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:

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions, Draft Guidance

April 13, 2023

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions, Draft Guidance

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Draft Guidance

- **Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions**

www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial

Learning Objectives

- ✓ Describe background on FDA's collaborative patient-centered approach to AI/ML-enabled devices
- ✓ Describe purpose and scope of draft guidance
- ✓ Explain FDA's current thinking on modifications for Machine Learning-Enabled Device Software Functions (ML-DSFs)
- ✓ Describe the proposed recommendations for information to be included in a Predetermined Change Control Plan (PCCP) in a marketing submission for a device that is or includes an ML-DSF

Background

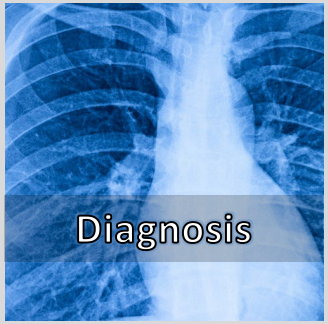
Patients are at the Heart of What We Do

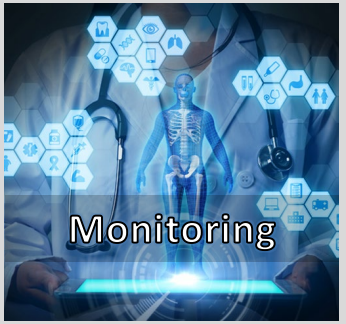
CDRH Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

Ensuring Patient Access to Safe and Effective AI/ML-Enabled Devices

- Digital health technologies play an increasingly significant role in many facets of our health and daily lives, across a broad spectrum of diseases and conditions
- AI/ML is powering important advancements in this field in a manner that lends itself to rapid technological improvement over time
- Ensuring these innovative devices are safe, effective, and can reach their full potential to help people, is central to the FDA's public health mission





Promoting Development of Safe and Effective AI/ML-Enabled Devices

The draft guidance:

- Proposes a science-based approach to put safe and effective advancements in hands of health care providers and users faster
  - Help to enable more personalized medicine and increase pace of medical device innovation
  - Informed by FDA's experience in regulating AI/ML-enabled devices

Supporting FDA's Strategic Priority to Promote Health Equity

- PCCPs can further this priority by:
  - Facilitating more rapid and continuous improvement of AI/ML-enabled device performance across diverse populations
  - Ensuring important performance considerations – including with respect to race, ethnicity, disease severity, gender, age, and geographical considerations – are addressed throughout the total product lifecycle
- Draft guidance proposes to place a significant and increased emphasis on importance of clearly communicating valuable information about these considerations to device users

FDA's Collaborative Patient-Centered Approach to AI/ML-Enabled Devices

Published AI/ML-SaMD Discussion Paper

2019

First joined Collaborative Community related to AI/ML

Evolving Role of AI in Radiological Imaging

Public Workshop on AI/ML in Radiological Imaging

2020

PEAC Mtg on Patient Trust in AI/ML Devices

Published AI/ML Medical Device Software Action Plan

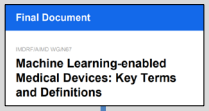
2021

Posted List of Currently Marketed AI/ML Devices

Transparency of AI/ML-Enabled Medical Devices

Public Workshop on Transparency of AI/ML Devices

Published GMLP Guiding Principles



2022

Contributed to IMDRF's Key Terms and Definitions

FINAL GUIDANCE
Clinical Decision Support (CDS) Software

Published Final Guidance: Clinical Decision Support

AI/ML Guidance

2023

We're working collaboratively with stakeholders to build a proactive, patient-centered approach to AI/ML-enabled devices that promotes health equity.

FDA's Collaborative Patient-Centered Approach to AI/ML-Enabled Devices

2019

Discussion Paper

Proposed regulatory framework for modifications to AI/ML-enabled medical device software to assure their safety and effectiveness, including **pre-specification of software changes to enable rapid improvement of software products**

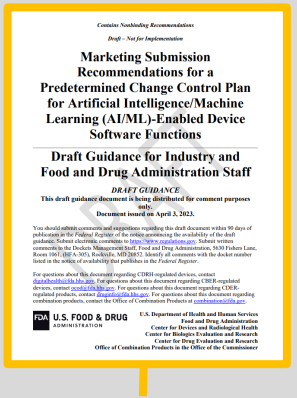
2021

Action Plan

Holistic, patient-centered strategic approach to AI/ML-enabled devices that promotes health equity, including aims to **update the proposed regulatory framework** and **foster a patient-centered approach, including transparency to users**

2023

Draft Guidance


Contains Nonbinding Recommendations

Draft – Not for Implementation

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on April 3, 2023.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

Proposed, least burdensome approach to support safe, iterative improvement through modifications to an AI/ML-enabled device

Food and Drug Omnibus Reform Act ("FDORA") Included a Provision for PCCPs

FDA

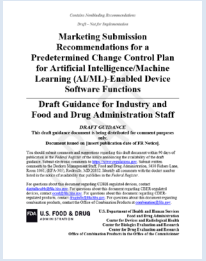
FDORA grants authority for PCCPs*

- *Changes to a device consistent with an approved predetermined change control plan do not require a supplemental application. It may also require that change control plans include labeling required for safe and effective use of the device.*

The PCCP provision applies to more than just AI/ML-enabled devices

- *This provision applies to all devices—it is not specific to AI/ML-enabled devices or software devices. It applies to both premarket approval (PMA) applications and 510(k) applications.*

2023 Draft Guidance on PCCPs for AI/ML-Enabled Devices



Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

- *This Draft Guidance provides proposed recommendations specifically for ML-DSFs that a manufacturer intends to modify over time. Consistent with the addition of section 515C, this draft guidance discusses the submission of PCCPs in marketing submissions for ML-DSFs.*

*Per section 3308 of FDORA, Title III of Division FF of the Consolidated Appropriations Act, 2023, enacted on December 29, 2022, which added section 515C to the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Purpose and Scope

