U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
CDRH's New Draft Guidances to Continue to Modernize the 510(k) Program

October 26, 2023

CDRH's New Draft Guidances to Continue to Modernize the 510(k) Program

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Center for Devices and Radiological Health
U.S. Food and Drug Administration

Modernization of the 510(k) Program

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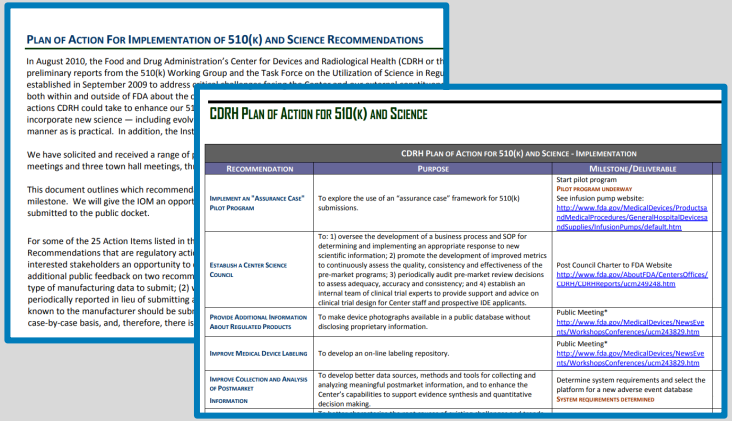
CDRH's New Draft Guidances to Continue to Modernize the 510(k) Program

- **Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-selecting-predicate-device-support-premarket-notification-510k-submission
- **Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-use-clinical-data-premarket-notification-510k-submissions
- **Evidentiary Expectations for 510(k) Implant Devices**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/evidentiary-expectations-510k-implant-devices

These are draft guidances and are not for implementation; submit comments by 12/6/23

CDRH Continues to Modernize the 510(k) Program

2011 **2014** **2018**



PLAN OF ACTION FOR IMPLEMENTATION OF 510(K) AND SCIENCE RECOMMENDATIONS

In August 2010, the Food and Drug Administration's Center for Devices and Radiological Health (CDRH or th
preliminary reports from the 510(k) Working Group and the Task Force on the Utilization of Science in Regu
established in September 2009 to address
both within and outside of FDA about the
actions CDRH could take to enhance our 51
incorporate new science — including evolv
manner as is practical. In addition, the Inst

We have solicited and received a range of
meetings and three town hall meetings, th

This document outlines which recommend
milestone. We will give the IOM an opport
submitted to the public docket.

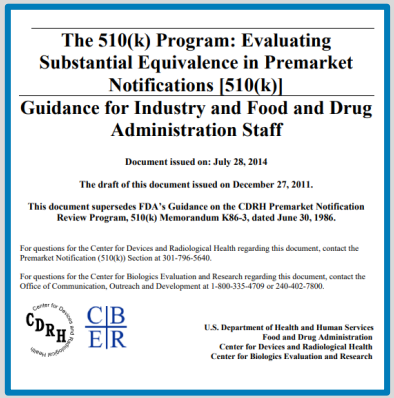
For some of the 25 Action Items listed in th
Recommendations that are regulatory acti
interested stakeholders an opportunity to
additional public feedback on two recomm
type of manufacturing data to submit; (2)
periodically reported in lieu of submitting
known to the manufacturer should be subi
case-by-case basis, and, therefore, there is

CDRH PLAN OF ACTION FOR 510(K) AND SCIENCE

CDRH PLAN OF ACTION FOR 510(K) AND SCIENCE - IMPLEMENTATION

RECOMMENDATION	PURPOSE	MILESTONE/DELIVERABLE
IMPLEMENT AN "ASSURANCE CASE" PILOT PROGRAM	To explore the use of an "assurance case" framework for 510(k) submissions.	Start pilot program PILOT PROGRAM UNDERWAY See infusion pump website: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/default.htm
ESTABLISH A CENTER SCIENCE COUNCIL	To: 1) oversee the development of a business process and SOP for determining and implementing an appropriate response to new scientific information; 2) promote the development of improved metrics to continuously assess the quality, consistency and effectiveness of the pre-market programs; 3) periodically audit pre-market review decisions to assess adequacy, accuracy and consistency; and 4) establish an internal team of clinical trial experts to provide support and advice on clinical trial design for Center staff and prospective IDE applicants.	Post Council Charter to FDA Website http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm249248.htm
PROVIDE ADDITIONAL INFORMATION ABOUT REGULATED PRODUCTS	To make device photographs available in a public database without disclosing proprietary information.	Public Meeting* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm
IMPROVE MEDICAL DEVICE LABELING	To develop an on-line labeling repository.	Public Meeting* http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm243829.htm
IMPROVE COLLECTION AND ANALYSIS OF POSTMARKET INFORMATION	To develop better data sources, methods and tools for collecting and analyzing meaningful postmarket information, and to enhance the Center's capabilities to support evidence synthesis and quantitative decision making.	Determine system requirements and select the platform for a new adverse event database SYSTEM REQUIREMENTS DETERMINED

[CDRH Plan of Action for 510(k) and Science]



The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

This document supersedes FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.

