

The 510(k) Program: Overview and Updates

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

May 29, 2024

Kathryn J. De Laurentis, PhD

Policy Analyst

Office of Regulatory Programs

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration

So, You Want to Market a Medical Device

510(k)



Comparative Process

**Most Common
Pathway**



Learning Objectives

Describe Updates to 510(k) Policy

Summarize the 510(k) Program

Explain How to Interact with FDA Before/During the Review

Discuss Best Practices/Tips for Preparing eSTAR

510(k) Policy Updates

- eSTAR for all 510(k)s - **Mandatory October 1, 2023**
- Submit 510(k) eSTAR through CDRH Customer Collaboration Portal (CDRH Portal) - **Mandatory October 1, 2023**
- eSTAR available for nIVD and IVD
- Submit and track progress for 510(k) via CDRH Portal
- Conversion hold available with Special to Traditional 510(k) conversion (CNVT) during Technical Screening (TS) Phase
 - Changes that are not appropriate for a Special 510(k)

electronic Submission Template And Resource

510(k) Program Overview

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.

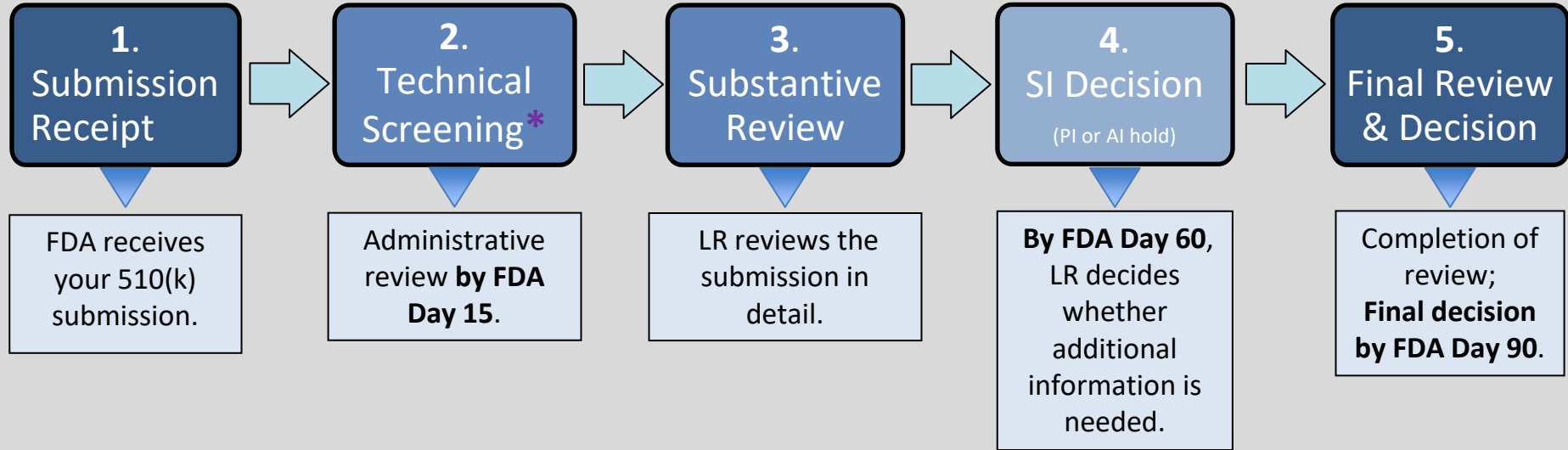


U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

510(k) Guidance Scope

- 510(k) Decision Making Process
- 510(k) Review Standard
 - Predicate Device
 - Intended Use
 - Technological Characteristics
 - Additional Information Requests
- Also check for device-specific guidance and Cross-cutting guidance docs, for example:
 - Contact Lenses Guidance
 - Sterility Guidance, Biocompatibility Guidance