Scope of Draft Guidance

- Applicable to machine learning-enabled device software functions (ML-DSFs) that a manufacturer intends to modify over time
- Describes proposed recommendations on information to be included in a Predetermined Change Control Plan (PCCP) provided as part of a marketing submission
- Generally, recommendations apply to device constituent part of a combination product, when the device constituent part is (or includes) an ML-DSF
- PCCP is an optional mechanism within a marketing submission for premarket authorization for modifications to an ML-DSF

Scope of Draft Guidance

- NOT intended to provide a complete description of what may be necessary to include in a marketing submission for an ML-DSF
- NOT intended to delineate types of modifications the Agency would consider acceptable in a PCCP
- FDA Review Team determines whether scope of modifications is appropriate for inclusion in a PCCP and what evidence and information are required to support proposed modifications in a marketing submission

Pathways for Authorization

- FDA considers the PCCP to be part of the technological characteristics of the device
- Per section 515C of the FD&C Act, a PCCP may be reviewed in a 510(k) if the device remains:
  - safe and effective without any such change
  - substantially equivalent to the predicate
- Per section 515C of the FD&C Act, only the version of an ML-DSF that has been cleared or approved, prior to implementing any changes made per an authorized PCCP, may be used as a predicate device

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Definitions

- **Device Software Function (DSF):**
  Software function that meets the device definition in section 201(h) of the FD&C Act. As discussed in other FDA guidances, the term “function” is a distinct purpose of the product, which could be the intended use or a subset of the intended use of the product

- ***Machine Learning-Enabled* Device Software Function (*ML*-DSF):**
  A device software function (as defined above) that implements an ML model trained with ML techniques

Definitions – Data Sets

- **Training Data**: These data are used by the ML-DSF manufacturer in procedures and ML training algorithms to build an ML model, including to define model weights, connections, and components
- **Tuning Data***: These data are typically used by the ML-DSF manufacturer to evaluate a small number of trained ML-DSFs in order to explore, for example different architectures or hyperparameters
- **Testing Data**: These data are used to characterize the performance of the ML-DSF. The testing phase is expected to provide data to establish a reasonable assurance of safety and effectiveness before an ML-DSF is marketed

The ML community sometimes refers to the tuning data and phase with the word **"validation." To be consistent with the definition of validation in 21 CFR 820.3(z), we recommend that the word "validation" not be used when referring to data or operations related to training or tuning ML models intended for medical applications.*

Definitions – Predetermined Change Control Plan

- **Predetermined Change Control Plan (PCCP):**

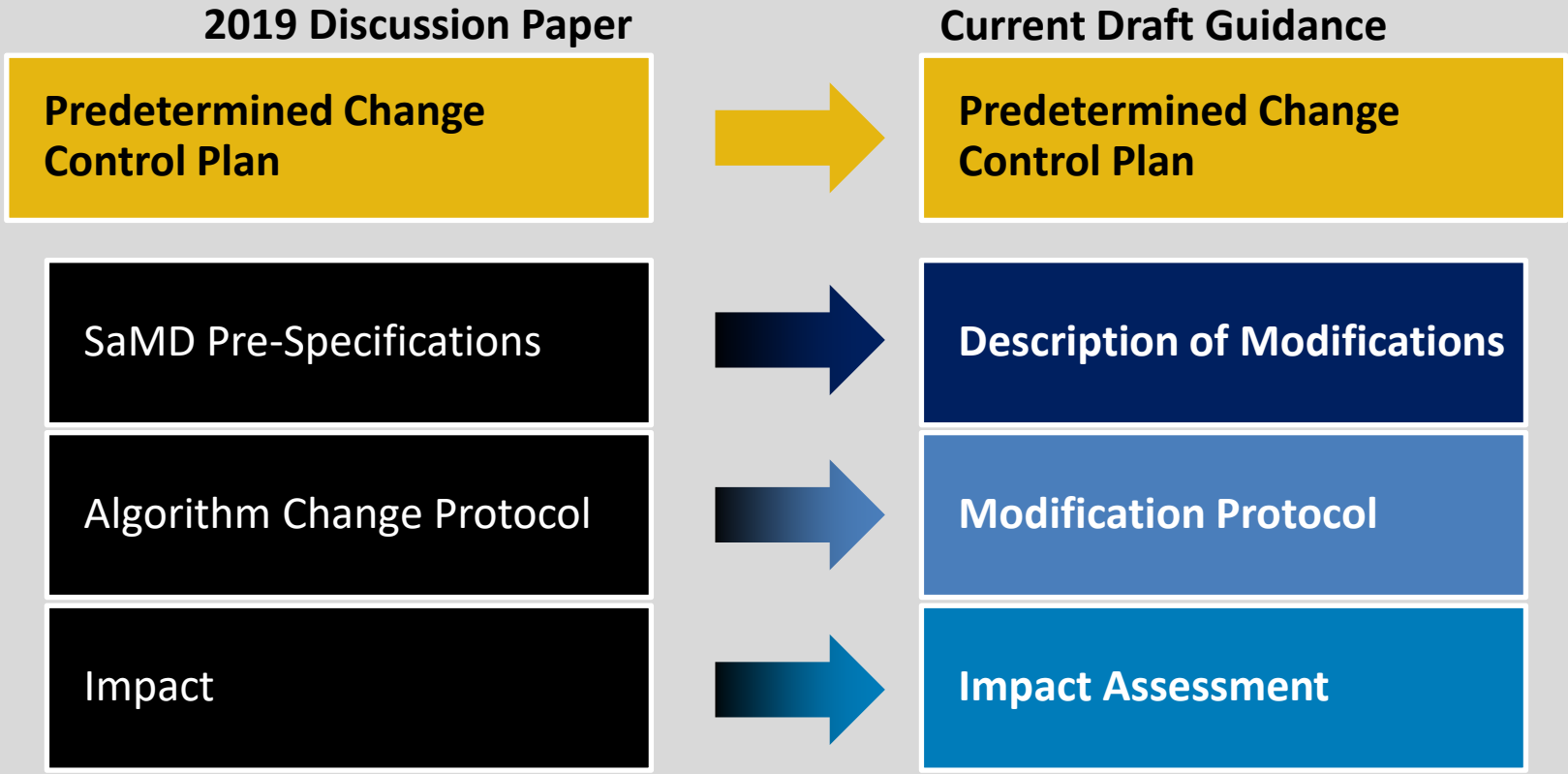
  Documentation describing what modifications will be made to the ML-DSF and how the modifications will be assessed. Includes:

