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:
Predetermined Change Control Plans for Medical Devices

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Predetermined Change Control Plans for Medical Devices

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Draft Guidance

- **Predetermined Change Control Plans for Medical Devices**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices

Learning Objectives

- ✓ Explain FDA's authority for predetermined change control plans (PCCPs)
- ✓ Describe FDA's proposed policy and recommendations for PCCPs
- ✓ Explain FDA's proposed thinking for how manufacturers should determine whether a modification may be appropriate for inclusion in a PCCP
- ✓ Encourage early engagement between FDA and manufacturers on PCCPs

What is a *Predetermined Change Control Plan*?

As proposed in the guidance, a **Predetermined Change Control Plan** or **PCCP** is the documentation for a device that includes a description of the **planned device modifications**, the **associated methodology** to develop, validate, and implement those modifications, and an **assessment of the impact** of those modifications.

What is the *value of a PCCP*?

Implementation of modifications through a PCCP can help facilitate safe and effective device innovation!

By including a PCCP in a marketing submission for a device…

Manufacturers

- **Reduce the need for subsequent, additional marketing submissions** for each planned modification in the PCCP
- **Can iterate their device more quickly**

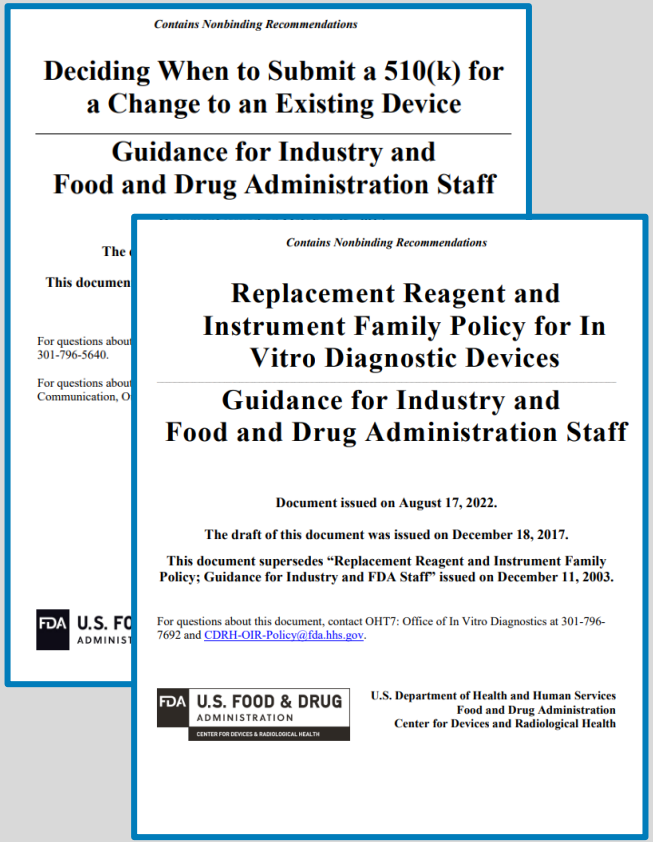
FDA

- **Reviews the PCCP** as part of a marketing submission for a device to **ensure the continued safety and effectiveness of the device**

Public

- **Has access to safe and effective advancements to devices faster**

PCCPs are not entirely new to FDA…



Contains Nonbinding Recommendations

Deciding When to Submit a 510(k) for a Change to an Existing Device

Guidance for Industry and Food and Drug Administration Staff

Contains Nonbinding Recommendations

Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on August 17, 2022.

The draft of this document was issued on December 18, 2017.

This document supersedes "Replacement Reagent and Instrument Family Policy; Guidance for Industry and FDA Staff" issued on December 11, 2003.

For questions about this document, contact OHT7: Office of In Vitro Diagnostics at 301-796-7692 and CDRH-OIR-Policy@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

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

FDA has generally leveraged similar concepts in prior guidances, including:

- "Deciding When to Submit a 510(k) for a Change to an Existing Device" for certain changes in expiration dates
- "Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices" for certain additional instruments for use with an IVD assay

Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)

Discussion Paper and Request for Feedback

- FDA introduced the term and description of the PCCP concept in this discussion paper
- PCCPs, which can support innovation for all devices, can be particularly helpful for AI/ML-based devices due to their ability to learn, adapt, and improve performance
- This discussion paper described a potential approach to premarket review of PCCPs for AI/ML-based software modifications

“Predetermined Change Control Plans for Devices” in section 515C of the FD&C Act

2022 Omnibus Appropriations Bill

Added *section 515C to the FD&C Act,* which has provisions regarding PCCPs for devices that would otherwise require a PMA supplement or a new 510(k).

Scope

This provision applies to all device types—it is not specific to software or AI/ML-based devices as described in the discussion paper. It applies to both PMA and 510(k).

Predetermined Change Control Plans

PCCPs describe planned changes that may be made to the device (and that would otherwise require a PMA supplement or 510(k) under section 515C) if the device remains safe and effective without any change.

