Multiple Function Device Products: Policy and Considerations

Draft Guidance for Industry and Food and Drug Administration

DRAFT GUIDANCE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 or at 301-796-6325 or the CDRH Digital Health Program at 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.
Preface

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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 This draft guidance explains FDA’s regulatory approach and policy for all multiple function device products.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 The purpose of this draft guidance is to identify the principles, premarket review practices, and policies for FDA’s regulatory assessment of such products and to provide examples of the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.¹

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities.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.

II. Background

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

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory which is:
  - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
  - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

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

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

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

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2 Section 510 of the FD&C Act.
3 Section 520(f) of the FD&C Act.
4 Section 519 of the FD&C Act.
5 Available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.
6 Available at https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.
describes the regulation and assessment of a software product with multiple functions, including at least one device function and at least one software function that is not a device.

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

In the case of a product with multiple functions that contains—
(A) at least one software function that meets the criteria under paragraph (1) or that otherwise does not meet the definition of device under section 201(h); and
(B) at least one function that does not meet the criteria under paragraph (1) and that otherwise meets the definition of a device under section 201(h),

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

III. Scope

As mentioned above, in 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. For example, a product with an intended use to analyze data has one function: analysis. A product with an intended use to store, transfer, and analyze data has three functions: (1) storage, (2) transfer, and (3) analysis. As this example illustrates, a product may contain multiple functions. For products containing multiple functions, some functions may meet the definition of a device under section 201(h) of the FD&C Act, and some “other functions” may:

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

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

Although section 520(o)(2) of the FD&C Act applies to the regulation of products containing at least one device function and at least one non-device software function, FDA believes the same principles apply to the assessment of all multiple function products that contain at least one device function. This document does not provide guidance on which functions do and do not meet the definition of a device. It also does not provide guidance on which functions meet the
device definition but are those for which FDA has expressed its intention not to enforce compliance with applicable requirements of the FD&C Act.

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

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

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

IV. Policy: Premarket Review of Multiple Function Device Products

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

7 21 CFR 3.2(e).
8 520(o)(2) of the FD&C Act.
9 520(o)(2) of the FD&C Act.
of a multiple function device product. Instead, FDA intends to review the device function(s) for which clearance or approval is being sought. For example, if a manufacturer seeks clearance or approval for a device function (e.g., analysis) only, and not the device function for which FDA has expressed its intention not to enforce compliance (e.g., track and trend), then FDA intends to only review the analysis function and assess the track and trend function only insofar as it impacts the analysis function. In that instance, because FDA is only reviewing the analysis function, FDA’s decision to clear or approve applies only to the analysis function. See Appendix 1: Summary of Premarket and Postmarket Policy for Multiple Function Device Products.

V. Considerations for Multiple Function Device Products

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

A. Separation in Design and Implementation of the Device Function

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

B. Impact of Other Function(s)

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

- the role of the other function(s) in the device function-under-review’s performance;
- any limitations of using the other function(s) with the device function-under-review;
- developing appropriate hardware and software resource specification(s) for the product with multiple functions to ensure performance of the other function(s) when used with the device function-under-review; and
- how to ensure appropriate actions are taken by the end user when using the other function(s) with the device function-under-review.
VI. Assessing the Impact of Other Functions on the Device Function-Under-Review

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

(A) Does the other function impact the safety or effectiveness of the device function-under-review?; and
(B) Does the impact result in increased risk or have an adverse effect on performance?

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

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

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

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

- Does the other function provide input data that is used for a critical calculation within the device function-under-review?
- Does the device function-under-review rely on results from the other function?
- Do the other function and the device function-under-review share code that is necessary for proper execution of the device function-under-review?
- Do the other function and the device function-under-review share the same output screen?
B. Does the Impact Result in Increased Risk or Have an Adverse Effect on Performance?

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

1. Impacts to Safety

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

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

2. Impacts to Effectiveness

The impacts to effectiveness are typically impacts to the performance of the device. If there may be adverse impacts to the device function-under-review as a result of the other functions, then appropriate verification and validation should be performed with the product to characterize the performance of the device function-under-review and evaluate if there may be an adverse effect on the performance. The following examples can be used as a guide to understand adverse impacts on performance.
The performance or clinical functionality of the device function-under-review depends on the other function for the device function-under-review to perform as specified.

The performance of the device function-under-review is decreased below the specified performance level due to the other function.

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

VII. Content of a Premarket Submission for Device Function-Under-Review

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

A. Indications for Use

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

B. Description of Functions

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

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

D. Risk Analysis

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

E. Requirements and Specifications

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

F. Submission Summary

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

This product has functions subject to FDA premarket review and functions that are not subject to FDA premarket review. For this application, FDA assessed functions not subject to premarket review only insofar as they might adversely impact the safety and effectiveness of the functions subject to FDA premarket review.
VIII. Application of Other Device Requirements to Device Functions

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

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10 Sections 501, 502, 510, 516, 518, 519, 520(e), and 520(f) of the FD&C Act.
Appendix 1: Summary of Premarket and Postmarket Policy for Multiple Function Device Products

