U.S. FOOD & DRUG ADMINISTRATION

Detangling the 510(k) Process

FDA Small Business Regulatory Education for Industry (REdI) Annual Conference

June 7, 2023

Andrew Sprau, MS
Consumer Safety Officer
Premarket Programs Branch
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Define 510(k)
- Describe Substantial Equivalence to a Predicate Device
- Discuss Review Process
- Provide tips from a lead reviewer

What is a 510(k)?

- A type of premarket submission
- Comparison of a new device (subject) to one or more legally marketed devices (predicate)
- Provide evidence that supports substantial equivalence (SE)

Types of 510(k)s

Traditional	Abbreviated	Special
Most common Review: 90 calendar days All data are provided	Similar to Traditional Review: 90 calendar days Relies on FDA-recognized standards, guidance documents, or special controls Full test reports not provided	For minor changes Review: 30 calendar days Full data should not need to be reviewed. Only **Summary**-level information focusing on the **modifications** Only available to owner of device

What is a Predicate Device?

- A **legally-marketed device**:
  - was legally marketed prior to May 28, 1976 (preamendments device)
  - has been reclassified from Class III to Class II or I
  - has been found substantially equivalent (SE) through the 510(k) process or safe and effective through the De Novo process
- Used as the **comparison** for Substantial Equivalence

Device Advice: How to Find and Effectively Use Predicate Device

Substantial Equivalence

Your device is **as safe and effective** as the predicate if:

- **Same intended use**

AND

- **Same** or **different technological characteristics**
  - Do not raise different questions of safety and effectiveness
  - Information submitted to FDA demonstrates your device is as safe and effective as legally marketed device

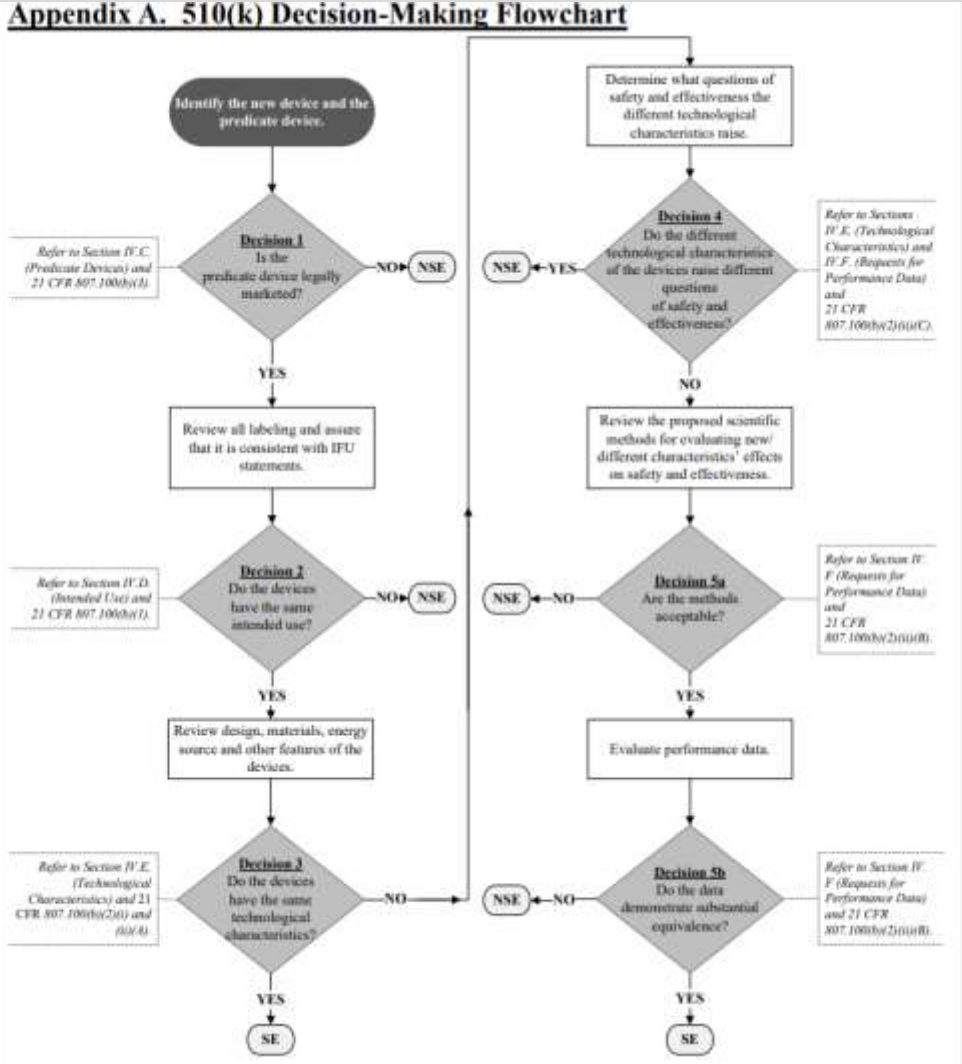
Determination of Intended Use for 510(k) Devices - Guidance for CDRH Staff (Update to K98-1)

