

# Multiple Function Device Products: Policy and Considerations

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## Draft Guidance for Industry and Food and Drug Administration

### *DRAFT GUIDANCE*

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For questions about this document regarding CDRH-regulated devices, contact Linda Ricci at [Linda.Ricci@fda.hhs.gov](mailto:Linda.Ricci@fda.hhs.gov) or at 301-796-6325 or the CDRH Digital Health Program at [DigitalHealth@fda.hhs.gov](mailto:DigitalHealth@fda.hhs.gov). For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.



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

## **Preface**

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# Multiple Function Device Products: Policy and Considerations

## Draft Guidance for Industry and Food and Drug Administration Staff

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### I. Introduction

Medical products may contain several functions, some of which are subject to FDA’s regulatory oversight as medical devices, while others are not. For purposes of this guidance, for any given product, the term “function” is a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product. Products with at least one device function are referred to as “multiple function device products.” This draft guidance explains FDA’s regulatory approach and policy for all multiple function device products. Specifically, this guidance clarifies when and how FDA intends to assess the impact of other functions that are not the subject of a premarket review on the safety and effectiveness of a device function subject to FDA review. The purpose of this draft guidance is to identify the principles, premarket review practices, and policies for FDA’s regulatory assessment of such products and to provide examples of the application of these policies.

For the current edition of the FDA-recognized standards referenced in this document, see the [FDA Recognized Consensus Standards Database](#).<sup>1</sup>

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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

<sup>1</sup> Available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>.

## 120 II. Background

121 Section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) defines a device as:

122  
123 an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other  
124 similar or related article, including any component, part, or accessory which is:

- 125
- 126 • recognized in the official National Formulary, or the United States Pharmacopoeia, or
  - 127 any supplement to them,
  - 128 • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation,
  - 129 treatment, or prevention of disease, in man or other animals, or
  - 130 • intended to affect the structure or any function of the body of man or other animals, and
- 131

132 which does not achieve its primary intended purposes through chemical action within or on  
133 the body of man or other animals and which is not dependent upon being metabolized for the  
134 achievement of any of its primary intended purposes. The term "device" does not include  
135 software functions excluded pursuant to section 520(o).

136  
137 Functions that fall within this definition are devices and, therefore, subject to FDA’s oversight.  
138 FDA’s regulation of devices is tailored based on risk. For example,

- 139 • Some devices are subject to premarket review, either through a premarket notification  
140 under section 510(k) of the FD&C Act, through a premarket approval application under  
141 section 515 of the FD&C Act, a De Novo classification request under section 513(f)(2) of  
142 the FD&C Act, an investigational device exemption (IDE) application under 21 CFR 812,  
143 or a humanitarian device exemption (HDE) under section 520(m) of the FD&C Act.
  - 144 • Other, lower-risk devices are exempt from premarket review, but are subject to general  
145 controls, including registration and listing,<sup>2</sup> good manufacturing practices,<sup>3</sup> and adverse  
146 event reporting.<sup>4</sup>
  - 147 • FDA has issued guidance that it does not intend to focus its regulatory oversight on some  
148 devices that pose a low risk to patients. FDA has done this for many low-risk software  
149 functions. See, for example, FDA’s guidance [Mobile Medical Applications](#)<sup>5</sup> and [General  
150 Wellness Policy for Low Risk Devices](#).<sup>6</sup>
- 151

152 On December 13, 2016, the 21st Century Cures Act (Cures Act) was signed into law. Section  
153 3060(a) of this legislation, titled “Clarifying Medical Software Regulation,” amended the FD&C  
154 Act to add section 520(o), which describes software functions that are excluded from the  
155 definition of the term device in section 201(h). In addition, section 520(o)(2), reproduced below,

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<sup>2</sup> Section 510 of the FD&C Act.

<sup>3</sup> Section 520(f) of the FD&C Act.

<sup>4</sup> Section 519 of the FD&C Act.

