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CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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Multiple Function Device Products: Policy and Considerations Final Guidance

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Center for Devices and Radiological Health (CDRH)

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Agenda

This presentation will cover:

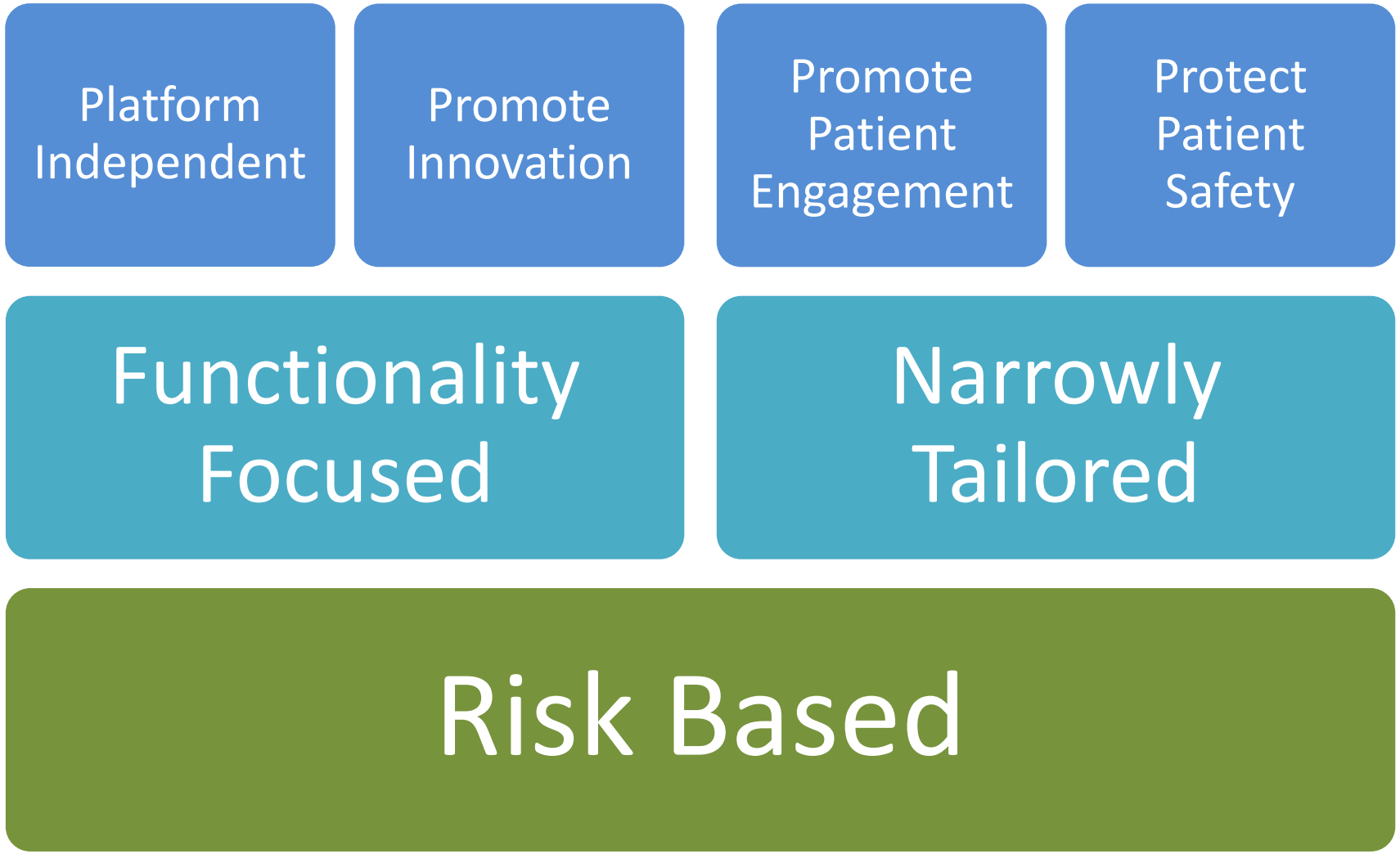
- Background
- Definitions
- Summary of Final Guidance
- Additional resources

Webinar Objectives

After this webinar, you should be familiar with:

- How the FDA defines *function* and other key terms for purposes of this guidance
- The FDA's regulatory approach and policy for all multiple function device products
- Considerations for the design and risks of multiple function device products
- How the FDA intends to assess the impact of non-device software functions/"other functions" on the safety and effectiveness of a device function
- Premarket submission content for a device function-under-review

Functionality Focused Approach to Software



21st Century Cures Act:
Building on FDA's Digital Health Policy

Recognition of low risk Digital Health products

Codification of existing enforcement discretion policies

Applying a least burdensome approach for device regulation

Overview of Cures Act Software Provisions (Section 3060)

- Defines software **functions** that are **not devices**
- States that the FDA shall **not regulate non-device functions of a product with multiple functions –** but can consider the impact of non-device functions on the device functions
- Provides for the FDA regulation of **software functions that are excluded from the device definition by the Cures Act**, if the FDA finds that it would be reasonably likely to have serious adverse health consequences (substantive and procedural criteria must be met)
- Exclusions from device definition **do not** include software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans

21st Century Cures Act (Section 3060) and FDA Policies

*Amended the definition of "device" in the Federal Food, Drug, and Cosmetic Act to **exclude** certain software functions intended for...*

FDA policies affected/codified

(A) Administrative support

FDASIA Categories of Health IT
Administrative Functionality

(B) General Wellness

FDA Policy for Low-Risk General Wellness Products

(C) Electronic Patient Records

FDASIA Categories of Health IT
Health Management Functionality

(D) Transfer, Store, Convert formats, Display related information

Medical Device Data System (MDDS)

(E) Clinical Decision Support

Policy for Clinical Decision Support Software included in
Health Management Functionality

(*) Multiple Function Device Products

Multiple Function Device Products: Policy and Considerations

*Addition of 520(o)(2) describes the regulation and assessment of a software product with multiple functions

21st Century Cures Act: Added Section 520(o)(2) to the FD&C Act

- **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.