  - **Description of Modifications**
  - **Modification Protocol**
  - **Impact Assessment**

- ***Authorized* Predetermined Change Control Plan:**

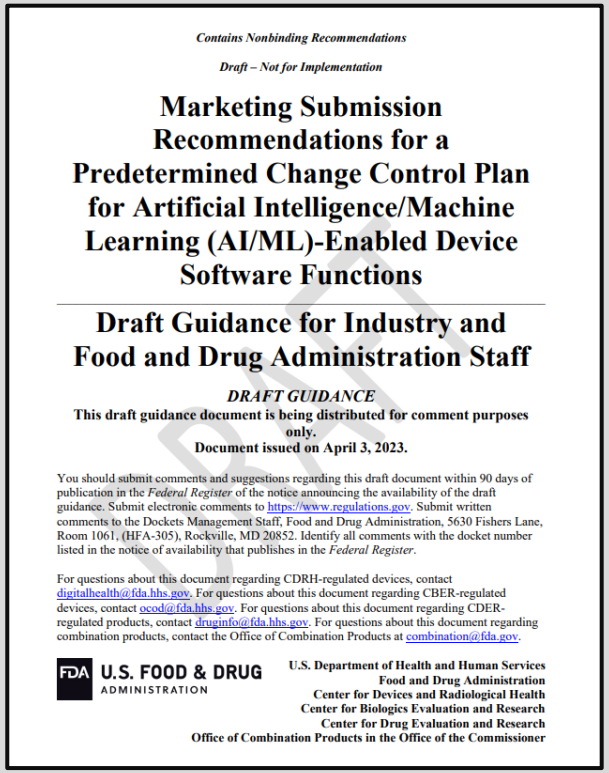
  A PCCP that has been reviewed and established through a device marketing authorization. An authorized PCCP is a technological characteristic of the authorized device with which it was established

Term Mapping



SaMD = Software as a Medical Device

Draft Guidance Document Outline



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You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact digitalhealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact druginfo@fda.hhs.gov. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research
Center for Drug Evaluation and Research
Office of Combination Products in the Office of the Commissioner

- Intro, Background, Scope
- Definitions
- Policy for PCCP
- Description of Modifications
- Modification Protocol
- Impact Assessment
- Appendix A: Example Elements of Modification Protocol Components
- Appendix B: Example ML-DSF Scenarios Employing PCCPs

Proposed Approach for Modifications for Machine Learning-Enabled Device Software Functions (ML-DSF)

Draft Policy for PCCPs

An authorized PCCP specifies planned modifications that, if not included in a PCCP, could otherwise require a new marketing submission*

The modifications can be implemented to the ML-DSF without triggering the need for a new marketing submission

Modifications made to an ML-DSF that are not specified in the authorized PCCP could require a new marketing submission*

*Note: pursuant to 21 CFR 807.81(a)(3) and 21 CFR 814.39(a), and in accordance with the "Modifications" guidances. For a list of the "Modifications" guidances, please see the Resources slide.

Proposed Components of PCCPs

Description of Modifications

"What" a manufacturer intends the algorithm to become as it learns

- Identifies specific, planned modifications to ML-DSF that the manufacturer intends to implement
- Draws a "range of FDA-authorized specifications" around initial device characteristics and performance

Modification Protocol

"How" the algorithm will learn/change while remaining safe and effective

- Describes methods that will be followed when developing, validating, and implementing the modifications to ensure the device remains safe and effective
- Methods described in Modification Protocol should be consistent with and support the modifications outlined in Description of Modifications

Impact Assessment

Describes modifications' benefits and risks, and how risks are mitigated

- Assesses benefits and risks of each individual modification, as well as collective impact of modifications, included in the Description of Modifications
- Discusses how activities proposed within Modification Protocol mitigate identified risks to continue to reasonably ensure the safety and effectiveness of the device