“Predetermined Change Control Plans for Devices” in section 515C of the FD&C Act

PCCP Requirements

Provides that FDA may require a PCCP include:

- **Labeling for safe and effective use of a device** as such device changes pursuant to such plan
- **Notification requirements if the device does not function as intended** pursuant to such plan
- **Performance requirements for changes** made under the plan

Substantial Equivalence

For devices subject to 510(k) requirements, in making a determination of substantial equivalence where the predicate device was authorized with a PCCP, the **subject device must be compared to the version of the predicate device cleared or approved prior to changes made under the PCCP**

Scope of Draft Guidance

Proposed recommendations on the **types of modifications** that generally may be appropriate for inclusion in a PCCP:

- **Includes device modifications that generally would otherwise require a new marketing submission,** i.e., a PMA supplement *(21 CFR 814.39(a))* or a new 510(k) *(21 CFR 807.81(a)(3))*
- **Does not include** device modifications that do not require a new marketing submission

Premarket authorization for a device with a PCCP:

- **May be established through the PMA, 510(k), or De Novo pathways** *(see sections 515C(a), 515C(b), and 513(f)(2) of the FD&C Act)*
- **Cannot be established** using pathways for which FDA does not make an affirmative decision

Proposed recommendations:

- **Apply to the device constituent part of device-led combination products**
- **Do not apply** to the drug or biologic constituent part of device-led combination products

Proposed Guiding Principles

Reasonable assurance of safety and effectiveness and substantial equivalence of devices with PCCPs

PCCPs may be a least burdensome option to support device modifications

PCCPs are specific

PCCPs are part of a device's marketing authorization

PCCPs harmonize with existing FDA Device Modifications guidances

Proposed Components of a PCCP

A PCCP is the documentation for a device that includes a description of the planned device modifications, the associated methodology to develop, validate, and implement those modifications, and an assessment of the impact of those modifications

Description of Modifications

- Detailed description of the specific, planned modifications that may be made to the device, including:
  - Device specifications
  - Performance characteristics

Modification Protocol

- Verification and validation activities, including pre-defined acceptance criteria, that will support each modification to ensure the device remains safe and effective

Impact Assessment

- Assessment of the benefits and risks of implementing a PCCP for a device
- Documentation of the risk mitigations

Proposed Marketing Submission Sections Related to the PCCP

Marketing submission sections to include PCCP…	PCCP should be a standalone section in marketing submission, with title and version number
	Cover letter and Table of Contents
	Device description, labeling, and other relevant sections for device comparison

Labeling Related to the PCCP

FDA may require that a device with an authorized PCCP include labeling required for safe and effective use of the device as such device changes pursuant to such plan

(see sections 515C(a)(3), 515C(b)(3), and 513(f)(2) of the FD&C Act)

Generally, FDA recommends that the labeling include a statement that the device has an authorized PCCP

As modifications are implemented consistent with an authorized PCCP, **FDA recommends that the labeling related to the PCCP be updated** so that users may be aware of modifications that have been implemented that impact use of the device:

- A description of the implemented modifications, including a **summary of current device performance, associated inputs/outputs, validation requirements, and related evidence**;
- A description of **how the modifications were implemented**; and
- A description of how users will be informed of implemented modifications, including, for example, **updated instructions for use or a version history**

Public Decision Summary Related to the PCCP

Generally, FDA recommends that details of the PCCP should be included in sufficient detail in the public-facing documents to support transparency to users of the assessment of reasonable assurance of safety and effectiveness or the substantial equivalence comparison for the device and the device's specifications

FDA recommends public-facing documents include a summary of the following information related to the PCCP:

- Planned modifications;
- Testing methods;
- Validation activities and performance requirements to be met in order for modifications to be implemented; and
- Means by which users will be informed of device modifications implemented in accordance with the authorized PCCP

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Proposed Recommendations to Establish a PCCP

A PCCP must be reviewed and established as part of a marketing authorization for a device prior to a manufacturer implementing any modifications under that PCCP
(see sections 515C and 513(f)(2) of the FD&C Act)

Said differently, a PCCP is authorized as part of the device marketing authorization

PMA
- Original PMA application
- Modular PMA application
- 180-Day PMA supplement
- 135-Day PMA supplement
- Panel Track PMA supplement
- Real-Time PMA supplement

510(k)*
- Traditional 510(k)
- Abbreviated 510(k)

*In making a determination of substantial equivalence where the predicate device was authorized with a PCCP, the subject device must be compared to the version of the predicate device cleared or approved prior to changes made under the PCCP

De Novo
- Original De Novo request

Proposed Recommendations to Modify a Previously Authorized PCCP

- **Modifications to an authorized PCCP will generally constitute changes to the device that would otherwise require a new marketing submission**
- **Modifications to a PCCP will need to be reviewed and established as part of the marketing submission for the modified device** *(see sections 515C(a)(2) and 515C(b)(2) of the FD&C Act, 21 CFR 807.81(a)(3), and 21 CFR 814.39(a))*
- **FDA intends to focus its review on the aspects of the device that are most significantly modified**