Sections Covered in Multiple Function Guidance

Policy: Premarket Review of Multiple Function Device Products

Considerations for Multiple Function Device Products

Assessing the Impact of "Other Functions" on the Device Function-Under-Review

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

Definitions*

Function	A distinct purpose of a product
Device Function	A function that meets the definition of a device under section 201(h) of the FD&C Act
Other Function	A function that: – does not meet the definition of a device; – meets the definition of device, but is not subject to premarket review (for example, 510(k)-exempt); or – meets the definition of device, but for which the FDA has expressed its intention not to enforce compliance with applicable regulatory controls.
Device Function-Under-Review	A function for which the FDA is conducting a premarket review
Multiple Function Device Product	A product that contains at least one device function and at least one other function.

***Function** could be the intended use or a subset of the intended use of the product.*

Examples

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.

*These terms are used for the purposes of this guidance.

Guidance Scope

- 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
- This guidance expands that policy to apply to the assessment of **all** multiple function device products, whether those functions are software-based, hardware-based, or both.
- This guidance applies in the premarket review context: a multiple function device product is a product with at least one device function-under-review and one “other function.”
- This guidance applies in the postmarket context: a multiple function device product is a product with at least one device function that is the focus of the FDA’s oversight and one “other function.”

Policy: Premarket Review of Multiple Function Device Products

- "Other functions" are not the subject of the FDA's review simply because they are part of a multiple function device product.
- However, the FDA may assess the impact of "other functions" when assessing the safety and effectiveness of the device functions-under-review of a multiple function device product.[1]

Other Function

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

Software Example:
A general-purpose computing platform is not regulated by the FDA.

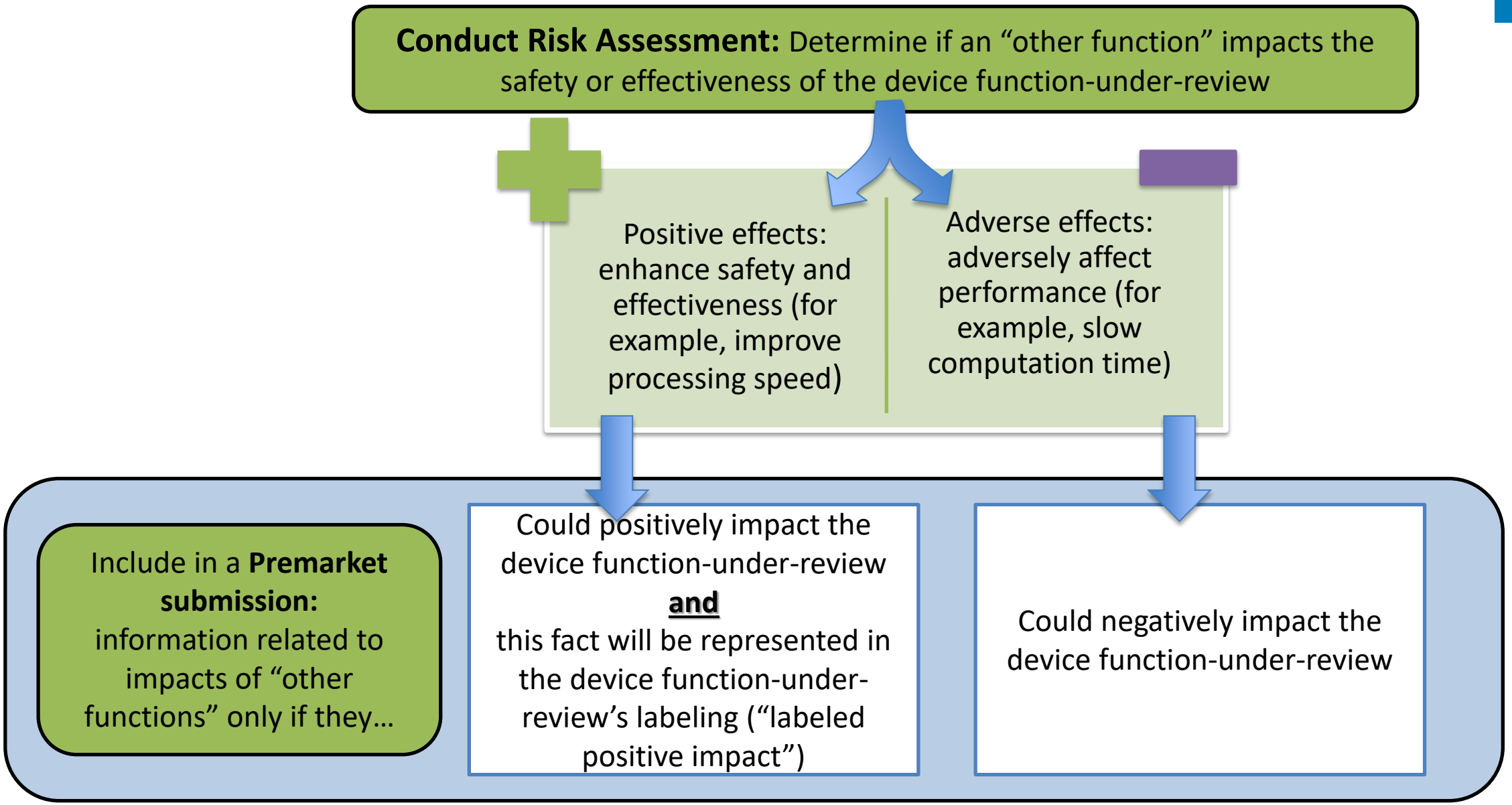
The FDA may assess its impact on the safety and effectiveness of a device function-under-review, such as a mobile medical application.

Hardware Example:
Product includes an intragastric balloon subject to premarket approval and an endoscope accessory that is 510(k)-exempt (for example, an endoscope guidewire).

The FDA may assess the impact of the endoscope accessory on the safety and effectiveness of the intragastric balloon.