Predetermined Change Control Plan

Proposed PCCP Recommendations for Marketing Submissions

Establishing a PCCP

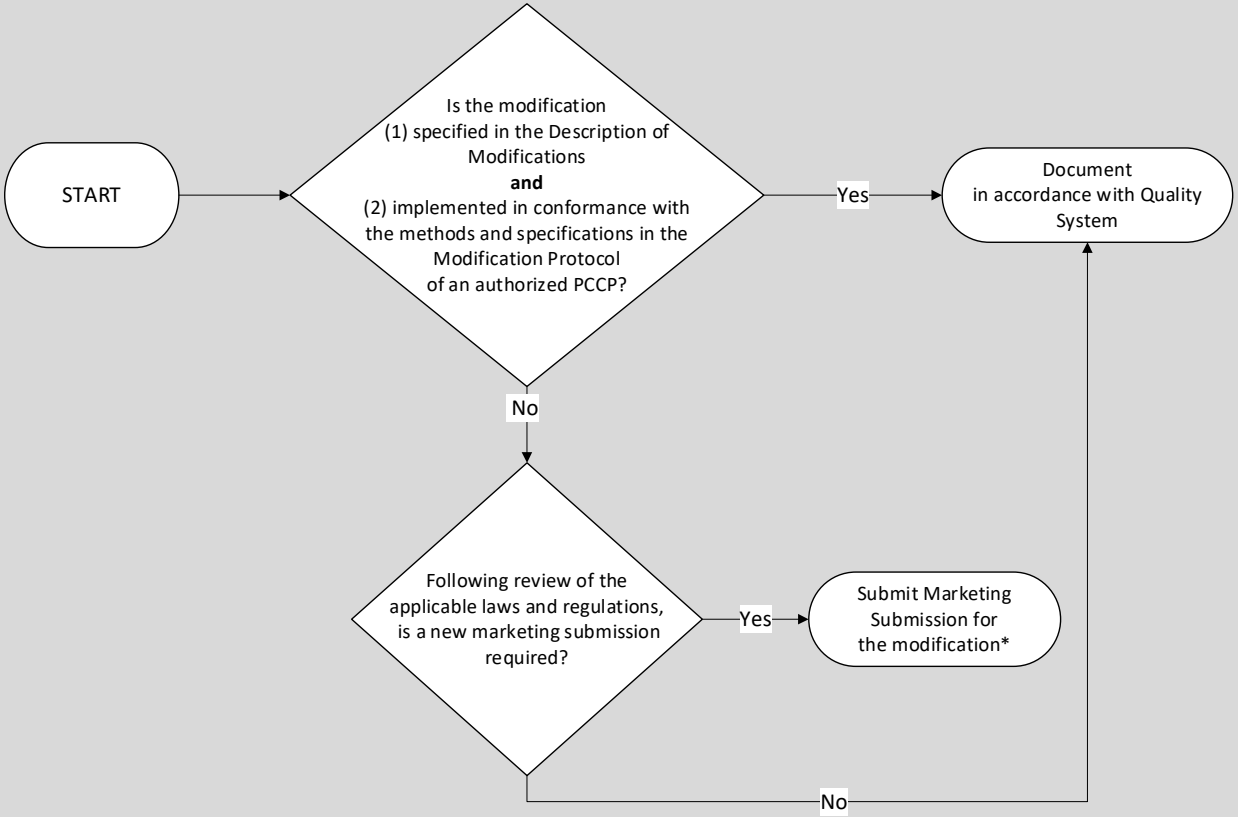
- A PCCP is **included in a marketing submission for a device and established as part of that authorization***
- An “authorized PCCP” is one that has been reviewed and established through the device marketing authorization
- To establish a new PCCP for a previously authorized device, the marketing submission must include appropriate marketing submission requirements and the proposed PCCP for the device

*Note: The term “authorization” is used to include clearance of a 510(k), granting of a De Novo, or approval of PMA

Identifying a PCCP in a Marketing Submission

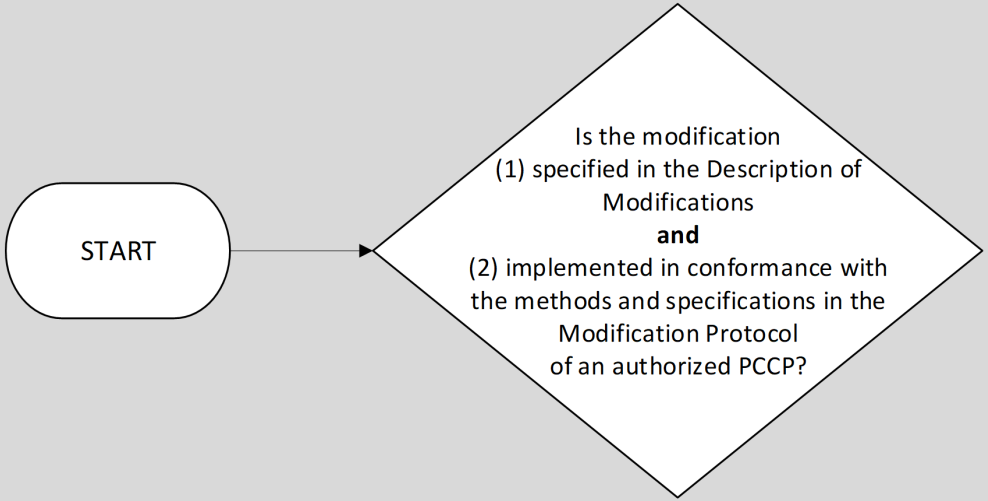
- In the marketing submission, the PCCP:
  - should be a standalone section, noted in the cover letter, and listed in the table of contents as "Predetermined Change Control Plan"
  - should be discussed as part of the device description, labeling, and other relevant sections
- The PCCP should be described in the:
  - 510(k) summary,
  - De Novo decision summary, or
  - PMA summary of safety and effectiveness document (SSED) and approval order
- Details of the PCCP should be included in sufficient detail to **support transparency to users** regarding the safety and effectiveness of the device
- Labeling should include an adequate description to **ensure appropriate use of the device**

Using an Authorized PCCP to Implement Modifications



*For the modified device to have a PCCP, a PCCP should be submitted with the marketing submission so that the device and PCCP can be authorized together.