PMA

- 180-Day PMA supplement
- 135-Day PMA supplement
- Panel Track PMA supplement
- Real-Time PMA supplement

510(k)*

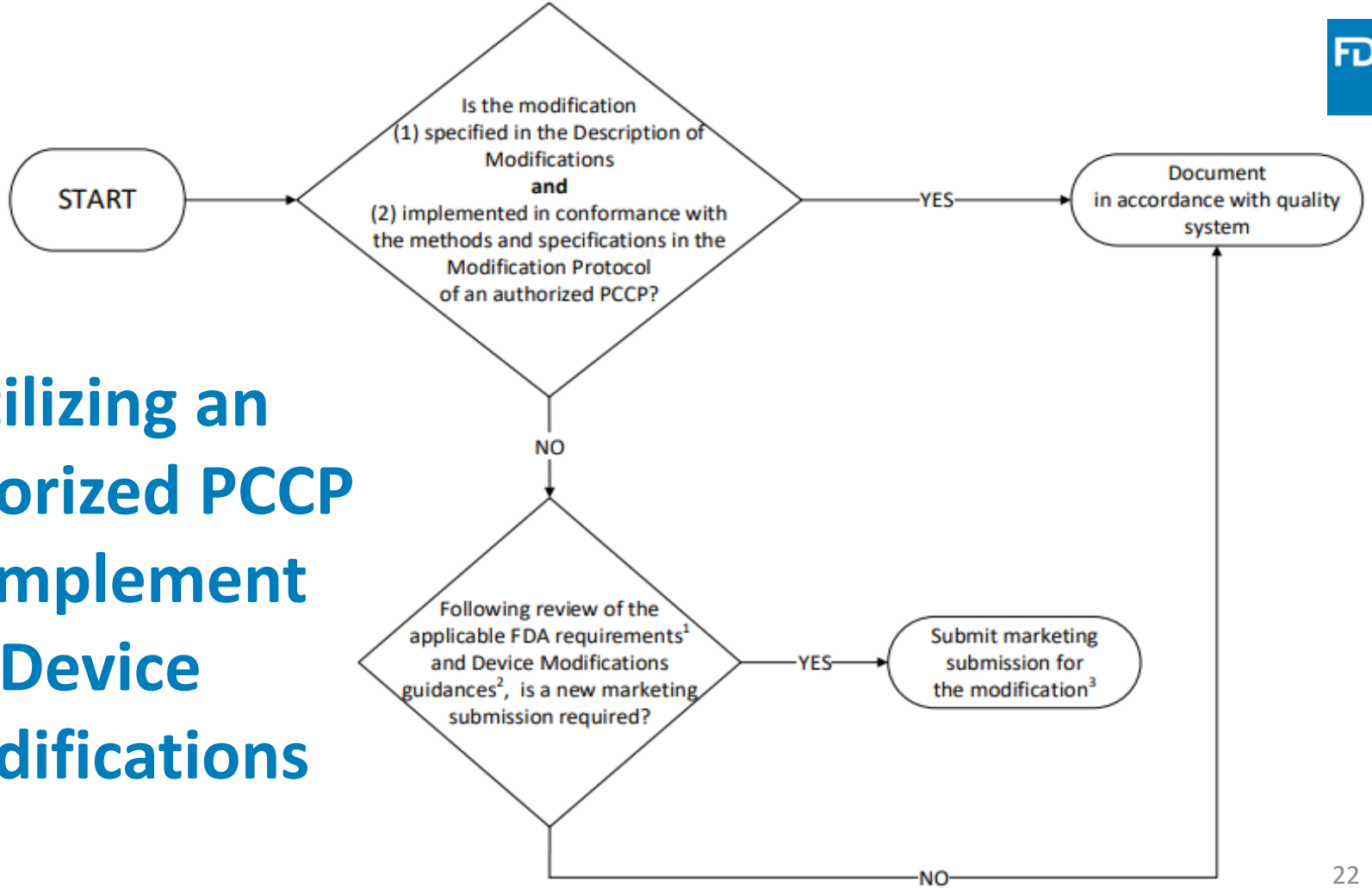
- Traditional 510(k)
- Abbreviated 510(k)
- Special 510(k)

Proposed Recommendations to Modify a Previously Authorized PCCP

- **Modifications to an authorized PCCP will generally constitute changes to the device that would otherwise require a new marketing submission**
- **Modifications to a PCCP will need to be reviewed and established as part of the marketing submission for the modified device** *(see sections 515C(a)(2) and 515C(b)(2) of the FD&C Act, 21 CFR 807.81(a)(3), and 21 CFR 814.39(a))*
- **FDA intends to focus its review on the aspects of the device that are most significantly modified**

TIP: Provide a summary of changes to the authorized PCCP, and where practicable, a tracked changes version compared to the authorized PCCP!