<sup>5</sup> Available at

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366>.

<sup>6</sup> Available at

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674>.

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156 describes the regulation and assessment of a software product with multiple functions, including  
157 at least one device function and at least one software function that is not a device.

158

159 Section 520(o)(2) of the FD&C Act (21 U.S.C. 360j(o)(2))

160 In the case of a product with multiple functions that contains—

161 (A) at least one software function that meets the criteria under  
162 paragraph (1) or that otherwise does not meet the definition of device  
163 under section 201(h); and

164 (B) at least one function that does not meet the criteria under  
165 paragraph (1) and that otherwise meets the definition of a device under  
166 section 201(h),

167 the Secretary shall not regulate the software function of such product  
168 described in subparagraph (A) as a device. Notwithstanding the  
169 preceding sentence, when assessing the safety and effectiveness of the  
170 device function or functions of such product described in subparagraph  
171 (B), the Secretary may assess the impact that the software function or  
172 functions described in subparagraph (A) have on such device function  
173 or functions.

### 174 **III. Scope**

175 As mentioned above, in this guidance for any given product, the term “function” is a distinct  
176 purpose of the product, which could be the intended use or a subset of the intended use of the  
177 product. For example, a product with an intended use to analyze data has one function: analysis.  
178 A product with an intended use to store, transfer, and analyze data has three functions: (1)  
179 storage, (2) transfer, and (3) analysis. As this example illustrates, a product may contain  
180 multiple functions. For products containing multiple functions, some functions may meet the  
181 definition of a device under section 201(h) of the FD&C Act, and some “other functions” may:

182

- 183 • not meet the definition of device;
- 184 • meet the definition of device, but are not subject to premarket review (e.g., 510(k)-  
185 exempt); or
- 186 • meet the definition of device, but for which FDA has expressed its intention not to  
187 enforce compliance with applicable regulatory controls.

188

189 A multiple function device product contains at least one device function and at least one other  
190 function. For the purposes of this guidance, FDA uses the term “device function-under-review”  
191 to describe those device functions for which FDA is conducting a premarket review.

192

193 Although section 520(o)(2) of the FD&C Act applies to the regulation of products containing at  
194 least one device function and at least one non-device *software* function, FDA believes the same  
195 principles apply to the assessment of *all* multiple function products that contain at least one  
196 device function. This document does not provide guidance on which functions do and do not  
197 meet the definition of a device. It also does not provide guidance on which functions meet the

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198 device definition but are those for which FDA has expressed its intention not to enforce  
199 compliance with applicable requirements of the FD&C Act.

200  
201 Sections IV – VII of this document discuss premarket submissions for device functions-under-  
202 review of multiple function products, including 510(k)s, De Novo requests, premarket approval  
203 (PMA) applications, humanitarian device exemption (HDE) applications, investigational device  
204 exemption (IDE) applications, Q-Submissions, Biologics License Applications (BLAs), and the  
205 review and requests for information regarding the classification for or the requirements  
206 applicable to a device under the FD&C Act submitted in accordance with 513(g) of the FD&C  
207 Act. Section VIII of this document addresses other requirements for device functions of multiple  
208 function products, including the applicability of general controls.

209  
210 This guidance applies to FDA’s review of the device constituent of a combination product. This  
211 guidance does not change FDA’s review of a drug or biologic constituent of a combination  
212 product. In addition, software intended for use with one or more drug(s) or biologic(s) may be  
213 subject to requirements applicable to drug or biologic labeling.<sup>7</sup> Furthermore, the Cures Act  
214 provides that a software function described in section 520(o)(1)(E) of the FD&C Act will not be  
215 excluded from the device definition under 201(h) if the software meets the criteria under section  
216 513(a)(1)(C) of the FD&C Act or if the software is used in the manufacture and transfusion of  
217 blood and blood components to assist in the prevention of disease in humans (section  
218 520(o)(4)(B) and (C) of the FD&C Act).