[1] Section 520(o)(2) of the FD&C Act

Policy: Premarket Review of Multiple Function Device Products



Sections Covered in Multiple Function Guidance

Policy: Premarket Review of Multiple Function Device Products

Considerations for Multiple Function Device Products

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

Considerations for Multiple Function Device Products

Separation in Design and Implementation of the Device Function

Separation and Architecture

- The device function-under-review should be separated from "other functions" in its design and implementation (for example, logical separation, architectural separation, code, and data partitioning).
- Architecture decisions early in the design cycle can facilitate optimal separation and support segregation necessary for risk control.

Risk Analysis

- Documenting the results of a thorough risk analysis of the impacts of "other functions" and mitigation strategies employed is a critical component of a risk management process.
- When considering cybersecurity risks, some level of separation of the device function-under-review from the "other function(s)" in design and implementation may be necessary to mitigate cybersecurity risks to the device function-under-review.

Considerations for Multiple Function Device Products

Impact of "Other Functions":

Manufacturer of a multiple function device product should consider the following regarding all "other functions" of the product:

- **Role** of the "other function" **in the device function-under-review's performance**;
- **Limitations** of the device function-under-review **when using** the "other function;"
- Developing **appropriate hardware and software resource specification(s)** for the product with multiple functions to **ensure minimal impact** of the "other function" on the performance of the device function-under-review;
- How to ensure appropriate **actions** are taken by the **end user** when using the device function-under-review with the "other function;" and
- **Identification, evaluation, and mitigation of any additional risks, including cybersecurity risks**, in the device-function-under-review when **used in combination** with the "other function."

Sections Covered in Multiple Function Guidance

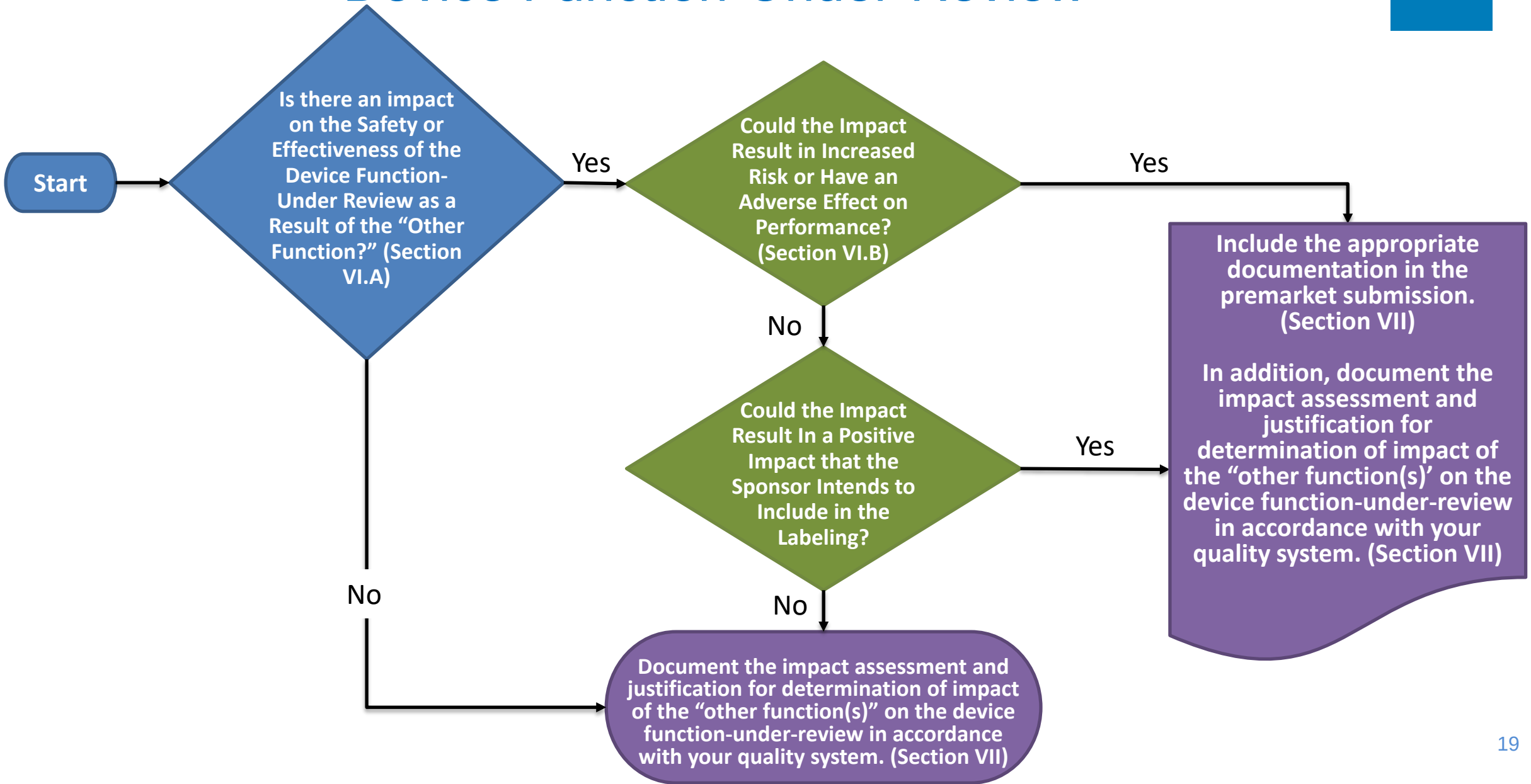
Policy: Premarket Review of Multiple Function Device Products

Considerations for Multiple Function Device Products

Assessing the Impact of "Other Functions" on the Device Function-Under-Review

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

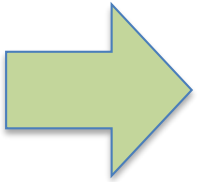
Assessing the Impact of "Other Functions" on the Device Function-Under-Review



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



B) Could the Impact Result in Increased Risk or Have an Adverse Effect on Performance, that is, a Negative Impact?