Using an Authorized PCCP to Implement Modifications



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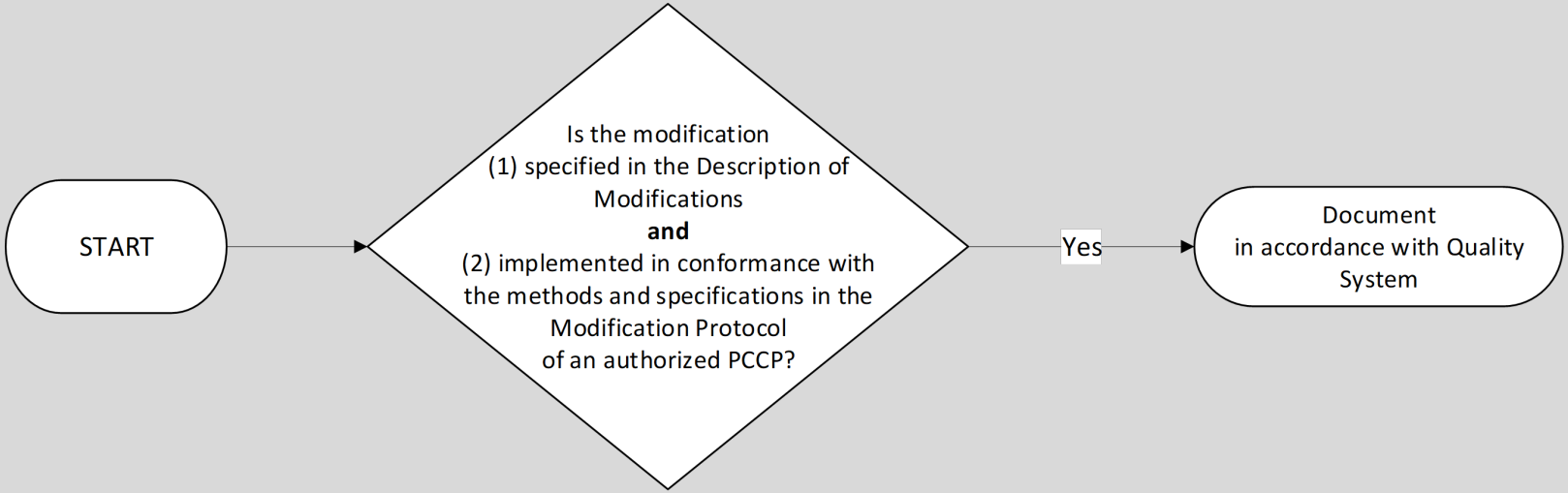

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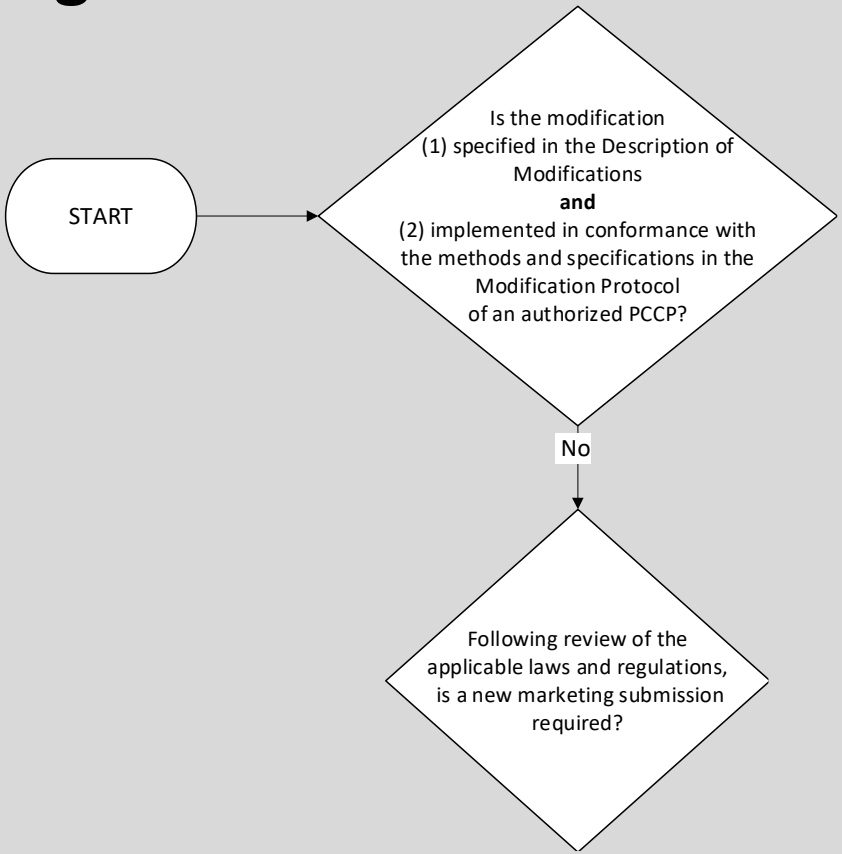

