
683 changes to the product are the stent design and coating, which are not user-interfacing and
684 are based on the submitter’s approved PMA. The submitter evaluated the critical tasks, and
685 none of them were impacted by the change in stent design and coating. The submitter can
686 leverage the previous HF validation test results in their new PMA.

687
688 **Analysis:** The recommended HF information in this marketing submission is **HF**
689 **Submission Category 1.** The submitter should include a statement justifying that the device
690 modifications do not affect the human factors considerations of the modified device and the
691 conclusion and high level summary of HF evaluation.

692
693

694 **C. New devices**

695 **Example C.1.**

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

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

700 No. The submitter is submitting a new PMA based on a new design of the catheter delivery
701 system with a new stent. The submitter should proceed to Decision Point C.

702 **Decision Point C: Based on the use-related risk analysis, are there:**

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

706 Yes. The submitter has determined based on the use-related risk analysis that there are
707 critical tasks associated with the subject device.
708

709 **Analysis:** The recommended HF information in this marketing submission is **HF**
710 **Submission Category 3.** The submitter should submit test results and analysis from a new
711 HF validation study for the subject device in an HF Report. The HF Report should include
712 the use-related risk analysis, along with the information referenced in Table 3.
713

714 **Example C.2.**

715 **Scenario:** The submitter submits a 510(k) to request clearance for a new portable fingertip
716 oximeter intended for spot checking oxygen saturation of arterial hemoglobin of adult
717 patients in professional healthcare facilities and the home. This is the first portable oximeter
718 device developed by the submitter. Therefore, the submitter uses a predicate device from a
719 different submitter. The subject device does not include any alarms or additional information
720 interpreting the oxygen saturation, nor is it intended for life supporting or life-sustaining
721 functions. The user of the device places the sensor on a finger and then reads the oxygen
722 saturation values calculated by the device. The submitter compares their device with the
723 predicate device to show the indications for use, use environment, and users are the same
724 between the two devices.

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

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

729 **Decision Point C: Based on the use-related risk analysis, are there:**

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

733 No. The submitter determined through their use-related risk analysis that the action of
734 placing the sensor on a user's finger and reading the oxygen saturation values could not

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735 cause serious harm to the user/patient. The submitter further justifies this conclusion by
736 stating the device is used as a spot-check and there are no alarms or additional information
737 interpreting the results from the device.
738

739 **Analysis:** The recommended HF Submission Category in this marketing submission is **HF**
740 **Submission Category 2**. The submitter should provide a rationale for why there are no
741 critical tasks.

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