Purpose of a Predicate Device

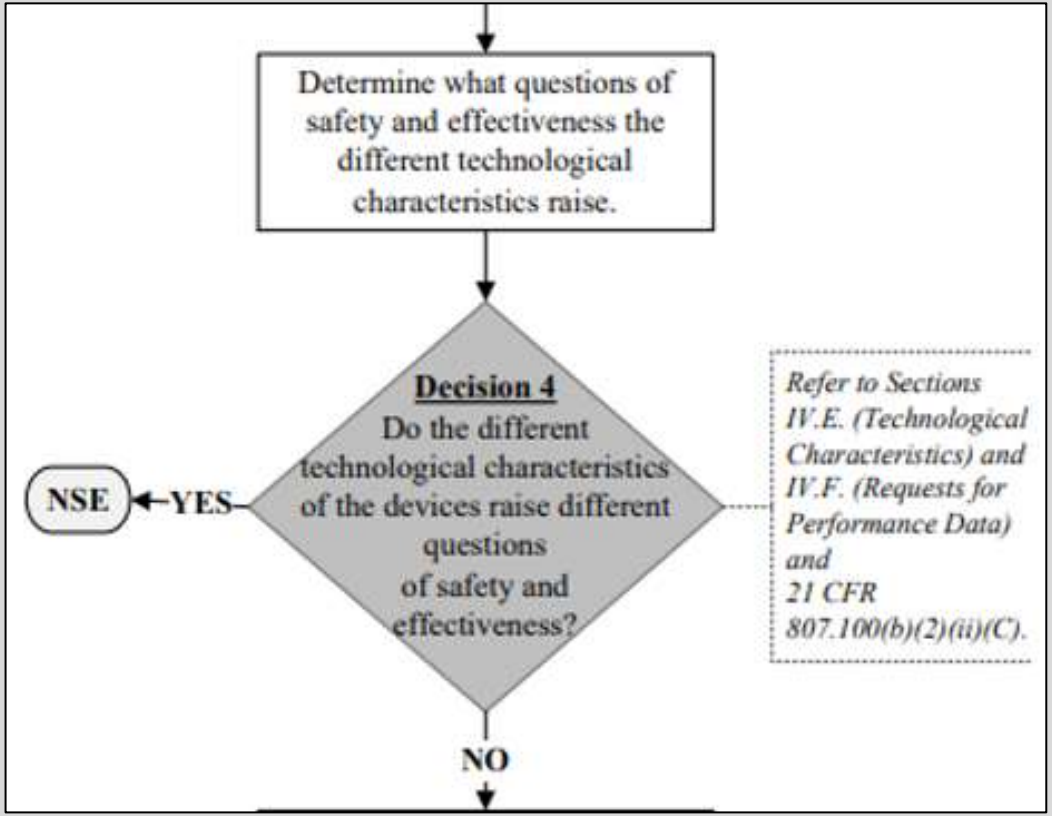
Serves as the basis for comparison:

Intended Use	Design
Materials	Performance
Safety	Effectiveness
Biocompatibility	Labeling
Standards	Energy used or delivered

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification

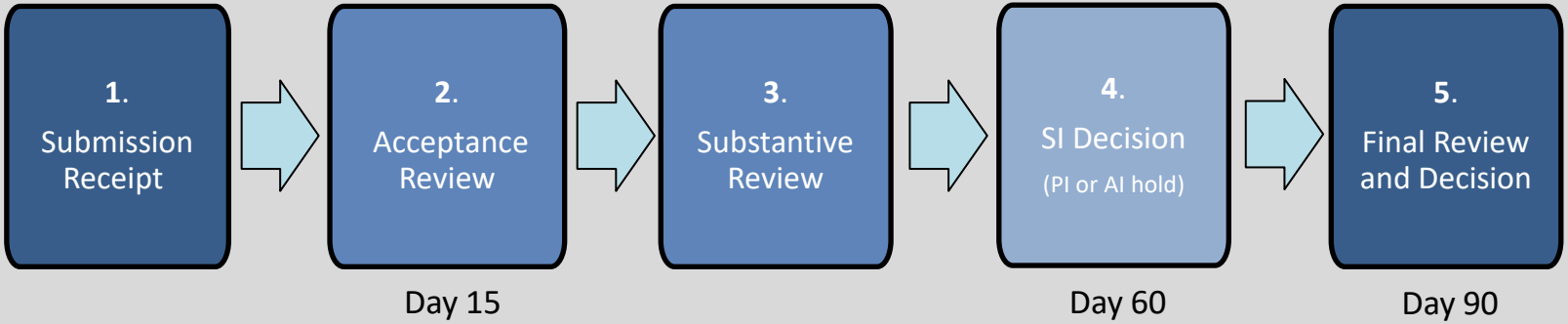


Decision Point #4



High-Level Process Overview

510(k) Submission Core Process



Acronyms:
LR = Lead Reviewer
SI = Substantive Interaction
PI = Proceed Interactively
AI = Additional Information

❖ Days are calendar days

Step #1: Submission Receipt

- FDA receives your Submission
- Information entered into FDA tracking system and assigned submission number
- Acknowledgement email issued to official correspondent
- Review clock begins

Step #2: Acceptance Review

- **Administrative review** checking that major topics have been addressed
- If **accepted**, the file moves on to the next step
- If **not accepted**, submitter receives notification and will have 180 calendar days to address
  - 15 day review clock (starts over at Day 0 with re-submission)

Step #3: Substantive Review

- Content of your 510(k) is reviewed for substantial equivalence to a predicate device
- Approximately 60 day review clock

Step #4: Substantive Interaction (SI)

- Typically results in either proceeding interactively (PI) or an Additional Information (AI) hold
- PI occurs immediately after SI and lasts for the remainder of the review clock

Additional Information (AI) Hold

- Review team has determined that your file needs additional information
- Information is requested through deficiencies listed in your **AI Hold letter**
- You have 180 calendar days to address deficiencies

Step #5: Final Review and Decision

- Review team reviews information provided during PI or AI Hold stages
- Typically takes around 30 days
- A final decision is issued

Q-Submissions and 510(k)s

- Q-Submissions can be useful for 510(k) submissions
- Opportunity to interact with the FDA prior to 510(k) submission or while your file is on AI hold
- Get feedback on your experimental plans or protocols
- IT’S FREE!!