510(k) Process Overview



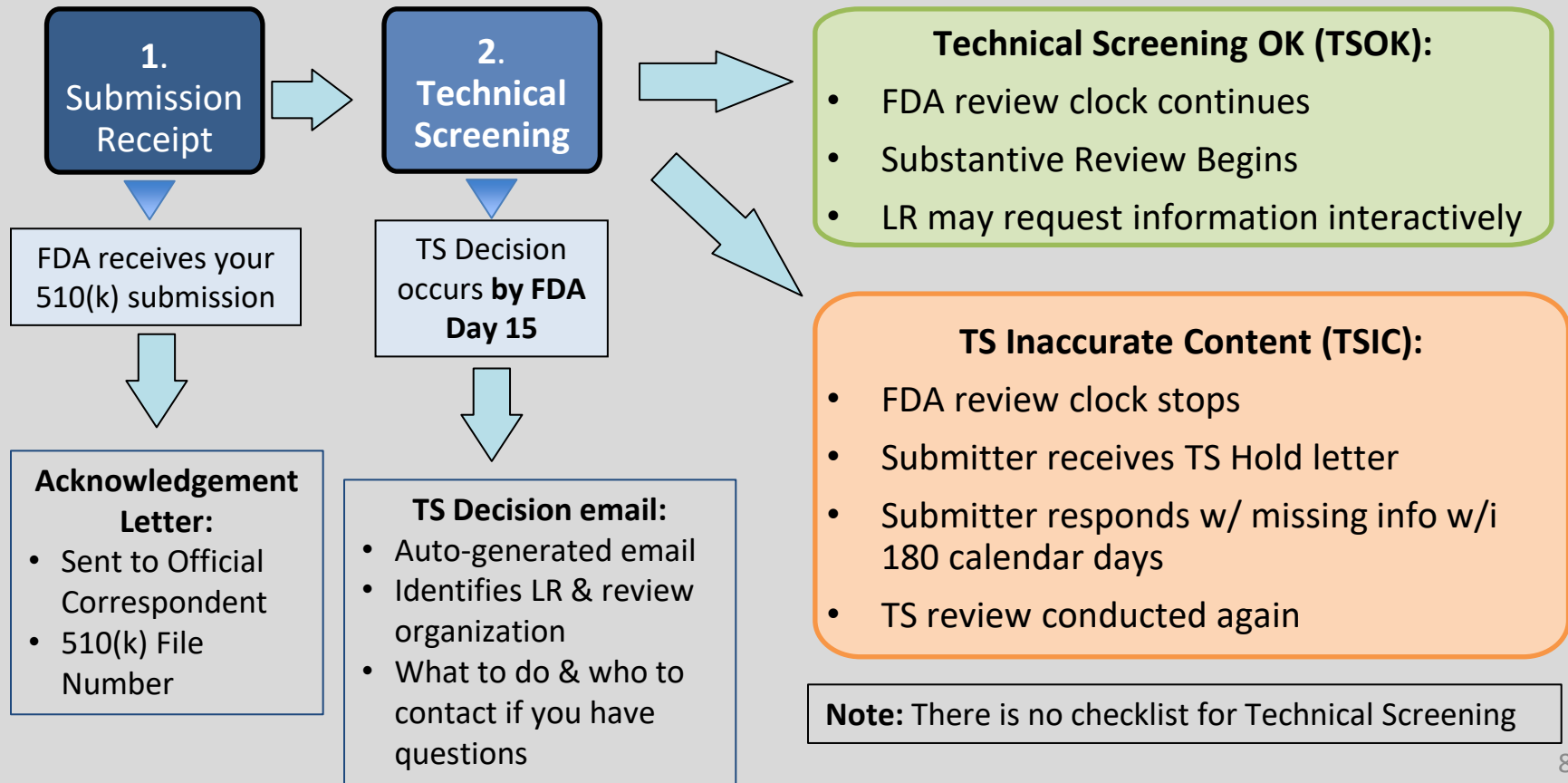
Acronyms:

TS = Technical Screening
 LR = Lead Reviewer
 SI = Substantive Interaction
 PI = Proceed Interactively
 AI = Additional Information

*Verification that:

- Responses are accurate, and
 - There is at least one relevant attachment per attachment type question
- Completeness check to ensure template is filled out correctly