- Impacts to Safety

Examples of Questions to Consider while answering…

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

- 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?
- Does the "other function" **write to memory** or other storage that stores code or data of the device function-under-review? (For example, does the "other function" directly modify the configuration of the device function-under-review, bypassing the designed input and output methods?)
- Do the "other function" and the device function-under-review **share the same output screen or graphical user interface**?
- Does the "other function" **affect the processing time** necessary for the performance of the device function-under-review when the functions share a processor?
- Does the "other function" **affect the memory requirements** for the performance of the device function-under-review when the functions share memory on the computer platform?
- Do the "other function" and the device function-under-review **share programming pointers**?
- Does the device function-under-review **need privileges** to prevent delays or interruptions that may result from the "other function?"

This is not a comprehensive list of considerations. Manufacturers should conduct their own risk assessments.

Examples of Questions to Consider while answering…

B) Could the Impact Result in Increased Risk or Have an Adverse Effect on Performance, that is, a Negative Impact?

Following examples help illustrate **impacts to safety**:

- The “other function” **introduces a new hazardous situation** or a new cause of an existing hazardous situation that is not otherwise present in the device function-under-review.
  - A “hazardous situation” exists when there is exposure to a hazard (that is, 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.

This is not a comprehensive list of considerations. Manufacturers should conduct their own risk assessments.

Examples of Questions to Consider while answering…

B) Could the Impact Result in Increased Risk or Have an Adverse Effect on Performance, that is, a Negative Impact?

Following examples help illustrate **adverse impacts to effectiveness:**

- 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 **fails to meet the specified performance level** due to the "other function."

This is not a comprehensive list of considerations. Manufacturers should conduct their own risk assessments.

Sections Covered in Multiple Function Guidance

Policy: Premarket Review of Multiple Function Device Products

Considerations for Multiple Function Device Products

Assessing the Impact of "Other Functions" on the Device Function-Under-Review

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

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

21 CFR 820.30(g):

Manufacturer must establish and maintain procedures for validating its device design. Design validation includes software validation and risk analysis, where appropriate.

Multiple Function Device Products: Manufacturers should include an impact assessment and rationale for manufacturer's determination of the impact of the "other function(s)," whether no impact, negative, or positive, on the device function-under-review in accordance with manufacturer's quality system.

Impact assessment should include:
1) Whether or not there is an impact on the safety or effectiveness of the device function-under-review as a result of the "other function," and if there is,
2) Whether the impact could result in increased risk or either an adverse or positive effect on performance.

Considerations for "Other Function(s)" in Premarket Submission Content for Device Function-Under-Review

If the "*other function*" could adversely impact the device function-under-review, or if the device function-under-review could be positively impacted by the *"other function"* 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 device function-under-review **should include** the documentation described to the right.

If the *"other function"* does not impact the device function-under-review then the premarket submission for the device function-under-review **does not need to include** the documentation described to the right. However, the labeling should include a description of the "other function(s)" adequate to ensure appropriate use of the device

Indications for Use	Not needed unless sponsor would like the positive impact of the *"other function(s)"* to be considered by the FDA.
Device Description – Description of Functions	Include description of *"other function(s)"* that could adversely impact the device-function-under-review and how it is impacted. Include the same information for positive impacts if included in label.
Labeling	Include description of the *"other function(s)"* adequate to ensure appropriate use of the device
Architecture and Design	Include architecture and design documents that provide adequate detail to understand how or if the *"other function(s)"* interact with or impact the device function-under-review when the latter includes software.
Device Hazard Analysis	Include results of a risk-based assessment of any potential adverse impact or labeled positive impact of the *"other function(s)" .*
Requirements and Specifications	Include adequate detail to describe any expected relationship, utility, reliance, or interoperability with any *"other function."*
Performance Testing	Include performance testing results that demonstrate that the impact of the "other function(s)" to safety or effectiveness is appropriately addressed.

Modifications to "Other Function" of Multiple Function Device Product

Modifications to the *"other function(s)"* of a multiple function device product should be assessed to determine if the change could significantly impact the safety or effectiveness of the device function that was the subject of the FDA's review.

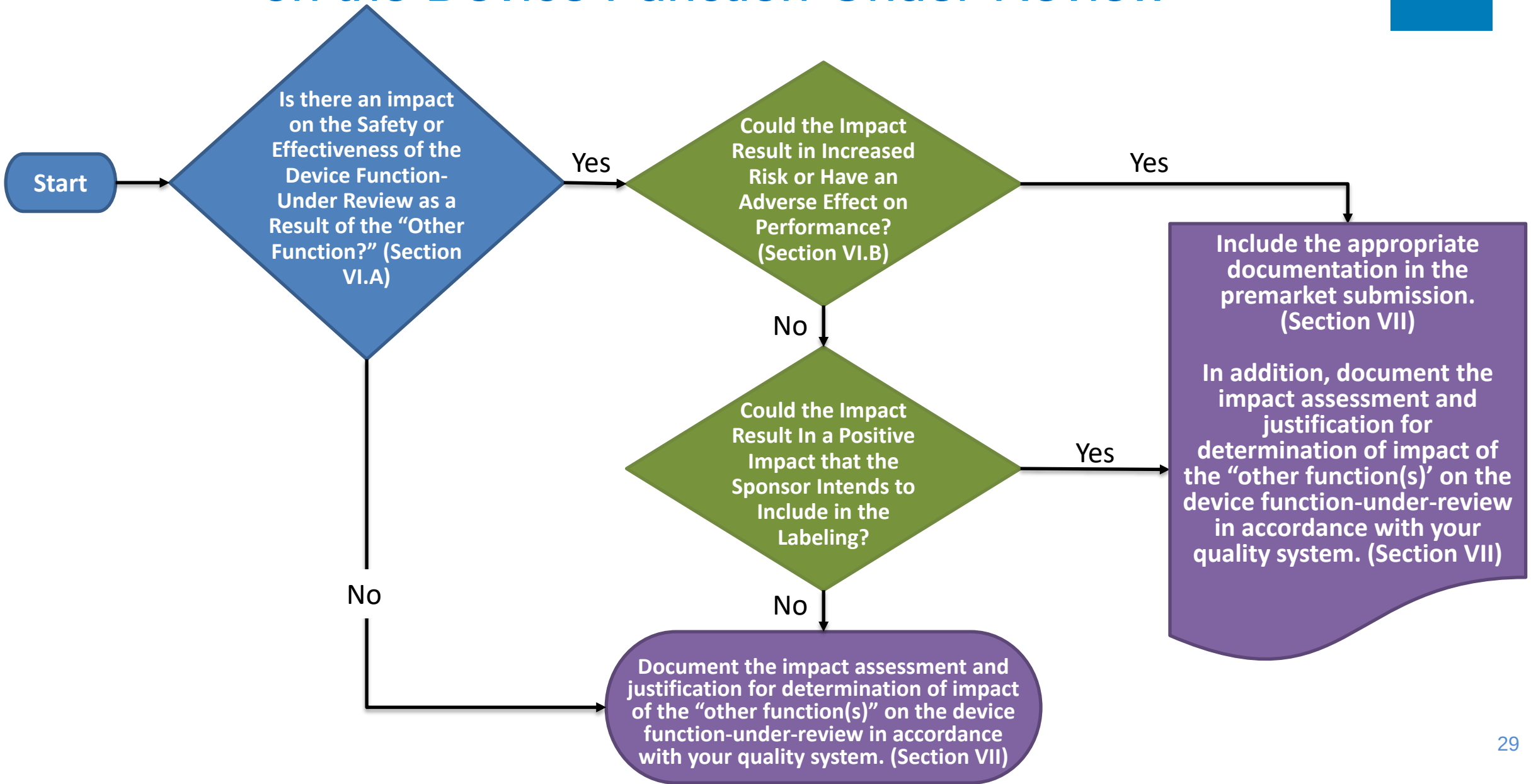
At this time, the FDA does not intend to enforce the applicable premarket submission requirements for modifications of "other function(s)" that could positively impact the device function unless the positive impact is included in the labeling.