For questions for the Center for Devices and Radiological Health regarding this document, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

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

[510(k) Program Guidance]

[Medical Device Safety Action Plan]

*From 2009-2023, CDRH has issued **more than 100 final cross-cutting and device-specific guidances** to clarify expectations for 510(k) review*

CDRH's Request for Feedback to Strengthen 510(k) Program

FDA STATEMENT

Statement from FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on latest steps to strengthen FDA's 510(k) program for premarket review of medical devices

Share Tweet Email

For Immediate Release:

January 22, 2019

Opened docket for feedback on:

- FDA's proposal to post on its website a list of FDA-cleared devices that demonstrated substantial equivalence to older predicate devices
- Actions that FDA should take to promote development and marketing of safer, more effective 510(k) devices
- If FDA should consider actions that may require new authority, such as making some older devices ineligible as predicates

FDA has continually reviewed feedback gathered to modernize the 510(k) Program to spur innovation and create safer devices for patients

Comments Received on CDRH's Request for Feedback

Feedback received through the docket spurred the development of 3 new draft guidances to improve the predictability, consistency, and transparency of the 510(k) Program:

- Received feedback that focusing on only older predicates may not optimally promote safer and more effective devices (such as implants, which may have a long history of safe use)
- In our new draft guidance "**Best Practices for Selecting a Predicate Device to Support a 510(k) Submission**," we recommend utilizing "best practices" when selecting a predicate device rather than solely focusing on the predicate's age

- Also received feedback that clarity and transparency would be helpful on the topics of clinical data in 510(k) submissions and recommendations for 510(k) implants
- Drafted 2 new guidances focused on these topic areas:
  - **Recommendations for the Use of Clinical Data in 510(k) Submissions**
  - **Evidentiary Expectations for 510(k) Implant Devices**

Learning Objectives

- ✓ Describe how these new draft guidances can help improve the predictability, consistency, and transparency of the 510(k) Program
- ✓ Explain how these new draft guidances are consistent with the 510(k) Program Guidance
- ✓ Explain the current policies in the new draft guidances, including:
  - ✓ FDA's proposal on the 4 best practices for selecting a predicate device to support a 510(k)
  - ✓ Proposed recommendations for when clinical data may be needed to demonstrate substantial equivalence
  - ✓ Proposed general recommendations and evidentiary expectations for all 510(k) implants

Draft Guidance

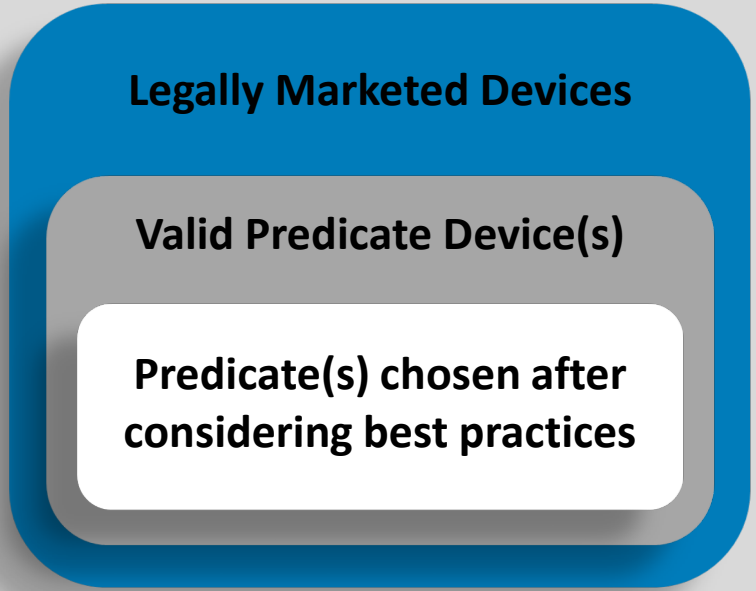
Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

Best Practices for Selecting a Predicate Device to Support a 510(k)

- Provides recommendations on the best practices for choosing a predicate device to support a 510(k) submission
- The use of best practices when selecting a predicate device is intended to:
  - Encourage the evolution of safer and more effective medical devices in the 510(k) Program
  - Encourage submitters to consider the characteristics of the predicate device rather than focusing on the age of the predicate

When to Use the Best Practices

- Guidance is intended to be used while a submitter is preparing their 510(k) submission to assist with the identification of potential predicate devices
- In selecting your predicate device for your 510(k) submission:
  1. Determine the list of legally marketed devices
  2. Consider, of the legally marketed devices, which could be considered a “valid predicate device”
  3. Use the best practices to help determine your predicate device to support your 510(k) submission



Proposed Best Practices when Selecting a Predicate Device

Predicate devices cleared using well-established methods

Predicate devices meet or exceed expected safety and performance

Predicate devices without unmitigated use-related or design-related safety issues

Predicate devices without an associated design-related recall

Predicate Device(s) Cleared Using Well-established Methods

- FDA recommends selecting a valid predicate device that was cleared using well-established methods, which can include those from:


Currently FDA-recognized voluntary consensus standards


FDA guidance documents


Qualified medical device development tools (MDDTs)


Widely available and accepted methods published in the public domain or scientific literature for the context of use, or found acceptable through the submitter's own previous premarket submission

- Selecting a predicate device cleared using well-established methods can help ensure that the subject device is evaluated using updated scientific methods whenever possible