219  
220 The principles outlined in this guidance reflect a safety-based approach to risk management  
221 aligned with ANSI/AAMI/ISO 14971: *Medical Devices – Application of risk management to*  
222 *medical devices*.

## 223 **IV. Policy: Premarket Review of Multiple Function Device** 224 **Products**

225 Consistent with the FD&C Act, as amended by the Cures Act, FDA does not regulate certain  
226 software functions contained in a multiple function device product as a device because they do  
227 not meet the statutory device definition.<sup>8</sup> However, when assessing the safety and effectiveness  
228 of the device function-under-review of a multiple function device product, FDA may assess the  
229 impact of the other function.<sup>9</sup> For example, FDA does not regulate a general purpose computing  
230 platform but may assess its impact on the safety and effectiveness of a device function-under-  
231 review. Similarly, for a product that includes an intragastric balloon subject to premarket  
232 approval and an endoscope accessory that is 510(k)-exempt (e.g., an endoscope guidewire), FDA  
233 may assess the impact of the endoscope accessory on the safety and effectiveness of the  
234 intragastric balloon. For some device functions, FDA has expressed its intention not to enforce  
235 compliance with applicable requirements. In accordance with existing policies, FDA intends not  
236 to review a device function subject to an enforcement discretion policy merely because it is part

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<sup>7</sup> 21 CFR 3.2(e).

<sup>8</sup> 520(o)(2) of the FD&C Act.

<sup>9</sup> 520(o)(2) of the FD&C Act.

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237 of a multiple function device product. Instead, FDA intends to review the device function(s) for  
238 which clearance or approval is being sought. For example, if a manufacturer seeks clearance or  
239 approval for a device function (e.g., analysis) only, and not the device function for which FDA  
240 has expressed its intention not to enforce compliance (e.g., track and trend), then FDA intends to  
241 only review the analysis function and assess the track and trend function only insofar as it  
242 impacts the analysis function. In that instance, because FDA is only reviewing the analysis  
243 function, FDA’s decision to clear or approve applies only to the analysis function. See Appendix  
244 1: Summary of Premarket and Postmarket Policy for Multiple Function Device Products.  
245

## 246 **V. Considerations for Multiple Function Device Products**

247 FDA guidances with premarket submission recommendations for medical devices apply to  
248 products with at least one device function-under-review. The following sections describe  
249 additional considerations for multiple function device products. However, there is no one-size-  
250 fits-all approach for the wide variety of multiple function device products, and manufacturers  
251 should consider their products’ specific functions and conditions of use.

### 252 **A. Separation in Design and Implementation of the Device** 253 **Function**

254 The device function-under-review should, to the extent possible, be separated from other  
255 functions in its design and implementation. The higher the degree of separation, the easier it is  
256 to independently review the safety and effectiveness of the device function-under-review.  
257 Separation will also increase the likelihood that the device function-under-review is not  
258 dependent on the other functions in the product. Architecture decisions early in the design cycle  
259 can facilitate optimal separation and support segregation necessary for risk control. When  
260 separation is not achievable, connectivity between the device function-under-review and other  
261 functions should be explained and appropriate controls should be created to reduce the adverse  
262 impact of the connectivity on the safety and effectiveness of the device function-under-review.

### 263 **B. Impact of Other Function(s)**

264 The manufacturer of a multiple function device product should consider the following regarding  
265 all other function(s) of the product:

- 266 • the role of the other function(s) in the device function-under-review’s performance;
- 267 • any limitations of using the other function(s) with the device function-under-review;
- 268 • developing appropriate hardware and software resource specification(s) for the product  
269 with multiple functions to ensure performance of the other function(s) when used with  
270 the device function-under-review; and
- 271 • how to ensure appropriate actions are taken by the end user when using the other  
272 function(s) with the device function-under-review.