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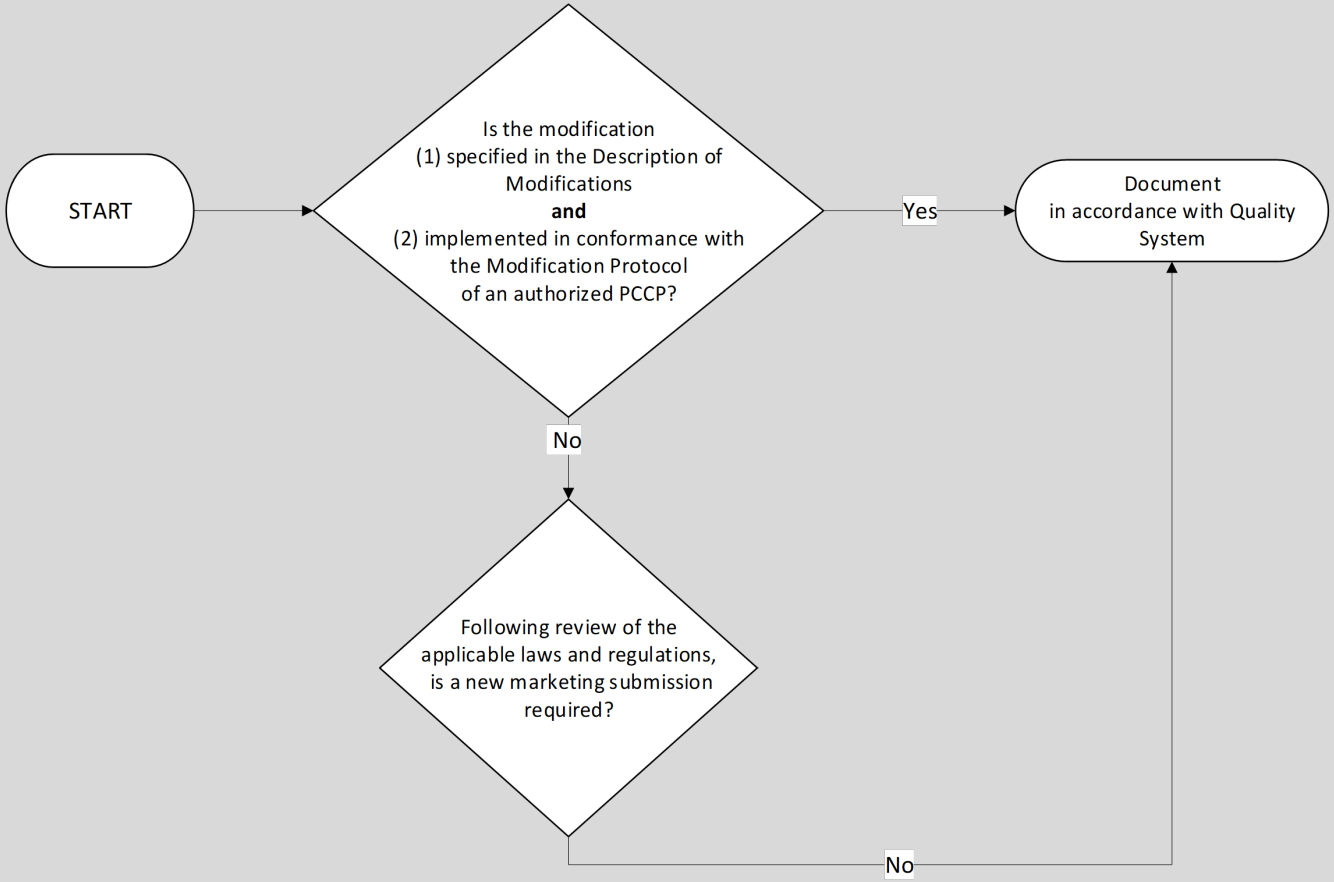
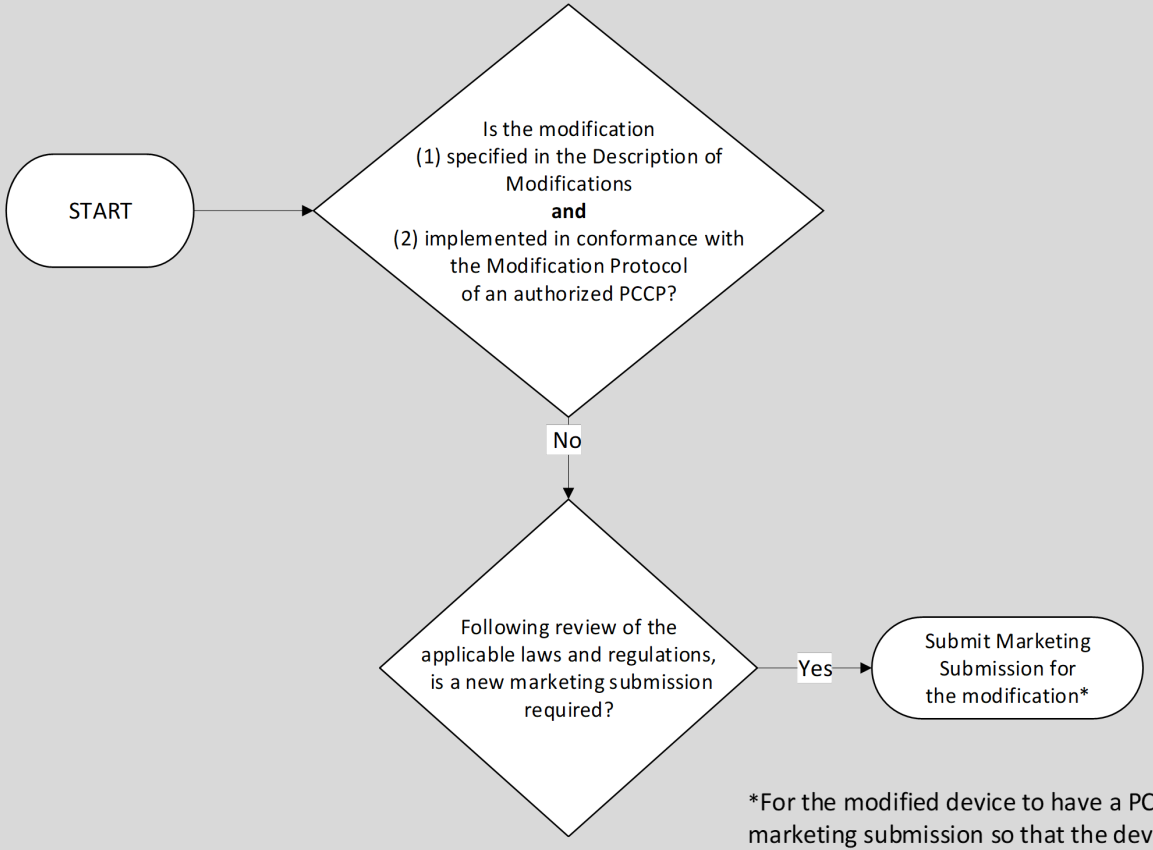
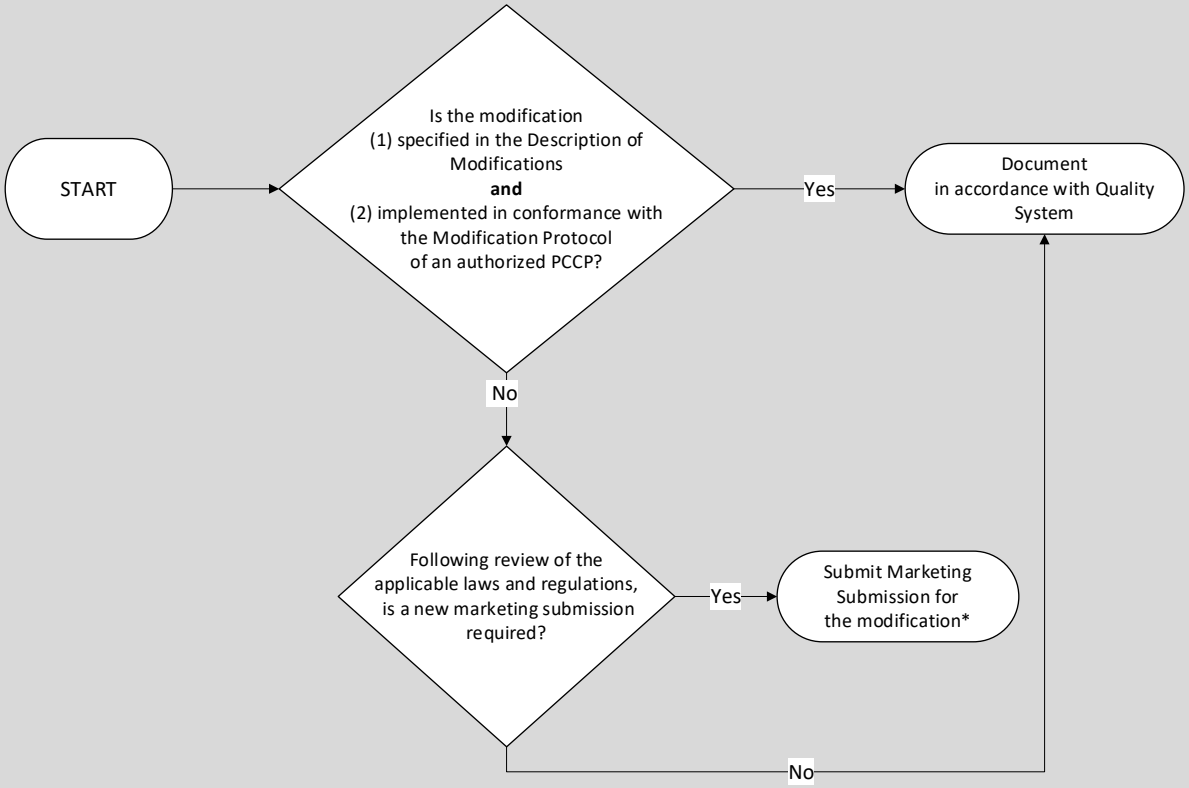