Utilizing an Authorized PCCP to Implement Device Modifications



Proposed Recommendations on Version Control of a PCCP

- FDA recommends submitting a copy of the proposed PCCP with a title and version number
  - If a PCCP is revised, a **final, revised version of the PCCP should be submitted as a clean copy, with a title and current version number**
- FDA authorizes the PCCP as part of the marketing authorization of a device
  - The PCCP will be referenced in the **device's letter of authorization, including the PCCP's title and version number**
- A manufacturer should only have **one version of an authorized PCCP for their device**
- A **PCCP can evolve over time through future marketing submissions**, where a new version of the PCCP can be authorized

Proposed Types of Modifications

Modifications that are appropriate for inclusion in a PCCP include those that:

- Are intended to maintain or improve the safety or effectiveness of the device
- Are specific
- Can be verified and validated

Modifications included in a PCCP must maintain the device within the device's intended use *(sections 515C(a)(2) and 515C(b)(2) of the FD&C Act)*

FDA believes that most modifications to the **indications for use** included in a PCCP would be **difficult for FDA to assess prospectively** to determine whether the device would remain safe and effective

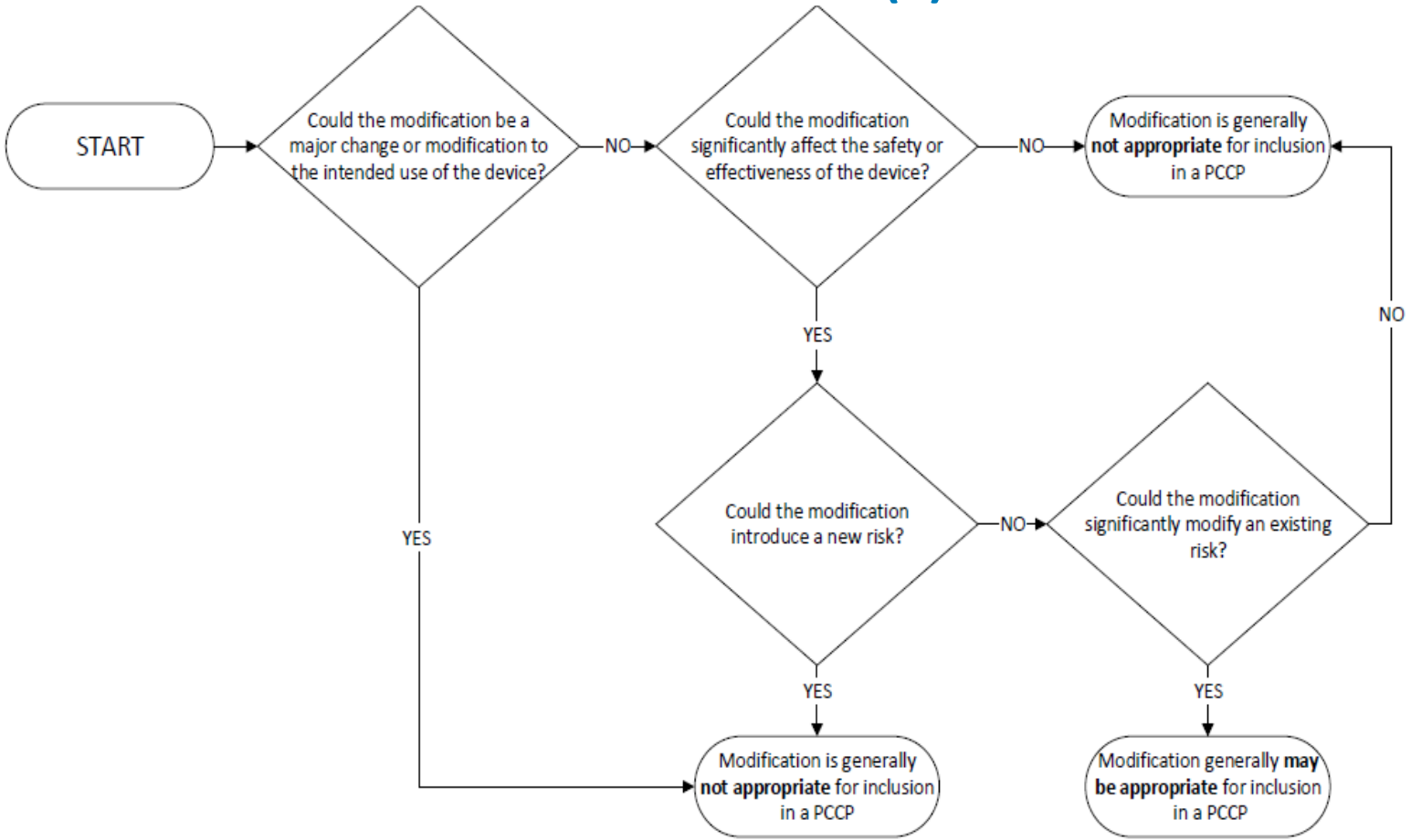
Determining Whether a Modification may be Appropriate for Inclusion in a PCCP in a 510(k) or De Novo Submission

- For devices subject to **510(k) requirements**, modifications must allow the device to remain **substantially equivalent** to the predicate device *(section 515C(b)(2)(B) of the FD&C Act)*