Technical Screening Overview



Technical Screening Definitions

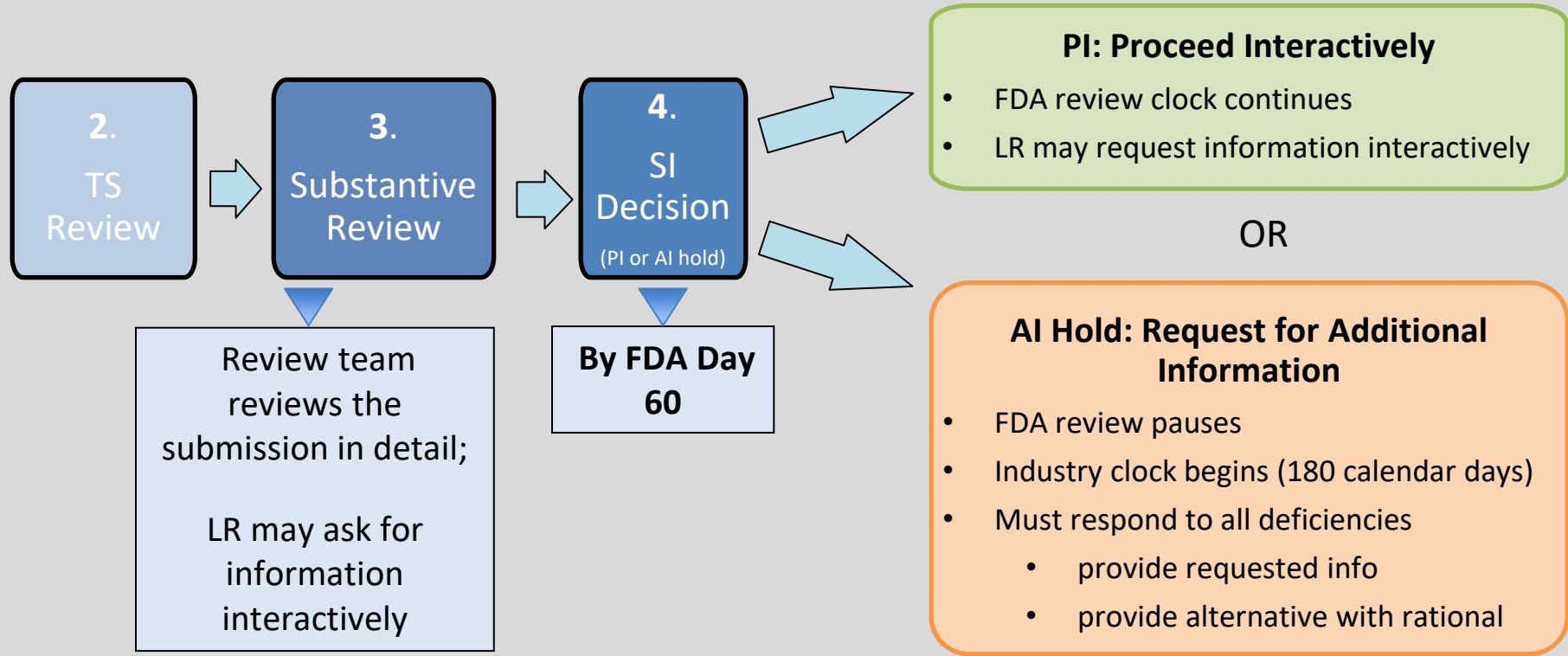
Inaccurate Response

Information provided within the eSTAR PDF, but not in any attachments, that is inconsistent, contradictory, or false based on the compilation of the rest of the information in the submission.

Irrelevant Attachment

An attachment within eSTAR that does not address any of the requests of the question to which it was attached. If an attachment cannot be opened or is not legible, it is automatically considered irrelevant.

Substantive Review Overview



Knowledge Check

The Technical Screening for a 510(k) is conducted:

- A. Only after getting hints from Wile E. Coyote**
- B. To ensure the eSTAR template is filled out correctly**
- C. To assess whether there are inaccurate responses and irrelevant attachments in the eSTAR template**
- D. On Traditional, Special, and Abbreviated 510(k)s**
- E. Before the substantive review**
- F. All of the above**
- G. B through E**

Interacting with CDRH

Inquiry Processes

Should be submitted BEFORE 510(k)

Q-Submission: Pre-Submission

- An opportunity to obtain FDA feedback **prior** to IDE or marketing submission (example inquiries: study design, applicable standards)

513(g):

- Device Determination: Is it a medical device?
- Device Classification: How CDRH regulates it?
 - Class based on risk: I/II/III

Communication Options:

During Review

- Q-Submission: Submission Issue Request (SIR)
 - An opportunity to obtain FDA feedback regarding an AI request
 - Discuss proposed approach to address issues
 - Facilitate resolution or clarify issues to fully address outstanding questions in formal responses

Communication Options:

During Review

- **Day-10 Call: Brief Clarification**
 - Teleconference: within 10 days after issuance of AI letter
 - Confirmation that submitter understands deficiencies in letter
 - Address clarification questions pertaining to deficiencies in letter
 - Can be used to determine whether a Submission Issue Request is needed

Communication Options:

During Review

- **Least Burdensome (LB) Flag: Confirm LB Adherence**
 - Opportunity to address potential LB discrepancies in AI letter
 - Discuss whether deficiency adheres to least burdensome principles
 - Request a discussion and review with a manager

Responding to Interactive Requests



- Submit documentation via email alone (copy DocMan, e.g., KXXXXXX@docs.fda.gov)
 - No need to submit eSTAR, just the requested information
- IF there are a lot of interactive information requests, submit an amended eSTAR*
 - Revise the current eSTAR; add new/revise attachments in the appropriate section(s)
 - Submit via the CDRH Portal
- Amended eSTAR Example: eSTAR converted to Traditional 510(k) post TS (not placed on conversion hold)
 - Revise current eSTAR as a Traditional 510(k)
 - Select Additional Information button (page 2)
 - Amendment/AI Response section, **select “Yes”**

Revise Current eSTAR

*What if you want to ...