Using an Authorized PCCP to Implement Modifications



*For the modified device to have a PCCP, a PCCP should be submitted with the marketing submission so that the device and PCCP can be authorized together.

Using an Authorized PCCP to Implement Modifications



*For the modified device to have a PCCP, a PCCP should be submitted with the marketing submission so that the device and PCCP can be authorized together.

Modifications that are not consistent with an Authorized PCCP

- The manufacturer should evaluate modifications to an authorized device that **are not consistent with an authorized PCCP** to **determine if a new marketing submission is required for the modification**, as would modifications to a device without an authorized PCCP
  - For 510(k), see 21 CFR 807.81(a)(3)
  - For PMA, see 21 CFR 814.39(a)

- If, after review of applicable laws and regulations, a new marketing submission is required, then **the manufacturer must submit the appropriate marketing submission before the modified device is marketed**

Modifying a Device and its PCCP

- To **modify a PCCP for a previously authorized device with a PCCP**, the marketing submission must include the appropriate marketing submission requirements for the device and a proposed PCCP

- If **the authorized device is significantly modified**, except for modifications specified in the authorized PCCP, a new marketing submission is required

An authorized PCCP is applicable only to the version of the authorized device with which it was established

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Description of Modifications

"What" a manufacturer intends the algorithm to become as it learns

Description of Modifications

- Includes a detailed description of each planned modification to an ML-DSF
  - All modifications included in a PCCP should maintain the device within the device's Indications for Use (IFU) statement
- Describes changes to device characteristics and performance resulting from implementation of modifications
  - Draws a "range of FDA-authorized specifications" around initial device characteristics and performance
- FDA recommends that a PCCP include only a limited number of modifications that are specific, and that can be verified and validated

Recommendations for Modification Descriptions

- Identify specific modifications that can be verified and validated
- Present modifications at a level of detail that permits understanding of specific changes that will be made to the ML-DSF
- Link each modification to a specific performance evaluation activity within the Modification Protocol
- State whether planned modifications will be implemented manually or automatically
- Specify if proposed modifications will be implemented globally or locally
  - For planned local adaptations, describe what local factors or conditions warrant a local change

Modifications Appropriate for a PCCP

- Modifications should maintain or improve the safety or effectiveness of the device
- Modifications should be able to be verified and validated within existing quality system of device
- Modifications should **maintain the device within the device's Indications for Use** (IFU) statement
- Not all modifications may be appropriate for inclusion within a PCCP

Types of Modifications for a PCCP

- Modifications related to quantitative measures of ML-DSF performance specifications
  - Example: Improvements to analytical and clinical performance resulting from re-training the ML model based on new data within the intended use population from the same type and range of input signal

- Modifications related to device inputs to the ML-DSF
  - Example: Expanding algorithm to include new sources of same signal type (such as different makes, models, or versions of a data acquisition system) or limited modifications related to new types of inputs

- Limited modifications related to device's use and performance
  - Example: Authorization of a device for specific subset of a population within originally indicated population based on re-training on a larger data set for that subpopulation not previously available

Modification Protocol

“How” the algorithm will learn/change while remaining safe and effective

Modification Protocol

- Methods described in Modification Protocol should be **consistent with and support** modifications outlined in Description of Modifications
- Four primary components of a Modification Protocol:
  - **(1) data management practices,**
  - **(2) re-training practices,**
  - **(3) performance evaluation protocols, and**
  - **(4) update procedures, including communication and transparency to users and real-world monitoring plans**
- Include description of how proposed methods are similar to, or are different from, methods used elsewhere in marketing submission