Reference "Deciding When to Submit a 510(k) for a Change to an Existing Device" Guidance, "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" Guidance, or "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" Guidance, to help determine if a new premarket submission is necessary for the modification to the "other function" as required by ***21 CFR 807.81(a)(3).***

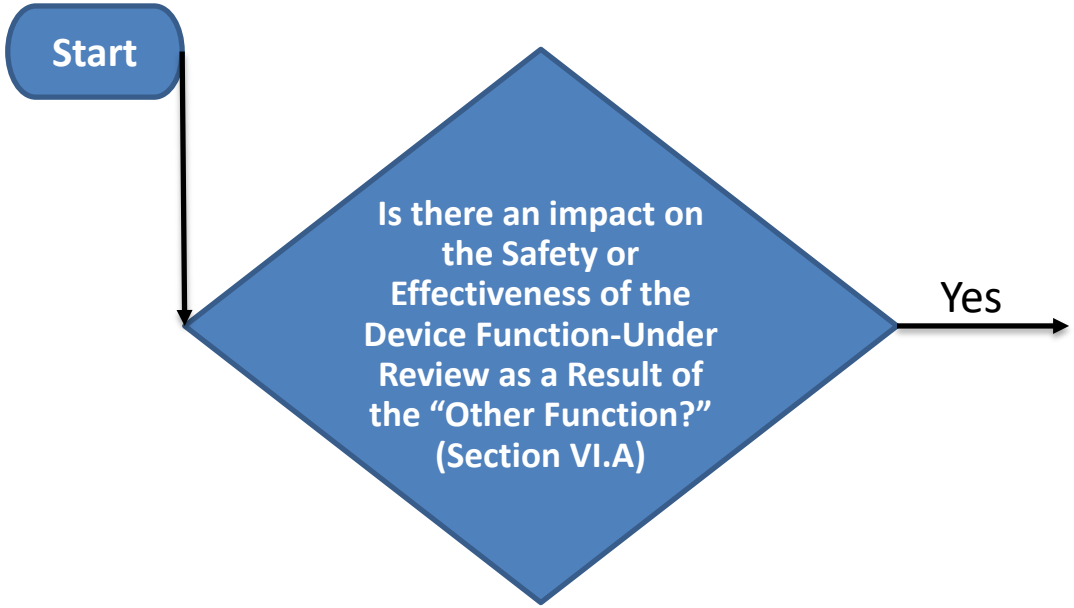
IX. Application of Other Device and Postmarket Requirements

General Control Requirements	Examples	Combination Products
…apply to device functions subject to 510(k), PMA, De Novo, or HDE requirements and to device functions that are 510(k)-exempt.	1) Device functions in multiple function device products must comply with design control requirements under the Quality System regulation (21 CFR Part 820). 2) In accordance with 21 CFR 803.50, the FDA expects the manufacturer of a device function to investigate the cause of an adverse event and 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.	For more information on current good manufacturing and postmarketing safety reporting requirements and policies applicable to combination products, see 21 CFR Part 4, the FDA "Current Good Manufacturing Practice Requirements for Combination Products" and the Office of Combination Product's (OCP's) "Postmarketing Safety Reporting for Combination Products" webpage.

Examples: Assessing the Impact of "Other Functions" on the Device Function-Under-Review



Example: A smart phone software application (app) that detects skin cancer from photos of suspicious lesions of moles