273 **VI. Assessing the Impact of Other Functions on the Device**  
274 **Function-Under-Review**

275 In the premarket review of a device function-under-review, FDA may assess the impact of other  
276 functions on the device function-under-review. The premarket assessment of a product with  
277 multiple functions is summarized in a two-step process:

278  
279 (A) Does the other function impact the safety or effectiveness of the device function-under-  
280 review?; and

281 (B) Does the impact result in increased risk or have an adverse effect on performance?  
282

283 Each step and its relevant considerations are described below. Section VII describes what should  
284 be included in the documentation for a premarket submission for a multiple function product, if  
285 the device function-under-review is impacted by the other functions and if the impact results in  
286 increased risk or an adverse effect on performance.

287 **A. Is There an Impact on the Safety or Effectiveness of the**  
288 **Device Function-Under-Review as a Result of the Other**  
289 **Function?**

290 Manufacturers should determine if an other function may impact the safety or effectiveness of  
291 the device function-under-review. If so, FDA recommends that manufacturers evaluate that  
292 impact.  
293

294 When assessing the impact of other functions on the device function-under-review, it is  
295 important to consider the various relationships between the functions that may exist in a multiple  
296 function device product. The existence of a relationship does not necessarily mean that there  
297 may be an impact on the safety or effectiveness of the device function-under-review. When  
298 assessing if an other function impacts the device function-under-review within the same product,  
299 considerations should include whether there are shared computational resources, data  
300 dependencies, or any other type of relationship between the functions. The following are  
301 examples of questions that may help to determine if an other function may impact the safety or  
302 effectiveness of the device function-under-review. Note that this is not intended to be a  
303 comprehensive list of considerations, and manufacturers should conduct their own assessments.  
304

- 305 • Does the other function provide input data that is used for a critical calculation within  
306 the device function-under-review?
- 307 • Does the device function-under-review rely on results from the other function?
- 308 • Do the other function and the device function-under-review share code that is  
309 necessary for proper execution of the device function-under-review?
- 310 • Do the other function and the device function-under-review share the same output  
311 screen?

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- 312 • Do the other function and the device function-under-review share processing time on  
313 the processor?
- 314 • Do the other function and the device function-under-review share memory on the  
315 computer platform?
- 316 • Do the other function and the device function-under-review share programming  
317 pointers?
- 318 • Does the device function-under-review have sufficient privileges to prevent delays or  
319 interruptions that may result from the other function?  
320

## 321 **B. Does the Impact Result in Increased Risk or Have an** 322 **Adverse Effect on Performance?**

323 If the other function impacts the device function-under-review, the extent of the impact should  
324 be evaluated. Although the inclusion of other functions in a product may impact the device  
325 function-under-review, the assessment should focus on identifying if there may be increased risk  
326 and/or an adverse effect on performance due to the *combination* of the other function with the  
327 device function-under-review.

### 328 **1. Impacts to Safety**

329 A risk-based assessment should be used to identify and analyze all risks of a device function-  
330 under-review, including those that may result from the inclusion of other functions in the  
331 product. If the impact results in no increased risk, then no additional risk mitigation is necessary.  
332 If there may be increased risk, then the risk should be appropriately mitigated, and the  
333 appropriate verification and/or validation should be performed to ensure the effectiveness of the  
334 mitigation. The following examples can be used as a guide to understand increased risk.  
335

- 336 • The other function introduces a hazardous situation or a cause of a hazardous situation.  
337 ○ A “hazardous situation” exists when there is exposure to a hazard (i.e., a potential  
338 source of harm) that can lead to physical injury or damage to the health of people.
- 339 • The other function increases the severity of harm associated with a hazardous situation  
340 identified for a device function-under-review.
- 341 • The other function is a risk control measure for a device function-under-review.
- 342 • The use of or implementation of the other function impacts a risk control measure for a  
343 device function-under-review.