Elements of a Modification Protocol

(1) Data Management	(2) Re-Training	(3) Performance Evaluation	(4) Update Procedures
• Collection Protocols • Assurance of Data Quality • Reference Standard Determination • Sequestration of Data Sets	• Re-training Objectives and Focus • Re-training Implementation	• Triggers to Initiate Performance Evaluation • Assessment Metrics and Elements • Statistical Analysis Plans • Performance Targets • Additional Testing Needs	• Software Verification and Validation • Update Implementation (When/How) • Communication and Transparency to Users • Device Monitoring Plan

From Appendix A

Traceability between Modification Protocol and Description of Modifications

PCCP should clearly delineate which parts of Modification Protocol are applicable to each modification within Description of Modifications

	Modification Protocol Component			
Modification	Data management practices	Re-training practices	Performance evaluation	Update procedures
Modification #1	Method A (see Section X.A)	Method D (see Section X.D)	Method G (see Section X.G)	Method J (see Section X.J)
Modification #2	Method A (see Section X.A)	Method E (see Section X.E)	Method H (see Section X.H)	Method J (see Section X.J)
Modification #3	Method B (see Section X.B)	Method F (see Section X.F)	Method I (see Section X.I)	Method J (see Section X.J)

Table 1. Example of Description of Modifications to Modification Protocol Traceability Table

Describes modifications' benefits and risks, and how risks are mitigated

Impact Assessment

Impact Assessment

Documentation for an Impact Assessment provided to the Agency in a marketing submission containing a PCCP should:

1. Compare version of device with each modification implemented to version of device without any modifications implemented
2. Discuss benefits and risks of each individual modification
3. Discuss how activities proposed within Modification Protocol continue to reasonably ensure safety and effectiveness of device
4. Discuss how implementation of one modification impacts implementation of another
5. Discuss collective impact of implementing all modifications

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Examples

Example

Device | *Proposed Modifications* | *Post-Authorization Scenarios*

Skin Lesion Analysis Software w/ Authorized PCCP

Device is an ML-DSF that analyzes images of skin lesions by identifying and characterizing its features (for example, color, quantification of area change over time) to aid in diagnosis.

Device was validated with a specific camera and is intended to be used by a primary healthcare provider.

Example

Device | **Proposed Modifications** | *Post-Authorization Scenarios*

Skin Lesion Analysis Software w/ Authorized PCCP

Manufacturer would like to extend ML-DSF for use on additional general-purpose computing platforms, including smartphones and tablets.

General-purpose computing platform must include a two-dimensional camera that meets the minimum specifications defined in the PCCP.

Updated device must achieve a minimum performance defined in Modification Protocol using a specified methodology.

Example

Device | *Proposed Modifications* | **Post-Authorization Scenarios**

Modification Scenario 1

Modification in input, as specified in PCCP and implemented in accordance with PCCP

Modification Scenario 2

Modification in input that was not specified in PCCP

Modification Scenario 3

Modification related to device's use and performance, which was not specified in PCCP

Modification Scenario 1

Modification Scenario

Modification in input, <u>as specified in the PCCP and implemented in accordance with the PCCP</u>

- Analytical validation demonstrated the ML-DSF can be deployed on two additional smartphones that meet the minimum specifications provided in the PCCP. The analytical performance using the new image acquisition systems was found to be statistically equivalent to the baseline performance
- Labeling was updated to reflect new ML-DSF compatibility with additional smartphones and communication updates on device compatibility were also provided

Because the device modification was specified in PCCP, and it was implemented in conformance with PCCP, device modification would not require a new marketing submission

Manufacturer should document modification that was specified in PCCP in accordance with their quality system

Modification Scenario 2

Modification Scenario

Modification in input that was <u>not specified in PCCP</u>

- Manufacturer would like to deploy a modified ML model that uses images captured by a thermographic camera
- However, new camera technology was not specified in PCCP

Because this modification was not included in PCCP, and it could significantly affect safety or effectiveness of the device a new marketing submission would be required

Modification Scenario 3

Modification Scenario

Modification related to the device's use and performance, which was <u>not specified in the PCCP</u>

- Manufacturer would like to distribute a new version of the ML-DSF that is patient-facing
- ML-DSF would provide an analysis of physiological characteristics of skin lesions, as it does currently, and direct patients to follow-up with a dermatologist based on the preliminary analysis of the malignancy of the skin lesion
- Modification introduces many new, unconsidered risks, given that the modified ML-DSF will be patient-facing

Because this modification was not included in PCCP, and it could significantly affect safety or effectiveness of the device a new marketing submission would be required

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Chief Medical Officer

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Summary

This Draft Guidance:

- ✓ Describes FDA's proposed approach to ML-DSFs to support their iterative development and improvement over time
- ✓ Builds on the Agency's longstanding commitment to developing innovative approaches to ensuring safe and effective digital health technologies are available to patients
- ✓ Includes proposed recommendations on information to be included in a PCCP provided as part of a marketing submission for an ML-DSF
- ✓ Specifies that modifications made to an ML-DSF in accordance with an authorized PCCP can be implemented to the ML-DSF without a new marketing submission
- ✓ Includes details on the proposed recommended content of these sections, and additional examples are provided in appendices

Resources

Slide Number	Cited Resource	URL
25	Deciding When to Submit a 510(k) for a Software Change to an Existing Device	www.fda.gov/regulatory-information/search-fda-guidance-documents/deciding-when-submit-510k-software-change-existing-device
25	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
25	Modifications to Devices Subject to Premarket Approval (PMA)	www.fda.gov/regulatory-information/search-fda-guidance-documents/modifications-devices-subject-premarket-approval-pma-pma-supplement-decision-making-process
37	21 CFR 807.81(a)(3)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-807/subpart-E/section-807.81#p-807.81(a)(3)
37	21 CFR 814.39(a)	www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814/subpart-B/section-814.39#p-814.39(a)

A Note about Draft Guidance

- 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 Dockets by: July 03, 2023

- **Docket: FDA-2022-D-2628**
  - www.regulations.gov/docket/FDA-2022-D-2628

- **Draft Guidance**
  - www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial


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