Predicate Device(s) Meet or Exceed Expected Safety and Performance

- New information about a device's safety and/or effectiveness, unanticipated adverse events, subsequent changes to the device, or other types of information may become available as a device is more widely distributed and used
- FDA recommends searching our databases for reports of injury, death, or malfunctions:
  - Manufacturer and User Facility Device Experience (MAUDE) Database
  - Medical Device Reporting (MDR) Database
  - MedSun Reports Database

Predicate Device(s) Without Unmitigated Use-related or Design-related Safety Issues

- New information about a device can become available once the device is more widely distributed and used, which could represent an emerging signal
- An emerging signal may represent new information about a device, such as a new association between a device and an adverse event or set of adverse events

- FDA recommends searching our websites for information about safety signals, emerging signals, or other safety communications:
  - Medical Device Safety Communications
  - CBER Safety & Availability (Biologics) Communications

Predicate Device(s) Without an Associated Design-related Recall

- Recalls can occur due to:
  - Design defects,
  - Manufacturing defects, or
  - Labeling defects
- Design-related recalls can indicate a flaw with the design of the device as cleared and commercially distributed
- To assess whether any of the valid predicate device(s) have an associated recall, FDA recommends conducting a search in the [Medical Device Recalls Database]

Improving Transparency of Predicate Devices

The 510(k) Summary provides a summary of the device, including any information regarding safety and effectiveness, and the basis for a determination of substantial equivalence (see 21 CFR 807.92 and Appendix B of the 510(k) Program Guidance)

FDA recommends that submitters include in their 510(k) Summary:

An explanation regarding their selection of the predicate device(s) used to support the 510(k) submission; and

A narrative of how the best practices were used to select the predicate device(s) proposed for use in the 510(k) submission; or

If a submitter cannot identify a valid predicate device consistent with the best practices:

A statement that a valid predicate device that is consistent with any of the best practices was not available; and

Summary performance data to describe the testing conducted to address any known safety or effectiveness concerns with the predicate device

Example: Bone Sonometer Associated with a Design-Related Recall

Example Scenario:

A submitter is preparing a **510(k) for a bone sonometer**. The submitter only identified **one valid predicate device**.

The valid predicate device:

- Used currently FDA-recognized versions of applicable consensus standards
- Has an expected frequency of reported adverse events
- Had no known unmitigated use-related or design-related safety issues
- Has been associated with a design-related recall

What does the Submitter do?

In their **510(k) submission**:

- References selected predicate device, along with a statement that it was the only valid predicate device that could be identified
- Describes performance testing conducted and the measures taken to mitigate the safety concerns relevant to the design-related recall

In their **510(k) summary**:

- Identifies predicate device, and that it is the subject of a design-related recall
- Summarizes selection process of the predicate device
- Summarizes performance testing conducted to address safety concerns relevant to the design-related recall

Summary of Proposed Best Practices when Selecting a Predicate Device

Predicate devices cleared using well-established methods

Predicate devices meet or exceed expected safety and performance

Predicate devices without unmitigated use-related or design-related safety issues

Predicate devices without an associated design-related recall

The use of best practices when selecting a predicate device is intended to encourage the evolution of safer and more effective medical devices in the 510(k) Program

Draft Guidance

Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

Mary Wen, PhD
Deputy Director
Division of Submission Support
Office of Product Evaluation and Quality

Recommendations for the Use of Clinical Data in 510(k)s

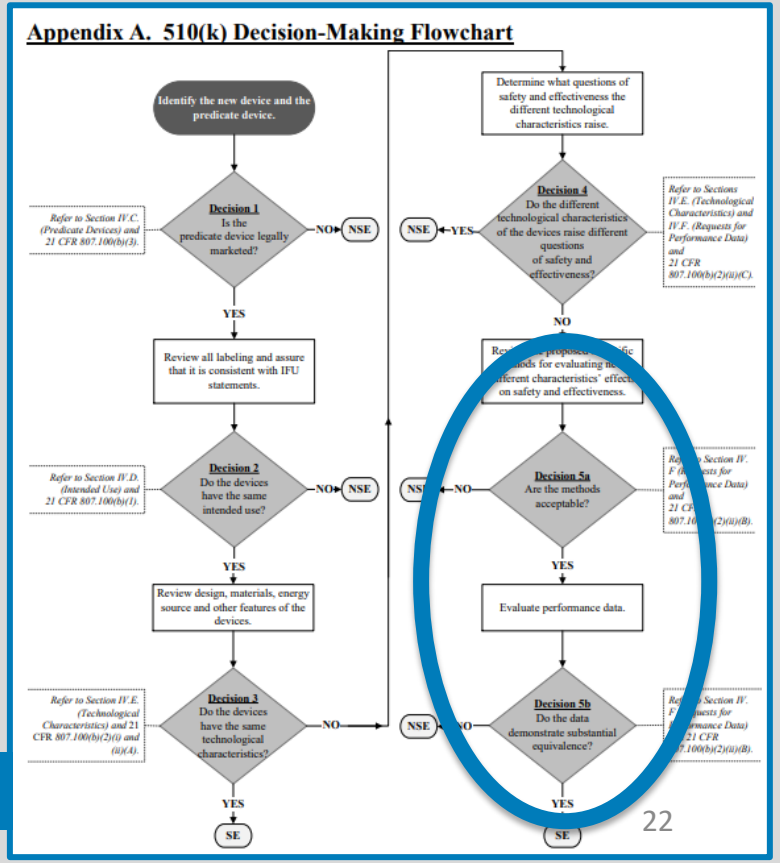
- Provides recommendations for when clinical data may be needed in a 510(k) to demonstrate that a new device is substantially equivalent (SE) to a predicate device
- FDA initially described scenarios for when clinical data may be necessary in a 510(k) to demonstrate SE in the 510(k) Program Guidance, Section IV.F., "Requests for Performance Data"
- Clarifies and provides additional context for situations when clinical data may be necessary to demonstrate SE by providing examples to clarify these concepts, illustrating when clinical data may or may not be needed
- These broad considerations may help provide predictability and transparency about when clinical data may be necessary in a 510(k)