### 344 **2. Impacts to Effectiveness**

345 The impacts to effectiveness are typically impacts to the performance of the device. If there may  
346 be adverse impacts to the device function-under-review as a result of the other functions, then  
347 appropriate verification and validation should be performed with the product to characterize the  
348 performance of the device function-under-review and evaluate if there may be an adverse effect  
349 on the performance. The following examples can be used as a guide to understand adverse  
350 impacts on performance.  
351

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- 352 • The performance or clinical functionality of the device function-under-review depends on  
353 the other function for the device function-under-review to perform as specified.
- 354 • The performance of the device function-under-review is decreased below the specified  
355 performance level due to the other function.

356  
357 Note that the relationship between a device function-under-review and other functions may be  
358 limited to sharing resources on a general purpose computing platform. If the only identified  
359 relationship between the device function-under-review and an other function is the sharing of a  
360 common computing platform, the risk assessment for the device function-under-review should  
361 include the hazards associated with running on a common computing platform. For examples of  
362 multiple function software device products and explanations of the assessment of other  
363 functions' impact to the device function(s)-under-review, see the Appendix 2: Examples of  
364 Multiple Function Device Products.

## 365 **VII. Content of a Premarket Submission for Device** 366 **Function-Under-Review**

367 If based on the sponsor's assessment, the other function could adversely impact the device  
368 function-under-review (i.e., the impact of the other function may be increased risk or adverse  
369 effect on performance of the device function-under-review), then the premarket submission for  
370 the product containing these functions should include the documentation identified below. If the  
371 device function-under-review is positively impacted by the other function (e.g., the other  
372 function improves the speed or cybersecurity of the device function-under-review), and the  
373 sponsor would like the positive impact to be considered in FDA's assessment of the device  
374 function-under-review, then the premarket submission for the product should include the  
375 documentation identified below.

### 376 **A. Indications for Use**

377 The indications for use should only include the indications for use of the device-function-under-  
378 review.  
379

### 380 **B. Description of Functions**

381 The device description should include a description of the other functions that impact the device  
382 function-under-review, and address how the device function-under-review is impacted by each of  
383 the other functions. Sponsors should describe how each of the other functions is meant to be  
384 used and in what ways they impact the device function-under-review.  
385

### 386 **C. Architecture and Design**

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387 The architecture and design documents included in the premarket submission for the device  
388 function-under-review should include adequate detail to understand how or if the other functions  
389 interact with or impact the device function-under-review. For example, an architecture diagram  
390 may demonstrate the independence of the device function-under-review from the other function,  
391 or design documents may demonstrate the use of shared resources.

#### 392 **D. Risk Analysis**

393 The risk analysis included in the premarket submission for the device function-under-review  
394 should include a risk-based assessment of any impact of the other function to the safety or  
395 effectiveness of the device function-under-review as discussed above. The risk-based  
396 assessment should document any risk mitigations employed to mitigate increased risk resulting  
397 from the combination of functions. For example, if the impact of the other function may result in  
398 decreased performance of the device function-under-review, documentation should include the  
399 results of the risk management that identifies and describe the hazards that could affect the safety  
400 or cause decreased performance and any necessary risk mitigations employed.  
401

#### 402 **E. Requirements and Specifications**

403 Documentation of requirements and specifications included in the premarket submission for the  
404 device function-under-review should include adequate detail to describe any expected  
405 relationship, utility, reliance, or interoperability with any other function. For example, the  
406 documentation may include minimum requirements, such as system memory necessary for the  
407 device function-under-review to safely run on a general purpose computing platform.  
408

#### 409 **F. Submission Summary**

410 Where the device function-under-review is not adversely impacted by an other function, FDA  
411 does not intend to assess that other function (unless the Sponsor would like FDA to consider the  
412 positive impact of the other function in FDA's assessment of the device function-under-review).  
413 Therefore, an approved or cleared device may include functionality that FDA has not assessed.  
414 FDA intends to make the extent of the product's assessment clear in the 510(k) Summary, PMA  
415 Summary of Safety and Effectiveness Data (SSED), De Novo Summary, or HDE Summary of  
416 Safety and Probable Benefit (SSPB) with a statement. For example, if a product includes a  
417 device function-under-review and a function that is not subject to premarket review, the  
418 statement could read:

419  
420 This product has functions subject to FDA premarket review and functions that are not  
421 subject to FDA premarket review. For this application, FDA assessed functions not  
422 subject to premarket review only insofar as they might adversely impact the safety and  
423 effectiveness of the functions subject to FDA premarket review.  
424

425 **VIII. Application of Other Device Requirements to**  
426 **Device Functions**

427 General control requirements<sup>10</sup> apply to device functions subject to 510(k), PMA, De Novo, or  
428 HDE and to device functions that are 510(k) exempt. For example, in accordance with 21 CFR  
429 803.50, FDA expects the manufacturer of a device function to submit an adverse event report  
430 when the manufacturer becomes aware of information that reasonably suggests that the device  
431 function may have caused or contributed to a death or serious injury, among other circumstances.  
432 If the manufacturer is not certain about whether the device function or another function in a  
433 product caused or contributed to a death or serious injury, the manufacturer would still be  
434 required to report it if the information *reasonably suggests* that the device function *may* have  
435 caused the death or serious injury. Similarly, as an additional example, device functions in  
436 multiple function products must comply with design control requirements under the Quality  
437 System regulation (21 CFR Part 820). FDA continues to intend not to enforce general control  
438 requirements for device functions for which FDA has expressed its intention to not enforce  
439 applicable regulatory controls. There are no FDA postmarket requirements for non-device  
440 functions. See Appendix 1: Summary of Premarket and Postmarket Policy for Multiple  
441 Function Device Products.

442  
443

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<sup>10</sup> Sections 501, 502, 510, 516, 518, 519, 520(e), and 520(f) of the FD&C Act.

444 **Appendix 1: Summary of Premarket and Postmarket Policy**  
445 **for Multiple Function Device Products**

446 Table 1 provides a summary of the premarket and postmarket statutory requirements, as well as  
447 the policies described in Sections IV and VIII of this guidance. Table 1 should be read in  
448 conjunction with these sections.  
449

<b>Function:</b>	<b>Premarket Oversight</b>	<b>Postmarket Oversight</b>
Device function under review (510(k), PMA, IDE, De Novo, or HDE)	Reviewed	General control requirements are applicable (except for IDE)
Device function that is 510(k) exempt	Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review	General control requirements are applicable
Device function for which no premarket review is sought and FDA does not intend to enforce applicable regulatory controls	Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review	General control requirements are applicable but not intended to be enforced
Non-device function	Not regulated but assessed only for impact on the safety and effectiveness of the device function-under review	Not regulated and therefore FDA requirements not applicable

450

451 **Appendix 2: Examples of Multiple Function Device**  
452 **Products**

453 The following are hypothetical examples of multiple function device products, explaining the  
454 assessment of other functions' impact to the device function(s)-under-review. These generalized  
455 examples are not intended to cover all possible details, risks, or considerations that should be  
456 evaluated for multiple function device products. In addition, the examples are not intended to  
457 describe all the details of the documentation necessary to demonstrate adequate risk mitigation.  
458