- FDA's proposed recommendations describe that modifications that could **significantly modify existing risks generally may be appropriate for inclusion in a PCCP** when the risks of implementing the modification are adequately mitigated by the existing risk management framework of the device and the manufacturer's quality system

- This proposed approach harmonizes with our policy for device modifications for devices subject to 510(k) or De Novo requirements

Determining Whether a Modification may be Appropriate for Inclusion in a PCCP for a 510(k) or De Novo Device



	510(k) / De Novo
Modifications that **Generally may be Appropriate** for PCCP	• Certain changes in device design, such as dimensions, performance specifications, wireless communication, or the patient/user interface • Changes in sterilization, packaging, transport, or expiration dating using well-established methods • Certain changes in software related to device compatibility or interoperability (such as changes to support device use on additional OS) • Certain changes in the labeling and/or the indications for use to specify use of the device with an additional device, component, or human genetic variant

	510(k) / De Novo
Modifications that **Generally may be Appropriate** for PCCP	• Certain changes in device design, such as dimensions, performance specifications, wireless communication, or the patient/user interface • Changes in sterilization, packaging, transport, or expiration dating using well-established methods • Certain changes in software related to device compatibility or interoperability (such as changes to support device use on additional OS) • Certain changes in the labeling and/or the indications for use to specify use of the device with an additional device, component, or human genetic variant
Modifications that are **Generally NOT Appropriate** for PCCP	• Change to device control mechanism, operating principle, or energy type • Change from single-use → reusable • Change from Rx → OTC • Change in the labeling or indications for use to include a new patient population • Changes that may need new clinical data* • Changes to address a recall or safety issue • Changes to a device constituent part that impact the biologic/drug constituent part *Certain changes that may need clinical data (method comparison data for IVDs) may be appropriate for PCCP

Determining Whether a Modification may be Appropriate for Inclusion in a PCCP in a PMA Submission

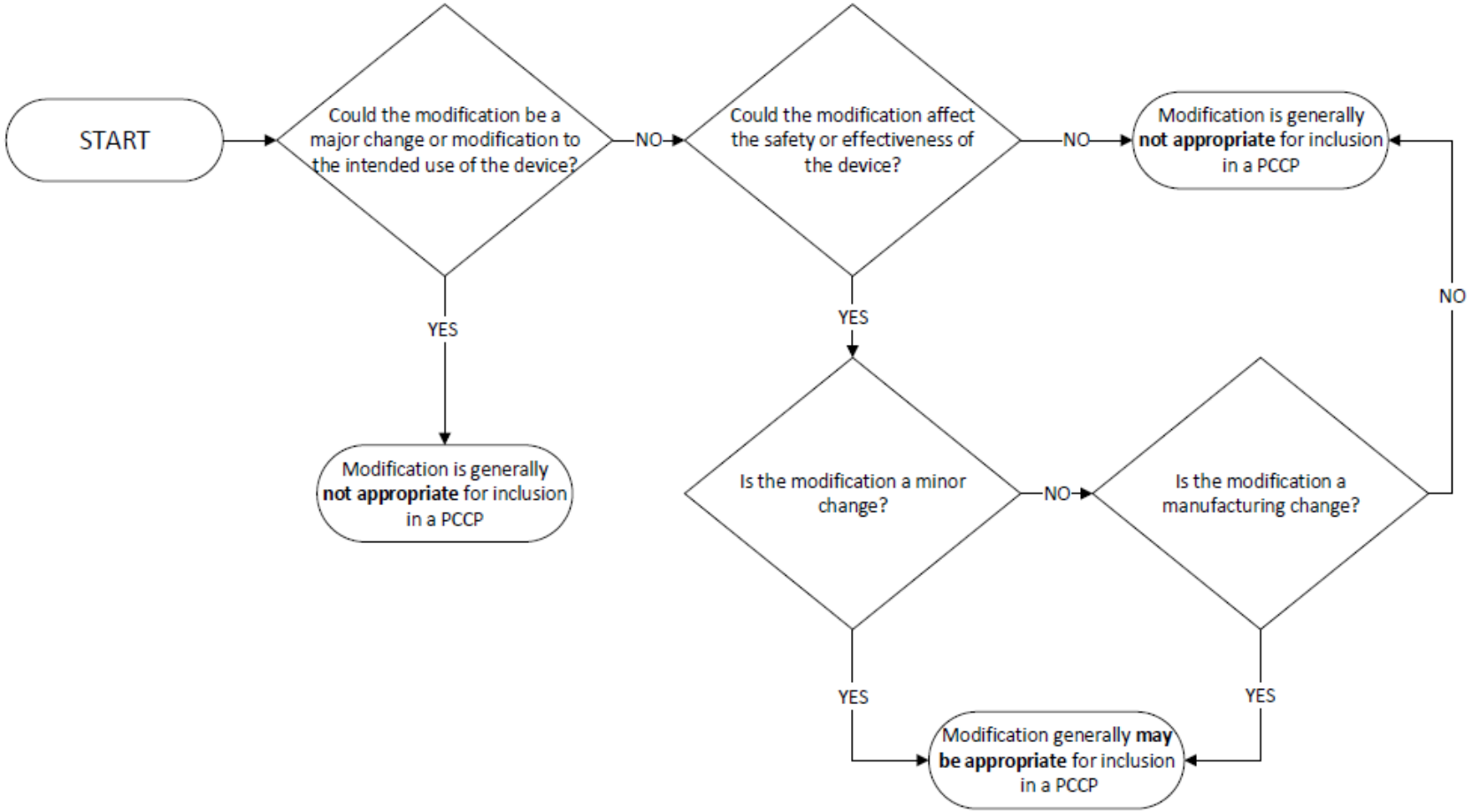
- **Minor changes** are those to the **design of the device, software, sterilization, or labeling** (think “real-time supplements”)