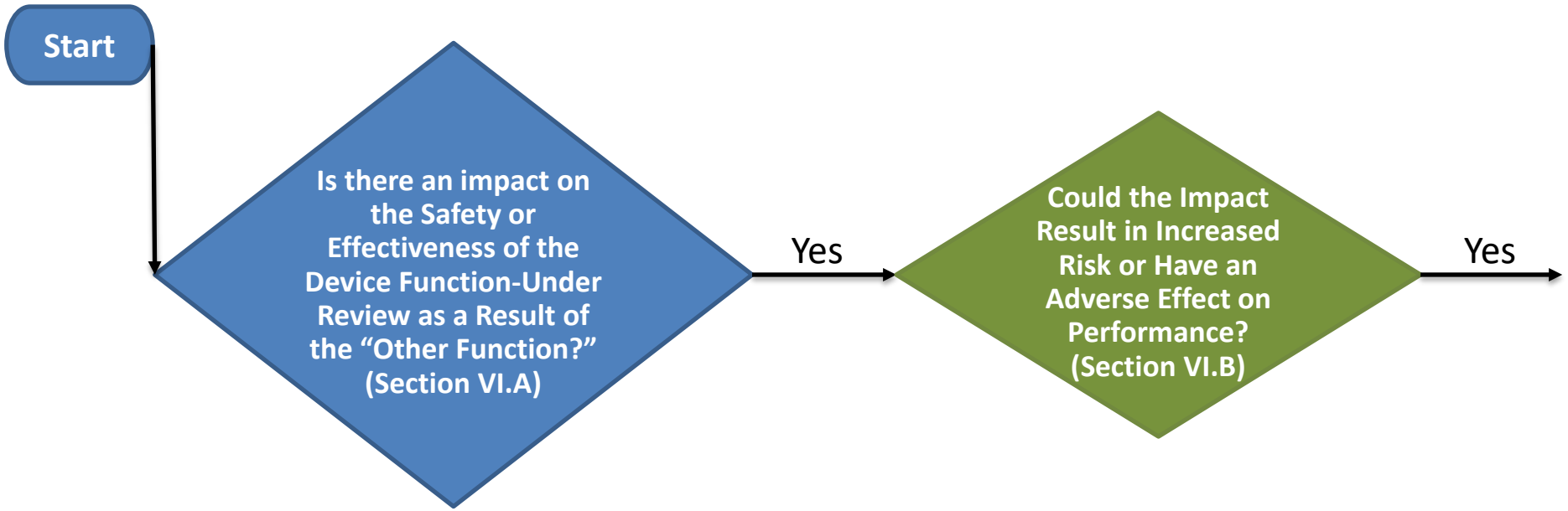
Device function-under-review:

- Software app that detects skin cancer

"Other function:"

- Smart phone computing platform
- Camera on the computing platform

Example: A smart phone software application (app) that detects skin cancer from photos of suspicious lesions of moles



Device function-under-review:

- Software app that detects skin cancer

"Other function:"

- Smart phone computing platform
- Camera on the computing platform

The software app depends on the smart phone camera for the photos and depends on the computing platform for the analysis.

Example: A smart phone software application (app) that detects skin cancer from photos of suspicious lesions of moles

Device function-under-review:

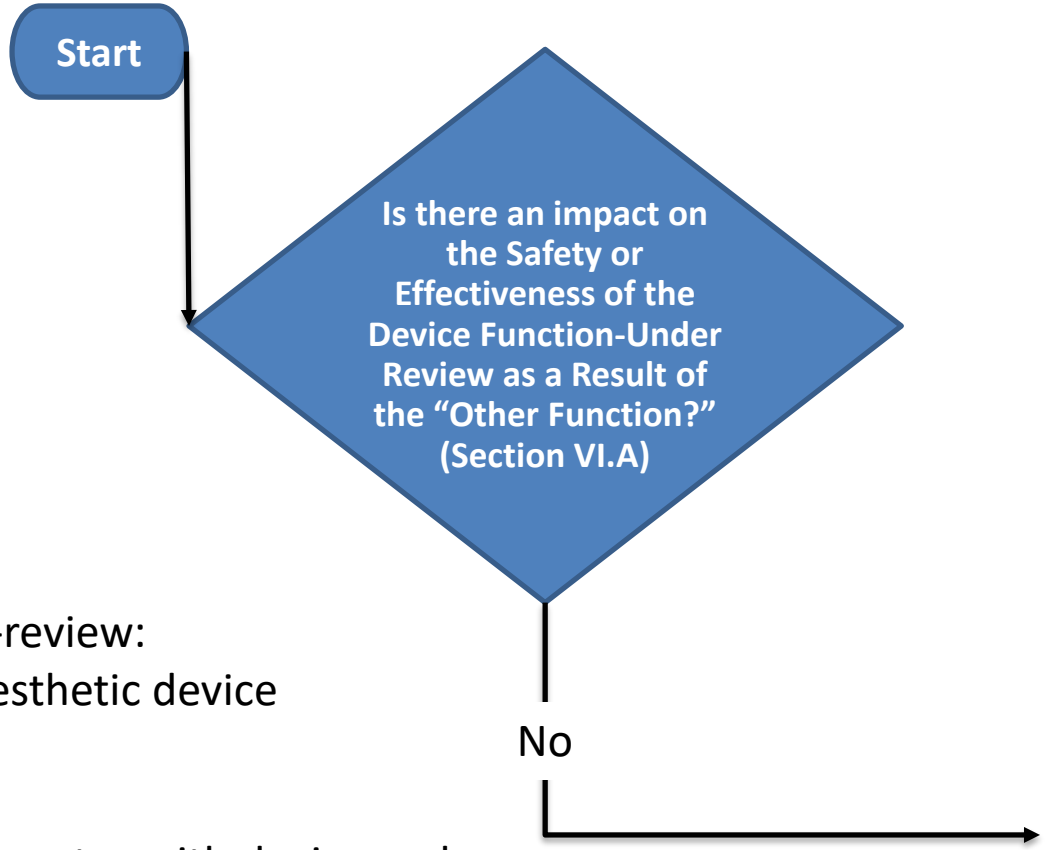
- Software app that detects skin cancer

"Other function:"

- Smart phone computing platform
- Camera on the computing platform

The software app depends on the smart phone camera for the photos and depends on the computing platform for the analysis.