When Clinical Data is Typically Reviewed

As initially described in the 510(k) Program Guidance, **clinical data may be used during the 510(k) review process to support an SE determination *at multiple points* in the 510(k) Decision-Making Flowchart**:

- Typically, clinical data is reviewed after we find that the intended use of the new device and the predicate device are the same, and that the devices have different technological characteristics that do not raise different questions of safety and effectiveness
- In such cases, **clinical data often is used to determine whether the new device is "*as safe and effective*" as a predicate device**

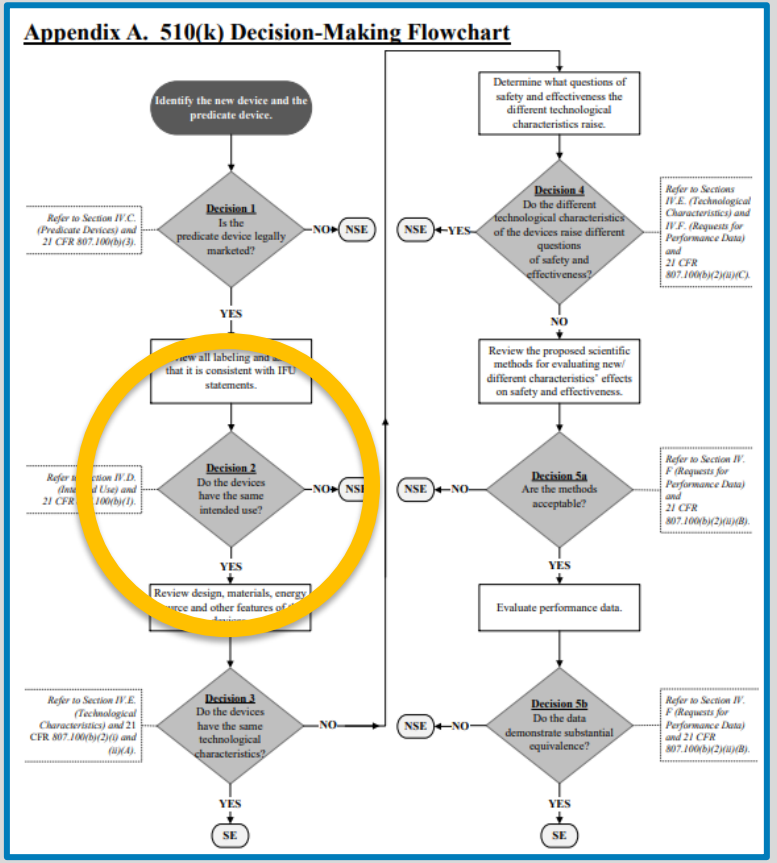
This is the most common use of clinical data in a 510(k)



When Clinical Data is Typically Reviewed

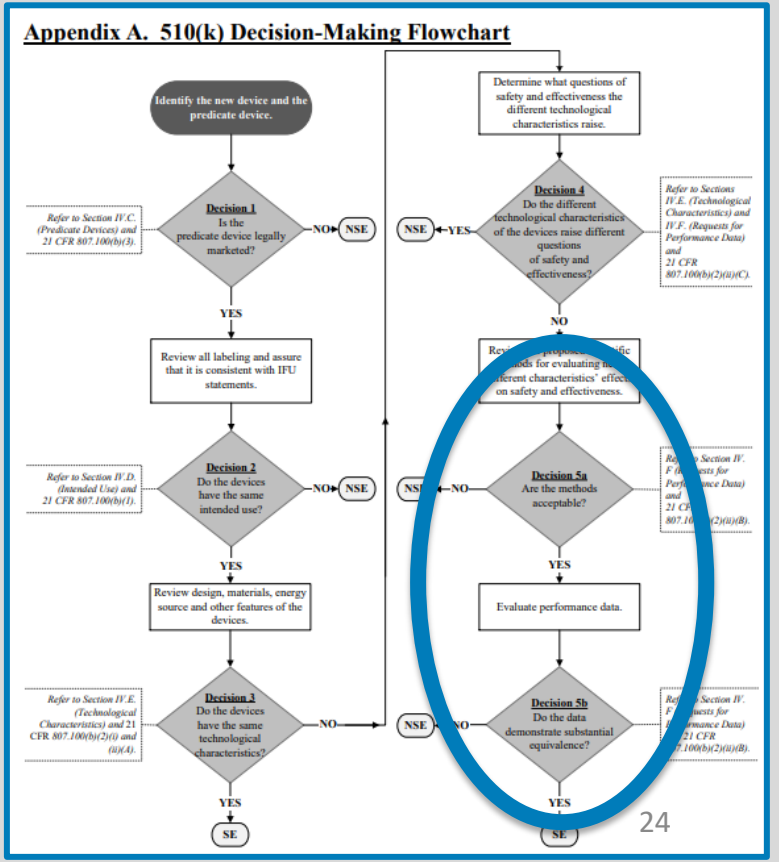
The 510(k) Program Guidance also describes other points at which clinical data may be used during the 510(k) review process to support an SE determination. For example:

- In rare instances, FDA may rely upon clinical data to determine that new or modified indications for use fall within the same intended use as a predicate device



When Clinical Data is Typically Reviewed

This guidance focuses on the more common uses of clinical data in a 510(k) to demonstrate SE



Scenarios When Clinical Data May be Necessary to Determine SE

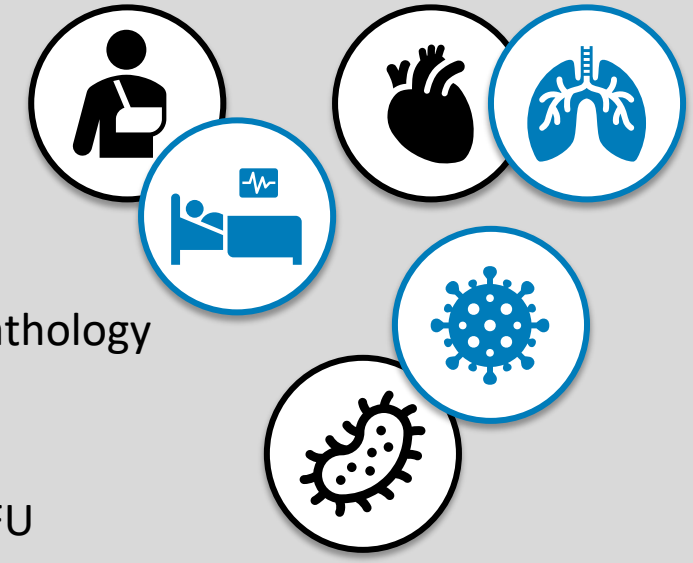
1. There are differences between the indications for use of the new device and the predicate device
2. There are differences between technological characteristics of the new device and the predicate device
3. SE between the new device and the predicate device cannot be determined by non-clinical testing (analytical, bench, and/or animal)
4. A newly identified or increased risk for the predicate device suggests clinical data may be needed for the new device

Differences in Indications for Use (IFU)

- When the IFU of a new device and predicate device differ, we must evaluate whether the IFU of the new device fall within the same intended use as that of the predicate device
- We determine the IFU of the new device based on:
  - Proposed labeling
  - IFU statement
- However, we may also rely upon other clinical and/or scientific information submitted with the 510(k)

Differences in IFU

- Clinical data may be necessary to include in a 510(k) to demonstrate SE when there are **differences between the IFU of the new device and the predicate device**
- FDA recommends considering the following factors:
  - Differences in the patient population
  - Differences in the disease
  - Differences in the anatomical site, structure, or pathology
  - General to specific considerations
  - Expansion of the new device's currently-cleared IFU
  - Unknown or different benefit-risk profile for the proposed IFU



Examples: Differences in IFU

Example 1-B:

- Device indicated for use in a specific anatomic location in proximity to critical organs
- Manufacturer wants to pursue an IFU in a different anatomic location that does not represent a new intended use and does not pose additional or different risks

Non-clinical data may suffice to demonstrate SE:

- IFU for the predicate device represents a higher/similar risk scenario than the new device
- Benefit-risk profile of the new device with the expanded IFU is comparable to that of the predicate device

Example 1-C:

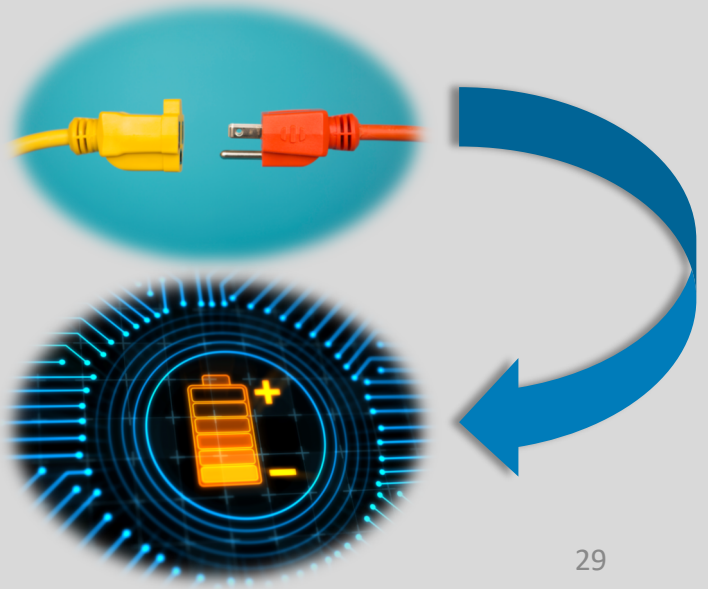
- Device indicated for use in a specific anatomic location
- Manufacturer wants to expand the IFU to a different anatomic location for the same intended use
- Based on literature and through clinical experience, using the device in this new anatomic location presents an increased risk because the procedure is technically complex

Clinical data may be necessary to demonstrate SE:

- Increased risk may adversely affect the benefit-risk profile of the new device when compared to the predicate device