- **Manufacturing changes** are those to the **manufacturing procedures or methods of manufacture affecting the safety or effectiveness of the device** (think “30-day notice”)

- FDA’s proposed recommendations describe that modifications that are **minor changes or manufacturing changes generally may be appropriate for inclusion in a PCCP** when the risks of implementing the modification are adequately mitigated by the existing risk management framework of the device and the manufacturer’s quality system

- This proposed approach harmonizes with our policy for device modifications for devices subject to PMA requirements

Inclusion in a PCCP for a PMA Device



	PMA
Modifications that **Generally may be Appropriate** for PCCP	• Minor change in device design, such as dimensions, performance specifications, wireless communication, or the patient/user interface • Minor change in a material/component that has similar technical specifications to those for the authorized device (such as different source or supplier for raw materials, reagents, or hardware components) • Minor change in software related to device compatibility or interoperability (such as changes to support device use on upgraded OS) • Certain changes in methods of manufacture, such as change in manufacturing materials or software

	PMA
Modifications that **Generally may be Appropriate** for PCCP	• Minor change in device design, such as dimensions, performance specifications, wireless communication, or the patient/user interface • Minor change in a material/component that has similar technical specifications to those for the authorized device (such as different source or supplier for raw materials, reagents, or hardware components) • Minor change in software related to device compatibility or interoperability (such as changes to support device use on upgraded OS) • Certain changes in methods of manufacture, such as change in manufacturing materials or software
Modifications that are **Generally NOT Appropriate** for PCCP	• Significant change to components, materials, design, specifications, software, or color additives • Change from single-use → reusable • Change in the labeling or indications for use to include a new patient population • Changes that may need new clinical data* • Changes to address a recall or safety issue • Changes to a device constituent part that impact the biologic/drug constituent part • Change to add, expand, or move the manufacturing of a finished device *Certain changes that may need clinical data (method comparison data for IVDs) may be appropriate for PCCP

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Regulation, Policy, and Guidance Staff
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Proposed PCCP Content: Description of Modifications

The Description of Modifications should identify the **specific, planned modifications to the device, including device specifications and performance characteristics**

- To ensure an **efficient review**, FDA recommends that a PCCP include only a **limited number of modifications that are specific, and that can be verified and validated**

- The Description of Modifications should:
  - Enumerate the **list of individual proposed device modifications**
  - Describe the **specific rationale for the device modifications**
  - Be presented at a **level of detail that permits understanding of the specific modifications** that will be made to the device

Proposed PCCP Content: Description of Modifications

TIPS:

- **Reference labeling sections that are anticipated to be impacted for each modification**
- **Link each modification to a specific performance evaluation activity in the Modification Protocol**

Proposed PCCP Content: Modification Protocol

The Modification Protocol should include the **verification and validation activities, including pre-defined acceptance criteria,** that will support each modification to ensure the device remains safe and effective

- The **Modification Protocol** should include information regarding the manufacturer's **performance evaluation methods**, and when appropriate, **update procedures**
  - Note: For a particular marketing submission, additional information in a Modification Protocol may need to be included

- **Documentation of modifications verified and validated per the Modification Protocol must be compliant with *21 CFR Part 820***, including that the manufacturer must document the change in accordance with the manufacturer's quality system

Performance Evaluation Methods

FDA may require that performance requirements for changes made under the plan be provided in a PCCP *(see sections 515C(a)(3), 515C(b)(3), and 513(f)(2) of the FD&C Act)*

Performance evaluation of the device is important to ensure that specified acceptance criteria for all proposed modifications will continue to be met for the device's specifications

- Performance evaluation methods should include plans to **verify and validate that the modified device will**:
  - **Meet the specifications identified as part of a specific modification**
  - **Maintain the specifications** that are not part of the modification, but **may be impacted by the modification**

- Performance evaluation methods should also include plans to **verify and validate the entire device** following the implementation of **each individual modification and in aggregate** for the planned modifications

Performance Evaluation Methods

Performance evaluation methods may be similar to methods used to support the original marketing submission for the device

TIP: When considering the specific, planned modifications to your device, review existing FDA guidances!