<b><u>Example: Skin cancer detection software application</u></b>	
<i>Product</i>	A smart phone software (SW) application (app) that detects skin cancer from photos of suspicious lesions of moles.
<i>Functions</i>	Device function-under-review: <ul style="list-style-type: none"><li>• SW app (SW)</li></ul> Other function: <ul style="list-style-type: none"><li>• Smart phone computing platform (HW/SW)</li><li>• Camera on the computing platform (HW/SW)</li></ul>
<i>Impact of the other function on the device function-under-review</i>	The SW app depends on the smart phone camera for the photos and depends on the computing platform for the analysis.
<i>Increased risk or adverse effect of the other function on the device function-under-review</i>	<ul style="list-style-type: none"><li>• The output of the camera may not be adequate for detecting skin cancer resulting in misdiagnosis.</li><li>• The smartphone's computing platform performance may not be adequate to support the software functions including the algorithm intended to detect skin cancer.</li></ul>
<i>Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated</i>	<ul style="list-style-type: none"><li>• Document testing outcomes that demonstrate that there are adequate computing resources (including screen size and resolution) and error handling to accommodate the common computing platform including the build-in camera.</li><li>• Document description of specific feature(s) with adequate testing outcomes that mitigate risk from software being used on a smartphone or inadequate camera.</li><li>• Documentation of specification for the use of the app with the camera and the computing platform</li></ul>
<i>Assessment of other function(s)</i>	The smart phone platform is not evaluated. The software manufacturer is not responsible for EMC or electrical safety testing of a commercial smartphone when used as intended by the smartphone manufacturer.

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<b><u>Example: Hand held coagulation device</u></b>	
<i>Product</i>	A hand-held coagulation (prothrombin time) test device that interfaces with a hospital information system (HIS) through a commercial off-the-shelf docking information station hardware (HW) that meets appropriate U.S. Consumer Product Safety Commission standards (electrical safety testing, safety certification, etc.) to transfer clinical in vitro test data.

## Contains Nonbinding Recommendations

### Draft – Not for Implementation

<i>Functions</i>	Device function-under-review: <ul style="list-style-type: none"><li>• Hand held coagulation instrument (HW)</li><li>• Coagulation (prothrombin time) test (SW/HW)</li></ul> Other function: <ul style="list-style-type: none"><li>• Docking station (HW)</li><li>• Interface to transmit the data to the HIS (SW)</li></ul>
<i>Impact of the other function on the device function-under-review</i>	The handheld instrument depends on the docking station for charging and data transfer.
<i>Increased risk or adverse effect of the other function on the device function-under-review</i>	<ul style="list-style-type: none"><li>• Charging of the handheld instrument is necessary for device performance.</li><li>• The recharging of the battery introduces new hazardous situations for the instrument itself.</li><li>• Instrument may be affected by erroneous or nontrusted data transfer from the HIS system.</li></ul>
<i>Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated</i>	<ul style="list-style-type: none"><li>• Demonstrate that appropriate mitigations were implemented to address hazards associated with battery charging.</li><li>• Document features authenticating data from trusted HIS system.</li></ul>
<i>Assessment of other function(s)</i>	The docking station and interface SW are not evaluated.

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#### **Example: Traumatic Brain Injury Determination**

<i>Product</i>	A product that analyzes a user's Electroencephalogram (EEG) signals recorded on a computer platform and specialized hardware and uses data generated from an electronic questionnaire to determine if the user has suffered from Traumatic Brain Injury (TBI).
<i>Functions</i>	Device function-under-review: <ul style="list-style-type: none"><li>• Collection and Recording of EEG signals (HW/SW)</li><li>• Analyzing EEG signals and diagnosing TBI (SW)</li><li>• Presentation of results (SW)</li></ul> Other function: <ul style="list-style-type: none"><li>• Computer Operating System functions (SW)</li><li>• Electronic administration of questionnaire (HW/SW)</li></ul>
<i>Impact of the other function on the device function-under-review</i>	The device algorithm depends on the results of the questionnaire.