Differences in Technological Characteristics

- Clinical data may be necessary to include in a 510(k) to demonstrate SE when there are **differences in technological characteristics of the new device and the predicate device**
- FDA recommends considering the following factors:
  - Significant change in materials
  - Significant change in device design
  - Significant change in energy source
  - Significant change in other device features



Examples: Differences in Technological Characteristics

Example 2-C:

Manufacturer wants to add additional sizes of an implanted device to its existing line of cleared, implanted devices

If the new sizes are within the minimum and maximum of the cleared, implanted devices, **non-clinical data may suffice to demonstrate SE:**

- New devices can be assessed using non-clinical testing methods

If the size of the new implanted device would be the new minimum/maximum of the cleared, implanted devices, **clinical data may be necessary to demonstrate SE:**

- Change in technological characteristic is expanding the range of device sizes

SE Cannot be Determined by Non-clinical Testing

- Clinical data may be necessary to include in a 510(k) when **non-clinical testing, such as analytical, bench, and/or animal testing, is not adequate to establish that the new device is SE to the predicate**
- FDA recommends considering the following factors:
  - There is no model available (such as analytical, bench, animal)
  - The available model(s) may not be adequate because the model has certain limitations that do not allow for an adequate assessment
  - The model may not be predictive of clinical outcomes
  - There are anatomical and/or pathophysiological species-specific questions that rely on clinical evidence

Examples: SE Cannot be Determined by Non-clinical Testing

Example 3-A:

Device intended to treat schizophrenia

Clinical data may be necessary to demonstrate SE:
- Limited availability of non-clinical models for schizophrenia

Example 3-D:

Device intended to screen donors of blood and blood products for transfusion-transmitted infections

Clinical data may be necessary to demonstrate SE:
- Analytical testing cannot be used to:
  - Evaluate clinical performance of assay
  - Evaluate the risks to the blood supply associated with incorrect results

Example 3-E:

IVD intended for point-of-care use where the predicate device is not intended for point-of-care use

Clinical data may be necessary to demonstrate SE:
- Variety of clinical environments
- Diverse populations that may use the device

Newly Identified or Increased Risk for Predicate

- As a device is more widely distributed and used, new scientific information about a device's safety may become available, which could include **newly identified or increased risk**
- New scientific information may affect the type and level of performance data needed in a 510(k)
- In requests for clinical data due to a new/increased risk, we will provide an explanation of the **reason(s) for the request and why such information is necessary for the SE determination**
- If possible, manufacturers should not use certain devices as predicates if they exhibit a new/increased risk, especially if an alternative predicate device exists without such new/increased risk

Examples: Newly Identified or Increased Risk for Predicate

Example 4-A:

Recalls, voluntarily-reported adverse events, and published scientific literature has made FDA aware of certain malfunctions for a device

Based on FDA's assessment of the totality of clinical and non-clinical data, **non-clinical data may suffice to demonstrate SE**:

- Non-clinical testing and appropriate instructions for use could demonstrate whether the risk is adequately mitigated by its design and technological features

Example 4-C:

- Device issue reported that could lead to significant patient injury in surgical procedures
- Primary evidence in current 510(k)s is non-clinical design verification and validation testing of the technological characteristics of the device
- Manufacturer recalled device with issue, and submitted a new 510(k) to address the issue; new 510(k) included non-clinical and clinical performance data

FDA issued device-specific guidance to outline **recommendations for non-clinical and clinical performance testing** for this device type

Summary of Clinical Data in 510(k)s

1. There are differences between the indications for use of the new device and the predicate device
2. There are differences between technological characteristics of the new device and the predicate device
3. SE between the new device and the predicate device cannot be determined by non-clinical testing (analytical, bench, and/or animal)
4. A newly identified or increased risk for the predicate device suggests clinical data may be needed for the new device

This guidance clarifies certain situations when clinical data may be necessary to demonstrate SE, and is intended to enhance the predictability, consistency, and transparency of the 510(k) Program

Draft Guidance

Evidentiary Expectations for 510(k) Implant Devices

Peter Yang, PhD, RAC
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Evidentiary Expectations for 510(k) Implant Devices

- Provides general recommendations for all implant devices for which a 510(k) is required
  - *Device-specific guidances may provide further specificity for a given device type*
- Clarify evidentiary expectations for 510(k) implants by assisting industry in design of appropriate performance testing that may be necessary to support a 510(k) for implant devices
- Provides general recommendations for other content in a 510(k), including:

Human Factors & Usability Testing

Patient Experience Information

Proposed Labeling & Implant Cards

What is an Implant?

An implant, as defined in 21 CFR 860.3(d), is "*a device that is placed into a surgically or naturally formed cavity of the human body*"

Further, "*[a] device is regarded as an implant … only if it is intended to remain implanted continuously for a period of 30 days or more…*"

- The term "implant" in this guidance refers to devices intended to be **implanted continuously for 30 days or more**
- However, many of the review considerations and associated recommendations in this guidance are **also applicable to devices that are intended to remain implanted continuously for fewer than 30 days**

General Considerations for 510(k) Implants

What are the indications for use of the device?

- Consider the specific intended patient population, disease state, and conditions of use when designing and conducting performance testing
- Consider performance testing representative of the way in which the device is indicated to be used, including the anatomical location(s) for which it is indicated
- Pediatric populations may have unique considerations, including whether it is appropriate to extrapolate adult data for pediatric use

What is the intended duration of implantation?