Device-specific guidance that may be applicable to your device
Performance testing guidances, such as non-clinical bench performance testing, analytical studies, non-clinical animal performance testing
Other horizontal, cross-cutting guidances, such as biocompatibility, electromagnetic compatibility

Update Procedures

FDA may require notification requirements if the device does not function as intended pursuant to the authorized PCCP *(see sections 515C(a)(3), 515C(b)(3), and 513(f)(2) of the FD&C Act)*

Update procedures are important to ensure manufacturers update their devices consistent with their authorized PCCP and *21 CFR Part 820*, and, if appropriate for such modifications, to provide appropriate transparency to users

Update procedures should include plans to describe:

- **How manufacturers will update their devices**
- **Post-market surveillance plans and procedures** (such as notification requirements, real-world monitoring)
- How manufacturers will provide **appropriate transparency to users**, including:
  - How manufacturers will **update labeling** (such as information about the current version(s) of the device available, new unique device identifiers)
  - **Updated user training**, as applicable

Traceability Table

Modification Protocol Component		
Modification	Performance Evaluation Methods	Update Procedures
Modification #1	Method A (see Section X.A)	Method J (see Section X.J)
Modification #2	Method A (see Section X.A)	Method K (see Section X.K)
Modification #3	Method B (see Section X.B)	Method L (see Section X.L)

TIP: Include a traceability table that delineates which parts of the Modification Protocol are applicable to each modification!

Proposed PCCP Content: Impact Assessment

The Impact Assessment should include an **assessment of the benefits and risks of implementing a PCCP for a device**, as well as **documentation of the risk mitigations**

The **Impact Assessment** should:

1) Compare the version of the device with each modification implemented individually to the version of the device without any modifications implemented;
2) Discuss the benefits and risks, including risks of harm, of each individual modification;
3) Discuss how the verification and validation activities proposed within the Modification Protocol continue to reasonably ensure the safety and effectiveness of the device;
4) Discuss how the implementation of one modification impacts the implementation of another; and
5) Describe the cumulative impact of implementing all modifications

Proposed PCCP Content: Impact Assessment

The Impact Assessment should include an **assessment of the benefits and risks of implementing a PCCP for a device**, as well as **documentation of the risk mitigations**

- Impact Assessment documentation should discuss how the individual modifications included in the PCCP impact not only the particular device function, but the overall functionality of the device, including:
  - How they impact other device software functions and/or device hardware
  - For combination products, how they impact the biologic and/or drug constituent part, and the combination product as a whole

TIP: Your risk assessment ≠ Impact Assessment in a PCCP! Consider the recommended documentation and, as appropriate, reference your risk assessment!

Example Modifications for PCCPs: Ion Selective Electrode IVD

Example 2: This device is an ion selective electrode IVD intended for use on a laboratory-based chemistry analyzer to quantify the concentrations of potassium ions in serum samples for the purposes of monitoring electrolyte balance in the diagnosis and treatment of diseases and conditions characterized by low or high blood potassium levels

Modifications that generally may be appropriate for inclusion in a PCCP:

- Addition of lithium heparin plasma as a sample type
- Extension of sample stability claims (for example, 2 hours at room temperature to 4 hours at room temperature)
- Addition of a new potassium ion selective electrode

Modifications that are generally <u>not</u> appropriate for inclusion in a PCCP:

- Addition of urine or capillary whole blood as a sample type
- Addition of at-home sample collection
- Addition of point of care use

Example Modifications for PCCPs: Surgical Suture

Example 3: This device is a non-absorbable polyethylene surgical suture intended for soft tissue approximation or ligation.

Modifications that generally may be appropriate for inclusion in a PCCP:

- Change to a different non-novel sterilization method
- Addition of sutures to the product line with different dimensions that are within the range of dimensions of those currently authorized
- Addition of dye with an appropriate FDA listed color additive per *21 CFR Part 74 Subpart D*

Modifications that are generally <u>not</u> appropriate for inclusion in a PCCP:

- Addition of antimicrobials
- Change in filament design to an atypical design
- Addition of a stiffening agent to the ends of the suture to address a recall

Example Modifications for PCCPs: Pacemaker

Example 8: This device is an implantable pulse generator pacemaker.

Modifications that generally may be appropriate for inclusion in a PCCP:

- Addition of an alternate component supplier where the component specifications and design requirements are identical to those of the currently approved component
- Minor software changes to improve the battery longevity estimation algorithm

Modifications that are generally <u>not</u> appropriate for inclusion in a PCCP:

- A manufacturing change to an adhesive application process step made in response to reported device failure events of premature battery depletion due to an identified process variation
- Addition of a new battery design or change to the battery chemistry

Summary – Draft Guidance

This draft guidance:

- ✓ Describes FDA's proposed policy for PCCPs
- ✓ Describes FDA's proposed recommendations on the information to include in a PCCP for a marketing submission for a device
- ✓ Explains FDA's proposed thinking for how manufacturers should determine whether a modification may be appropriate for inclusion in a PCCP

Summary – Section 515C of the FD&C Act

***Section 515C of the FD&C Act*, "Predetermined Change Control Plans for Devices," has provisions regarding PCCPs for devices that would otherwise require a PMA supplement or a new 510(k)**

- ✓ It is in effect, and self-executing
- ✓ Manufacturers may submit, and FDA may approve or clear, a PCCP for a device at this time

Pre-Subs for PCCPs can be helpful!