Example: Energy-delivering aesthetic device with an optional mobile application (app) that transfers treatment parameter data for cloud-based storage for later review by a physician



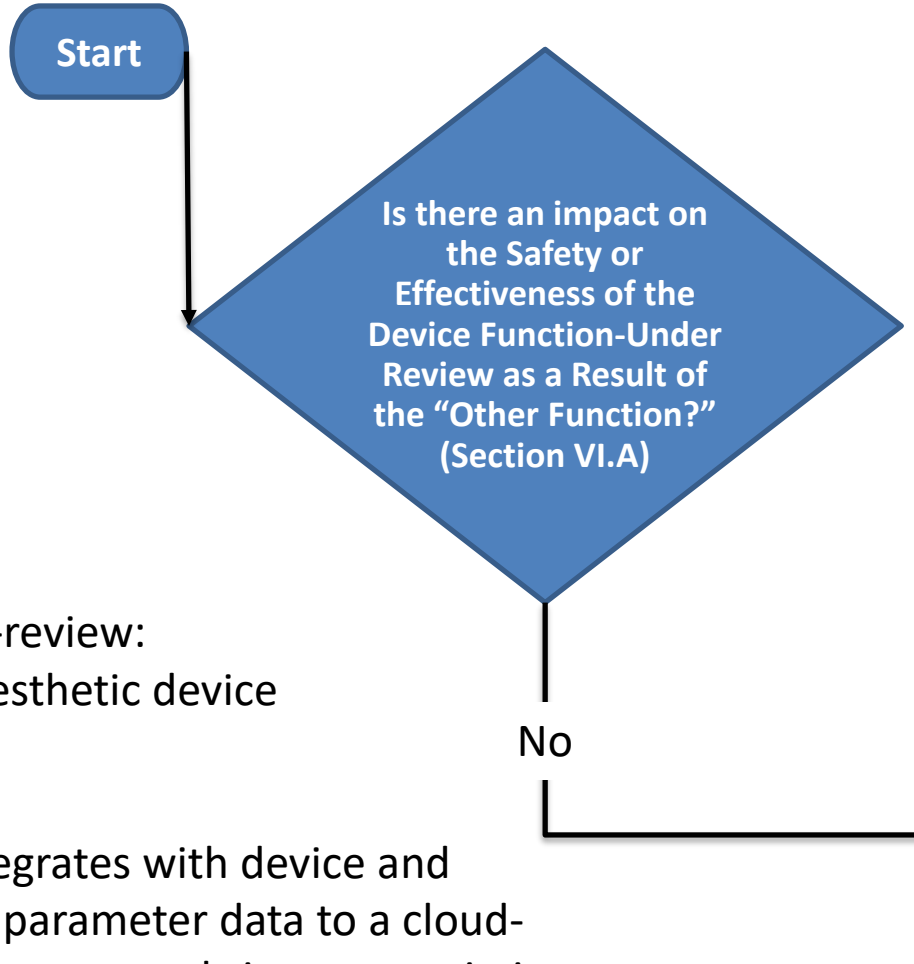
Device function-under-review:

- Energy-delivering aesthetic device

"Other function:"

- Mobile app that integrates with device and transfers treatment parameter data to a cloud-based storage system – no real-time transmission
- Smart phone computing platform

Example: Energy-delivering aesthetic device with an optional mobile application (app) that transfers treatment parameter data for cloud-based storage for later review by a physician



The energy-delivering device function is not impacted by the mobile app or smart phone computing platform because the transmission of data cannot occur during energy delivery

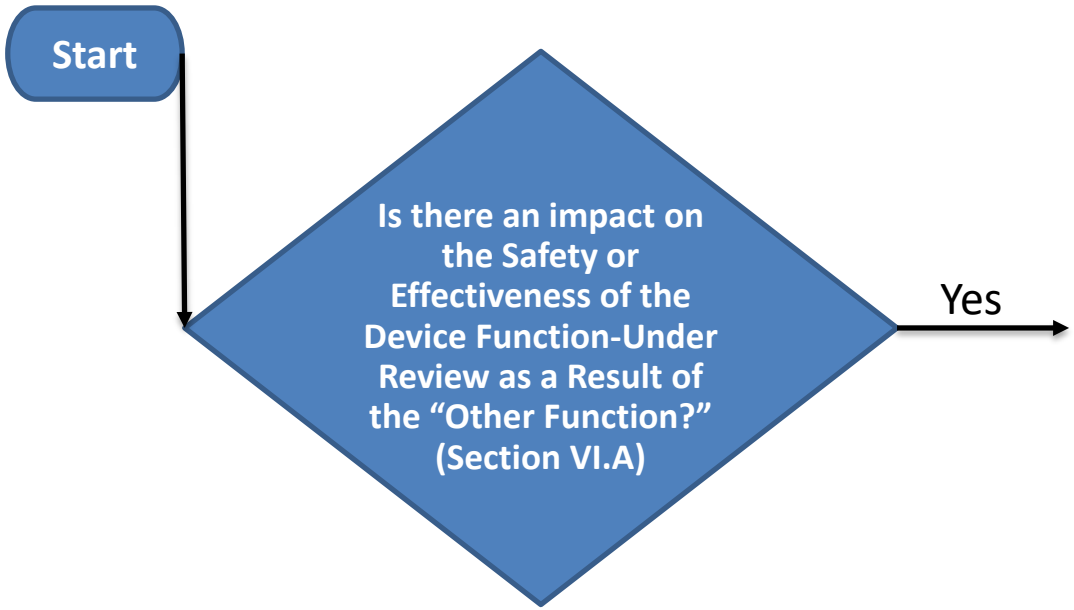
Device function-under-review:

- Energy-delivering aesthetic device

"Other function:"

- Mobile app that integrates with device and transfers treatment parameter data to a cloud-based storage system – no real-time transmission
- Smart phone computing platform