What is the anticipated patient and physician experience with the implant?

General Considerations for 510(k) Implants

What are the indications for use of the device?

What is the intended duration of implantation?

- Consider the intended duration of implantation or of patient exposure to the device when designing and conducting performance testing
- Consider whether results from shorter non-clinical or clinical duration testing can be extrapolated to provide information about long-term performance
- Consider whether testing should be conducted to address potential implant wear or degradation; use “worst-case” implantation conditions

What is the anticipated patient and physician experience with the implant?

General Considerations for 510(k) Implants

What are the indications for use of the device?

What is the intended duration of implantation?

What is the anticipated patient and physician experience with the implant?

- Consider both the patient and the physician experience with the implant in performing risk analysis and identifying performance testing
- Such risks can include:
  - ➢ Risks associated with everyday activities
  - ➢ Risks associated with user interaction with the implant
  - ➢ Risks associated with implantation procedure
  - ➢ Risks that may vary between different patient populations

Non-clinical Recommendations for 510(k) Implants

Non-clinical performance testing that is generally relevant across 510(k) Implants

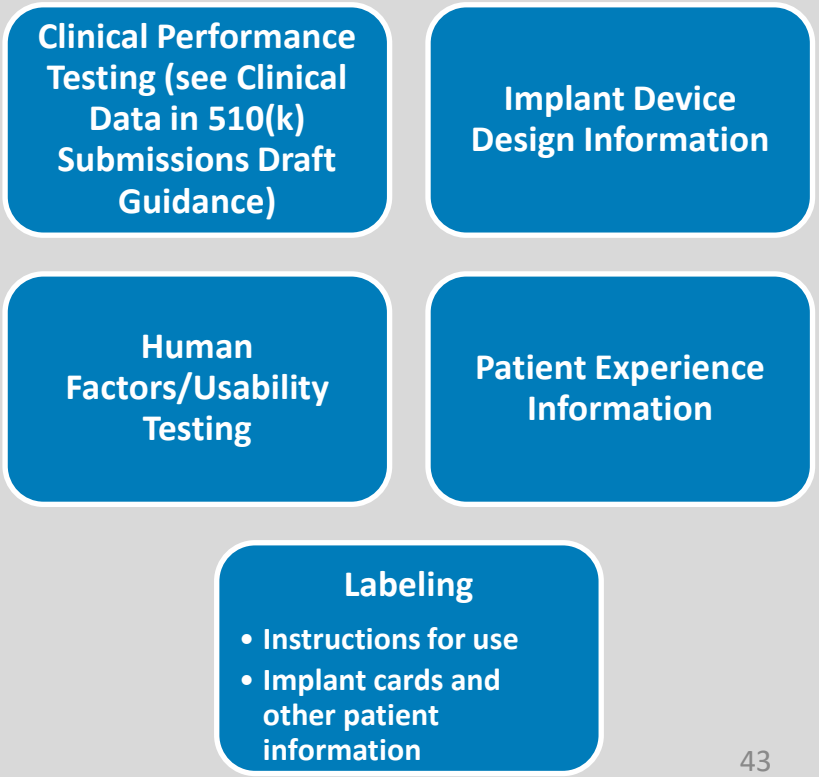
Biocompatibility	Sterility and Shelf Life	Reprocessing and Cleaning	Software and Cybersecurity
Electrical Safety and Electromagnetic Compatibility	MR Compatibility	Corrosion and Fatigue	Degradation
Particulates and Coatings	Imaging / Radiotherapy Compatibility	Bench Model Testing and Engineering Analyses	Animal Testing

Type and quantity of non-clinical performance data to support an SE determination will vary depending on the device and/or device type and on the differences from the predicate device

Clinical and Other Recommendations for 510(k) Implants

Type and quantity of clinical performance data to support an SE determination will vary depending on the device and/or device type and on the differences from the predicate device

Some recommendations, such as **implant labeling**, **implant cards**, and **patient information**, are important to consider for **any 510(k) implant**



Labeling Recommendations for 510(k) Implants

Instructions for Use

- A 510(k) must include **proposed labeling describing the device**, its **intended use**, and **directions for use** (21 CFR 807.87(e))
- Most implants are also generally **prescription devices** (21 CFR 801.109(d))
- Information for physician and patient about the **implantation procedure**, and **benefits and risks of the device after implantation**
  - **Separate patient labeling may be helpful**

Implant Cards

Certain information may be helpful to provide to patients or caregivers as an implant ID card:

- **Implant identifying information**, e.g., implant model name and manufacturer, and implant location
- **Device composition and patient contacting materials**
- Information on **how to report malfunctions or adverse events**
- **MR compatibility information**

Such information should be provided in a **format that can be easily conveyed to patients**

References

Slide Number(s)	Cited Resource	URL
5	CDRH Plan of Action for 510(k) and Science	https://public4.pagefreezer.com/browse/FDA/26-06-2023T13:52/https:/www.fda.gov/about-fda/cdrh-reports/cdrh-plan-action-510k-and-science
5, 8, 17, 21-23, 48	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
5	Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health	www.fda.gov/about-fda/cdrh-reports/medical-device-safety-action-plan-protecting-patients-promoting-public-health
6	Modernizing FDA's 510(k) Program; Establishment of a Public Docket; Request for Comments	www.regulations.gov/docket/FDA-2018-N-4751/document
13	FDA-Recognized Consensus Standards: Medical Devices	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
13	FDA Guidance Documents	www.fda.gov/regulatory-information/search-fda-guidance-documents
13	Medical Device Development Tools	www.fda.gov/medical-devices/medical-device-development-tools-mddt