We encourage manufacturers to engage early with FDA by submitting a Pre-Submission to discuss a proposed PCCP!

Pre-Subs can be a helpful way to obtain feedback on:

- ✓ A proposed PCCP for a device prior to submitting a marketing submission
- ✓ A proposed submission type for a device and PCCP
- ✓ Specific, proposed modifications for a device
- ✓ Proposed modifications to a PCCP

TIP: Engage with FDA early and often on your PCCP!

Resources

Slide Number	Cited Resource	URL
8	Deciding When to Submit a 510(k) for a Change to an Existing Device	www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-change-existing-device
8	Replacement Reagent and Instrument Family Policy for In Vitro Diagnostic Devices	www.fda.gov/regulatory-information/search-fda-guidance-documents/replacement-reagent-and-instrument-family-policy-in-vitro-diagnostic-devices
9	Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) – Discussion Paper and Request for Feedback	www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf

Acronyms

PCCP	Predetermined Change Control Plan
IVD	In vitro diagnostic
AI/ML	Artificial Intelligence/Machine Learning
FD&C Act	Federal Food, Drug, and Cosmetic Act
PMA	Premarket approval
510(k)	Premarket notification
CFR	Code of Federal Regulations
OS	Operating system
Rx	Prescription
OTC	Over-the-counter

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 draft guidance before closure date to ensure that FDA considers your comment on a draft guidance before we work on final guidance

Submit Comments to Docket by November 20, 2024

- **Docket: FDA-2024-D-2338**
  - www.regulations.gov/docket/FDA-2024-D-2338/document

- **Predetermined Change Control Plans for Medical Devices Draft Guidance**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/predetermined-change-control-plans-medical-devices


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Additional Panelist

Brittany Schuck, PhD
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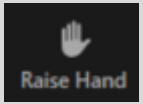
Office of Health Technology 7: Office of In Vitro Diagnostic Devices
Office of Product Evaluation and Quality

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

Let's Take Your Questions

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

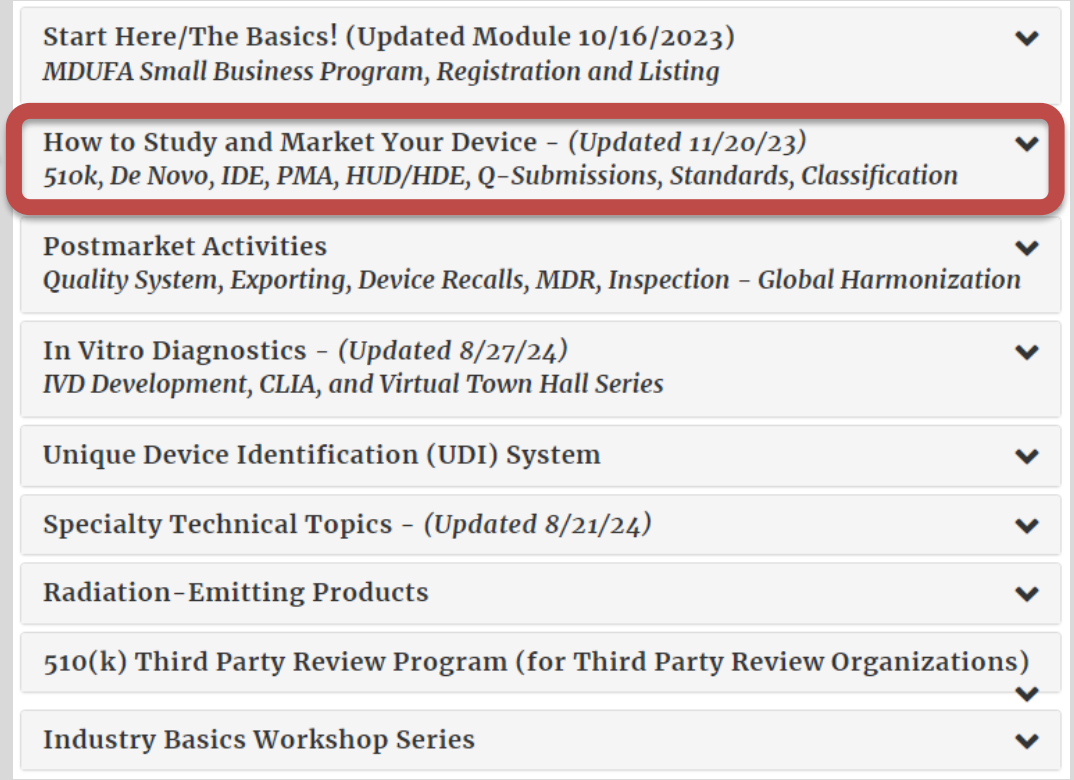
  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **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
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHevents

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