Example: Pulsed ultrasound and biopsy needle guide kit



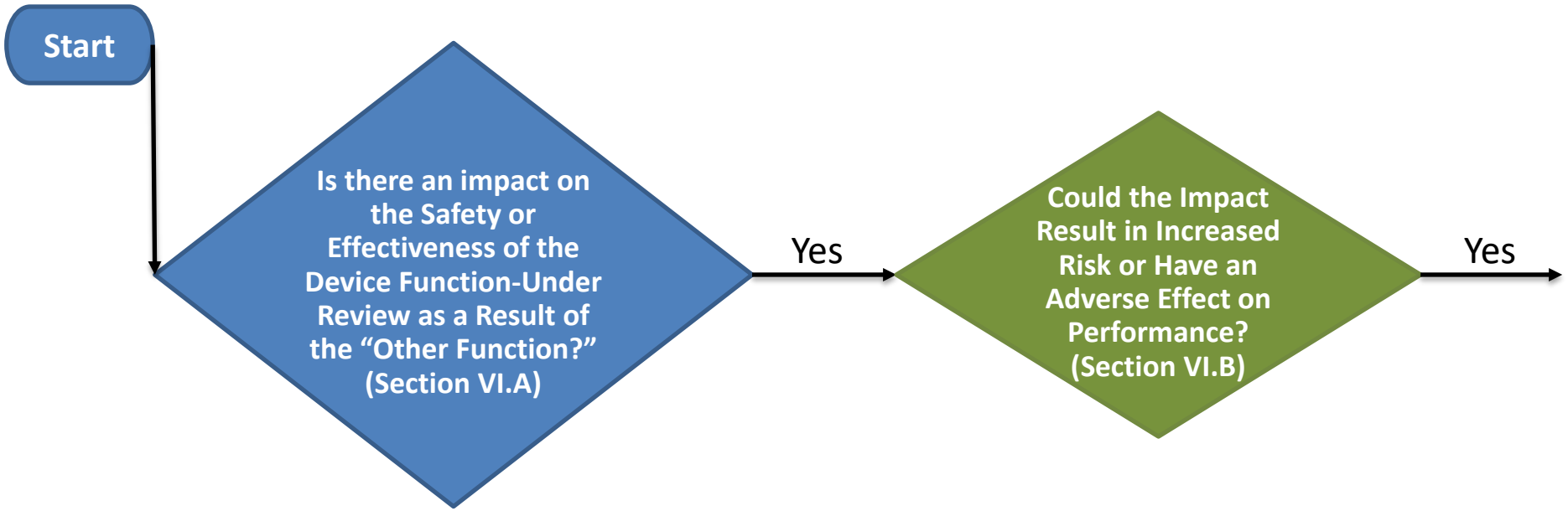
Device function-under-review:

- General purpose diagnostic ultrasound system
- Biopsy needle tracking functionality

"Other function:"

- 510(k)-exempt biopsy needle guide kit

Example: Pulsed ultrasound and biopsy needle guide kit



Device function-under-review:

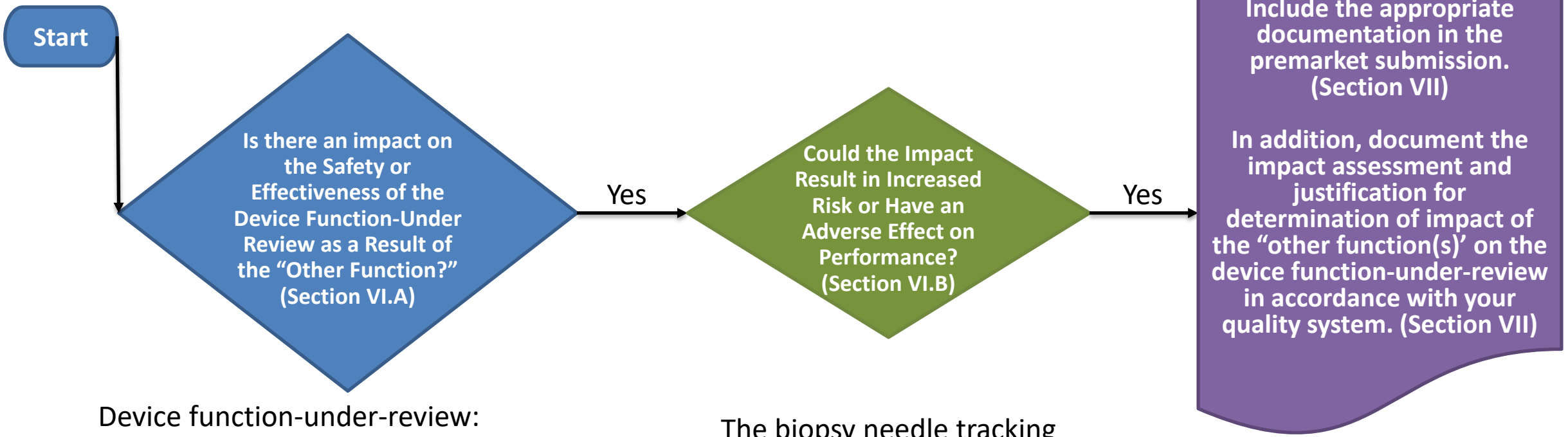
- General purpose diagnostic ultrasound system
- Biopsy needle tracking functionality

"Other function:"

- 510(k)-exempt biopsy needle guide kit

The biopsy needle tracking software may not be compatible with all ultrasound needle biopsy kits. Incompatibility may lead to inaccurate or imprecise guiding of the needle to the target area.

Example: Pulsed ultrasound and biopsy needle guide kit



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"Other function:"

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The biopsy needle tracking software may not be compatible with all ultrasound needle biopsy kits. Incompatibility may lead to inaccurate or imprecise guiding of the needle to the target area.

Summary

- The FDA recognizes that regulations play a crucial role in the development of technologies that could significantly impact everyday life. The FDA believes that our approach to regulating these products should foster innovation while protecting public health.
- This guidance is aimed at clarifying the FDA’s policy for all multiple function products that contain at least one device function.
- The final guidance incorporates feedback from the public comments to clarify and provide examples to describe the FDA’s policy on products with multiple functions.
- The guidance intends to provide clarity for manufacturers, the FDA’s staff, and other stakeholders on the medical software provisions of the 21st Century Cures Act, which is part of the FDA's long-term Digital Health Innovation Action Plan.

Resources

Web link to “Multiple Function Device Products: Policy and Considerations”:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations

If you are unsure whether your product that contains software functions would be considered a multiple function device, please contact DigitalHealth@FDA.HHS.gov

Questions?

Division of Industry and Consumer Education:
DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn Under the Heading: How to Study and Market Your Device; Sub heading: Cross-Cutting Premarket Policy

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