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

<table>
<thead>
<tr>
<th>Function:</th>
<th>Premarket Oversight</th>
<th>Postmarket Oversight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device function under review (510(k), PMA, IDE, De Novo, or HDE)</td>
<td>Reviewed</td>
<td>General control requirements are applicable (except for IDE)</td>
</tr>
<tr>
<td>Device function that is 510(k) exempt</td>
<td>Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>General control requirements are applicable</td>
</tr>
<tr>
<td>Device function for which no premarket review is sought and FDA does not intend to enforce applicable regulatory controls</td>
<td>Not reviewed but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>General control requirements are applicable but not intended to be enforced</td>
</tr>
<tr>
<td>Non-device function</td>
<td>Not regulated but assessed only for impact on the safety and effectiveness of the device function-under review</td>
<td>Not regulated and therefore FDA requirements not applicable</td>
</tr>
</tbody>
</table>
Appendix 2: Examples of Multiple Function Device Products

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

**Example: Skin cancer detection software application**

**Product**
A smart phone software (SW) application (app) that detects skin cancer from photos of suspicious lesions of moles.

**Functions**
Device function-under-review:
- SW app (SW)

Other function:
- Smart phone computing platform (HW/SW)
- Camera on the computing platform (HW/SW)

**Impact of the other function on the device function-under-review**
The SW app depends on the smart phone camera for the photos and depends on the computing platform for the analysis.

**Increased risk or adverse effect of the other function on the device function-under-review**
- The output of the camera may not be adequate for detecting skin cancer resulting in misdiagnosis.
- The smartphone’s computing platform performance may not be adequate to support the software functions including the algorithm intended to detect skin cancer.

**Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated**
- 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.
- Document description of specific feature(s) with adequate testing outcomes that mitigate risk from software being used on a smartphone or inadequate camera.
- Documentation of specification for the use of the app with the camera and the computing platform

**Assessment of other function(s)**
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.

**Example: Hand held coagulation device**

**Product**
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**

<table>
<thead>
<tr>
<th>Functions</th>
<th>Device function-under-review:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Hand held coagulation instrument (HW)</td>
</tr>
<tr>
<td></td>
<td>• Coagulation (prothrombin time) test (SW/HW)</td>
</tr>
<tr>
<td>Other function:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Docking station (HW)</td>
</tr>
<tr>
<td></td>
<td>• Interface to transmit the data to the HIS (SW)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Impact of the other function on the device function-under-review</th>
<th>The handheld instrument depends on the docking station for charging and data transfer.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased risk or adverse effect of the other function on the device function-under-review</td>
<td></td>
</tr>
<tr>
<td>• Charging of the handheld instrument is necessary for device performance.</td>
<td></td>
</tr>
<tr>
<td>• The recharging of the battery introduces new hazardous situations for the instrument itself.</td>
<td></td>
</tr>
<tr>
<td>• Instrument may be affected by erroneous or nontrusted data transfer from the HIS system.</td>
<td></td>
</tr>
</tbody>
</table>

| Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated |  |
|  |
| • Demonstrate that appropriate mitigations were implemented to address hazards associated with battery charging. |
| • Document features authenticating data from trusted HIS system. |

| Assessment of other function(s) | The docking station and interface SW are not evaluated. |

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**Example: Traumatic Brain Injury Determination**

**Product**
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).

**Functions**
Device function-under-review:

- Collection and Recording of EEG signals (HW/SW)
- Analyzing EEG signals and diagnosing TBI (SW)
- Presentation of results (SW)

Other function:

- Computer Operating System functions (SW)
- Electronic administration of questionnaire (HW/SW)

**Impact of the other function on the device function-under-review**

The device algorithm depends on the results of the questionnaire.
**Example: Pain treatment app**

**Product**
A Transcutaneous Electrical Nerve Stimulation (TENS) device controlled by an app on a mobile platform worn by the user to treat pain.

**Functions**
- Device function-under-review:
  - Electrical Nerve Stimulation as a treatment for pain (HW/SW)
  - App used to control the level of stimulation (SW)
- Other function:
  - Mobile platform Bluetooth transceiver and connectivity

**Impact of the other function on the device function-under-review**
The Bluetooth functionality of the mobile platform provides connectivity to the worn device enabling remote control of the stimulation.

**Increased risk or adverse effect of the other function on the device function-under-review**
The reliability and security of the Bluetooth connectivity could be compromised causing the TENS device to operate in an uncontrolled manner.

**Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated**
- 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.
- 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.

**Assessment of other function(s)**
The mobile platform Bluetooth transceiver is not evaluated.
**Example: Transmission of vital sign measures to an Electronic Health Record (EHR)**

| **Product** | 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. |
| **Functions** | **Device function-under-review:**
  - Vital signs acquisition, condition, and display (SW/HW)

  **Other function:**
  - Transmission software for sending data to the EHR system (SW)
  - Wi-Fi card (HW) |

| **Impact of the other function on the device function-under-review** | 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. |

| **Increased risk or adverse effect of the other function on the device function-under-review** | • The Wi-Fi card may affect both the performance and safety of the device or other devices in the area.
• The network connection may affect the safety of the device by introducing cybersecurity risks.
• The misfunction 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. |

| **Documentation demonstrating that the increased risk or adverse effect resulting from the combination of functions is mitigated** | • Demonstrate that appropriate cybersecurity controls were included in the design and implementation of the product.
• Demonstrate that appropriate EMC and wireless testing was conducted and document that the Wi-Fi card does not affect the performance of the monitor. |

| **Assessment of other function(s)** | The Wi-Fi card and transmission to the EHR are not evaluated. |