References

Slide Number(s)	Cited Resource	URL
14	Manufacturer and User Facility Device Experience (MAUDE) Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
14	Medical Device Reporting Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmdr/search.cfm
14	MedSun Reports	www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/searchreporttext.cfm
15	Medical Device Safety Communications	www.fda.gov/medical-devices/medical-device-safety/safety-communications
15	CBER Safety & Availability (Biologics) Communications	www.fda.gov/vaccines-blood-biologics/safety-availability-biologics
16	Medical Device Recalls	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm
47	FDA-2023-D-3132	www.regulations.gov/docket/FDA-2023-D-3132
47	FDA-2023-D-3133	www.regulations.gov/docket/FDA-2023-D-3133
47	FDA-2023-D-3134	www.regulations.gov/docket/FDA-2023-D-3134

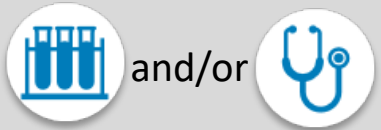
A Note about Draft Guidances

- You may comment on any guidance at any time
  - see 21 CFR 10.115(g)(5)
- Please submit comments on the draft guidances before the comment period closes (12/6/23) to ensure that FDA considers your comments on the draft guidances before we begin work on the final guidances
  - Evidentiary Expectations for 510(k) Implant Devices: FDA-2023-D-3132
  - Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions: FDA-2023-D-3133
  - Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: FDA-2023-D-3134

Summary

- ✓ Recommendations proposed in these new draft guidances are consistent with the 510(k) Program Guidance, and do not change applicable statutory regulatory standards, such as how FDA evaluates SE or applicable 510(k) requirements
- ✓ New draft guidances provide clarity on the 510(k) Program in areas requested by public comment
- ✓ New draft guidances help improve the predictability, consistency, and transparency of the 510(k) Program by providing:

Recommendations on the 4 best practices for selecting a predicate device



Clarity and predictability on when clinical data may be necessary in a 510(k)

General recommendations for 510(k) implants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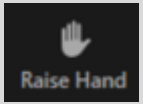
Let's Take Your Questions

- **To Ask a Question:**
  - Raise your hand in Zoom 

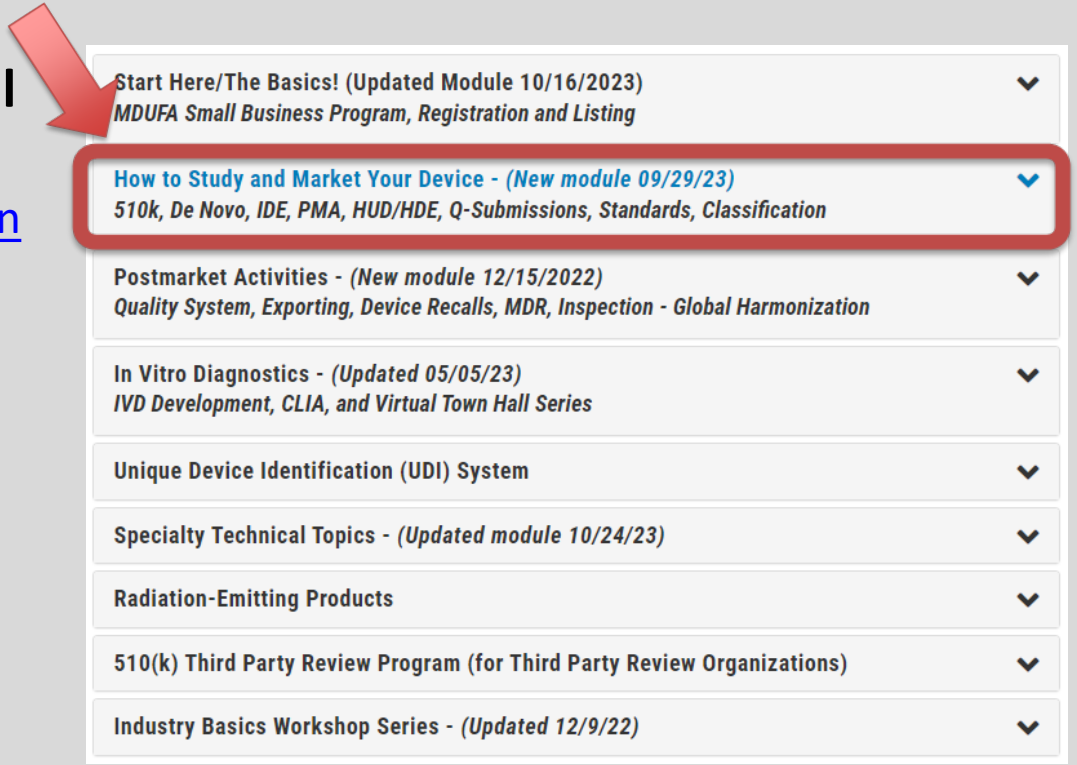
  - Moderator will announce your name and invite you to ask your question
  - Unmute yourself when invited to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at CDRH Learn**
  - www.fda.gov/Training/CDRHLearn
- **Additional questions about today's presentation**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHWebinar

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