eSTAR

electronic

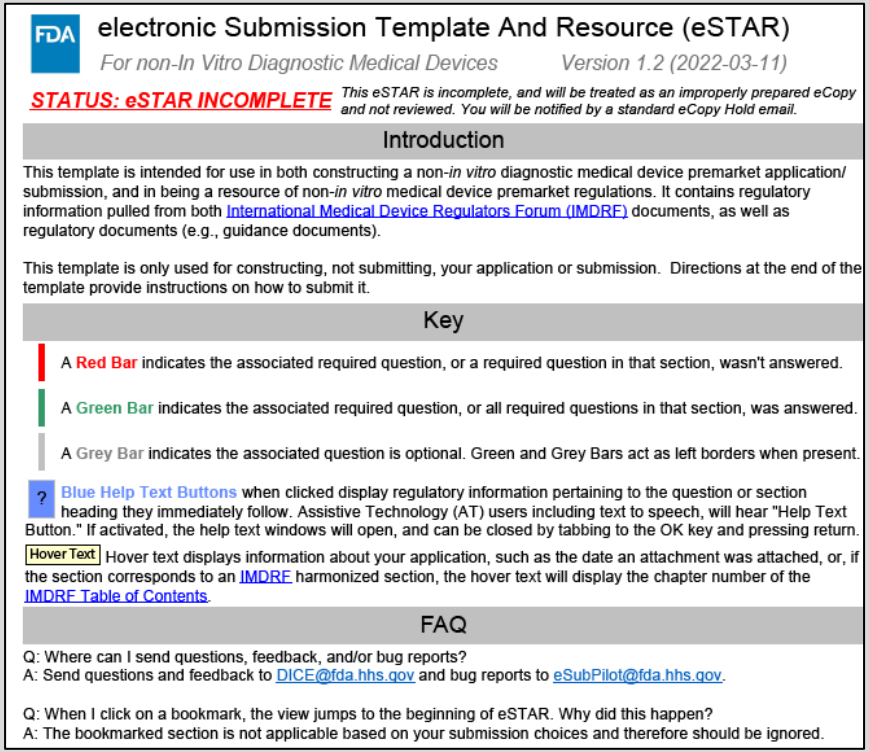
Submission

Template

And

Resource

- Dynamic PDF submission template
- Contains resources for submission preparation
- Starting October 1, 2023, all 510(k) submissions must use eSTAR, unless exempted



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices *Version 1.2 (2022-03-11)*

STATUS: eSTAR INCOMPLETE *This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified by a standard eCopy Hold email.*

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both International Medical Device Regulators Forum (IMDRF) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A Red Bar indicates the associated required question, or a required question in that section, wasn't answered.

A Green Bar indicates the associated required question, or all required questions in that section, was answered.

A Grey Bar indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an IMDRF harmonized section, the hover text will display the chapter number of the IMDRF Table of Contents.

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Tips from a Lead Reviewer

Tips from a Lead Reviewer

- Review team may be made up of engineers, scientists and clinicians
- We're often excited to see new devices
- But, we're also tasked with ensuring that your device is safe and effective for patients

Tips from a Lead Reviewer

Tip #1: Keep in mind that your file will be reviewed by a human

- Keep your file organized
- Must be submitted in English

Tips from a Lead Reviewer

Tip #2: Check your email often

- Work to get you a decision as soon as possible, within MDUFA deadlines
- Sometimes, this makes it necessary to issue communications during non-business hours
- Don’t forget about your spam folder!

Knowledge Check #1

True or False:

A new (subject) device need to be “identical” to the predicate device.

Knowledge Check #2

True or False:

A Q-Submission is a way to get FDA feedback regarding your 510(k).

Resources

Slide Number	Cited Resource	URL
5	510(k) Submission Programs	https://www.fda.gov/medical-devices/premarket-notification-510k/510k-submission-programs
6-8	Device Advice: How to Find and Effectively Use Predicate Device	www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices
6-8	Device Advice: Premarket Notification 510(k)	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k
6-8	CDRH Learn: Premarket Notification 510(k) Section: Under title “how to study and market your device”	www.fda.gov/training-and-continuing-education/cdrh-learn

Resources

Slide Number	Cited Resource	URL
7	Determination of Intended Use for 510(k) Devices - Guidance for CDRH Staff (Update to K98-1)	www.fda.gov/regulatory-information/search-fda-guidance-documents/determination-intended-use-510k-devices-guidance-cdrh-staff-update-k98-1
19	Voluntary eSTAR Program	https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
All	Guidance: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
All	21 CFR 807-Subpart E - Premarket Notification Procedures	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5

Questions

U.S. FOOD & DRUG
ADMINISTRATION