## Contains Nonbinding Recommendations

### Draft – Not for Implementation

<i>Increased risk or adverse effect of the other function on the device function-under-review</i>	<ul style="list-style-type: none"><li>• Inaccurate input of questionnaire results may impact the performance of the software.</li><li>• Computer performance may not be adequate to support the software functions including the algorithm intended to determine if the patient has TBI.</li><li>• The output of the questionnaire may not be adequate for determining if the patient has TBI.</li></ul>
<i>Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated</i>	<ul style="list-style-type: none"><li>• Demonstrate that appropriate mitigations were implemented to limit or minimize inaccurate input to the questionnaire.</li><li>• Demonstrate that the algorithm includes features to detect inaccurate input that may impact the performance of the software.</li><li>• Testing outcomes demonstrating adequate computing resources (including screen size) and error handling to accommodate the common computing platform.</li><li>• Description of specific feature(s) with adequate testing outcomes that mitigate risk from software being used on a common computing platform.</li></ul>
<i>Assessment of other function(s)</i>	The computing platform and the questionnaire are not evaluated.

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<b>Example: Pain treatment app</b>	
<i>Product</i>	A Transcutaneous Electrical Nerve Stimulation (TENS) device controlled by an app on a mobile platform worn by the user to treat pain.
<i>Functions</i>	Device function-under-review: <ul style="list-style-type: none"><li>• Electrical Nerve Stimulation as a treatment for pain (HW/SW)</li><li>• App used to control the level of stimulation (SW)</li></ul> Other function: <ul style="list-style-type: none"><li>• Mobile platform Bluetooth transceiver and connectivity</li></ul>
<i>Impact of the other function on the device function-under-review</i>	The Bluetooth functionality of the mobile platform provides connectivity to the worn device enabling remote control of the stimulation.
<i>Increased risk or adverse effect of the other function on the device function-under-review</i>	<ul style="list-style-type: none"><li>• The reliability and security of the Bluetooth connectivity could be compromised causing the TENS device to operate in an uncontrolled manner.</li></ul>
<i>Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated</i>	<ul style="list-style-type: none"><li>• Demonstration of applicable wireless coexistence and electromagnetic compatibility (EMC) safety standards for the intended operating environment for the TENS worn part of the device to ensure the reliability of the connection.</li><li>• Demonstrate that appropriate cybersecurity controls are included in the design and implementation of the device-function-under-review to ensure the reliability and security of the connection.</li></ul>
<i>Assessment of other function(s)</i>	The mobile platform Bluetooth transceiver is not evaluated.

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## Contains Nonbinding Recommendations

### Draft – Not for Implementation

#### **Example: Transmission of vital sign measures to an Electronic Health Record (EHR)**

<i>Product</i>	A monitor that measures and displays vital physiological parameters, and transmits them to an Electronic Health Records (EHR) system through the hospital network using a built-in Wi-Fi card.
<i>Functions</i>	Device function-under-review: <ul style="list-style-type: none"><li>• Vital signs acquisition, condition, and display (SW/HW)</li></ul> Other function: <ul style="list-style-type: none"><li>• Transmission software for sending data to the EHR system (SW)</li><li>• Wi-Fi card (HW)</li></ul>
<i>Impact of the other function on the device function-under-review</i>	As an integral part of the device that allows for a network connection, the Wi-Fi card has inherent risks associated with EMC and other wireless related risks (e.g., the vital physiological parameters may be corrupted in transit to the EHR system), including cybersecurity risks.
<i>Increased risk or adverse effect of the other function on the device function-under-review</i>	<ul style="list-style-type: none"><li>• The Wi-Fi card may affect both the performance and safety of the device or other devices in the area.</li><li>• The network connection may affect the safety of the device by introducing cybersecurity risks.</li><li>• The malfunction of the interface software may impact the safety of the device as the vital physiological parameters may be corrupted in transit to the EHR system.</li></ul>
<i>Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated</i>	<ul style="list-style-type: none"><li>• Demonstrate that appropriate cybersecurity controls were included in the design and implementation of the product.</li><li>• Demonstrate that appropriate EMC and wireless testing was conducted and document that the Wi-Fi card does not affect the performance of the monitor.</li></ul>
<i>Assessment of other function(s)</i>	The Wi-Fi card and transmission to the EHR are not evaluated.