Amend eSTAR but there are no additional requests for information (e.g., conversion hold (CNVT))

→ Amendment/AI Response section, **Enter “No”**

Show Application Introduction	
Application Type (Choose Abbreviated if you are submitting a Safety & Performance based submission.)	<input checked="" type="radio"/> Traditional <input type="radio"/> Abbreviated <input type="radio"/> Special
Show Application Type Introduction	
Application Sub-Type (Modify the Original eSTAR when responding to Additional Information requests. See Help Text)	<input type="radio"/> New Application/Submission <input checked="" type="radio"/> Additional Information
Please enter the parent application/submission number.	

Additional Information Response	
Is this a response to an Additional Information request?	No
Provide a summary of the unsolicited information you are providing.	

Responding to TS/AINN

Show Application Type Introduction

Application Sub-Type

(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)

☐ New Application/Submission
 ☒ **Additional Information**

?

Please enter the parent application/submission number.

Kxxxxxx



- Revise current eSTAR
- Fill out Additional Information section as instructed
- Include the reviewer's request & page/section numbers where response can be found
- Provide a rationale for why a missing item is not relevant

Additional Information Response

Is this a response to an Additional Information request?

Yes

Additional Information

Changes that are necessary to resolve deficiencies should be made in the respective section. For example, if additional Sterilization information will be provided to resolve a deficiency, this documentation should be added to the Sterilization documentation that is already present. If attachments need to be updated, remove the old attachments and replace them with the new attachments (be sure to give new attachments a different name in comparison to the old attachments to ensure they are distinguished). Data that are typed in can also be modified. If you need to respond to subsequent Additional Information requests, you should replace the deficiencies below with those from the latest Additional Information request when responding. Although previously submitted data and attachments will remain in the FDA database, old data superseded by new data will not be considered the final data in our final review.

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).

Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).

Add Response

Delete Response



- Skip a question/response
- Ignore revisions to an attachment

Knowledge Check

What would you do?

I think one of the deficiencies asked is not relevant for my device.

The best practice is:

- A. Email the CDRH Ombudsman and OHT Director to get their opinion.**
- B. Email the Lead Reviewer and ask for a Day-10 call to clarify the rationale for the deficiency. I can escalate and throw the LB Flag if I still disagree.**
- C. Respond to the deficiency with the requested info.**

Preparing 510(k) eSTAR Content

Submit a 510(k) → eSTAR

- electronic Submission Template And Resource
- Dynamic PDF template for assembling submission
 - eSTAR is a submission preparation template, NOT a new type of 510(k)
- Guides the medical device applicant through the process of preparing a comprehensive medical device submission
 - Contains automation, guides, integrated databases, policies and procedures in a single package
- 510(k) eSTAR templates (nIVD, IVD) posted online

**Mandatory –
eSTAR for all 510(k)s
Submit via CDRH Portal**

Prepare Based on Specifications

Inaccurate (Inconsistent) Response → TS Hold



Consistency with device specifications and indications

Device Description

Listing of Device(s) ?

Add Device

Provide the Product Trade Name and (optionally) Model Number/Name

Trade Name

Model Number/Name

Delete Device

General Device Characteristics

Is the device life-supporting or life-sustaining? ?

Are there any direct or indirect tissue contacting components? ?

No ?

Biocompatibility ?

Based on the answer provided in the Device Description section, no biocompatibility information is needed.

“Yes” opens Biocompatibility section

- Responses should correspond with the device description and specifications
- Fill out all sections to agree with the Indications for Use (IFU)
- Responding accurately will open the appropriate section later in eSTAR

Double-Check Consistency

Inaccurate (Inconsistent) Response → TS Hold

Classification	
<p>Add a primary product code and any associated product codes below. You may type in the primary product code directly (only the product code field is required) or you may filter down by choosing first a medical specialty, regulation, then product code. If a device specific guidance is available for the product code, the guidance name and web link will be displayed. Use the Product Classification Website resource in the help text to obtain information about your product code and check the regulation text for any special controls that need to be considered (e.g., PAE and 21 CFR 890.3450).</p>	
Medical Specialty	Dental
Regulation	872.4200 - Dental handpiece and accessories
Product Code	EFB (Class 1) - Handpiece, Air-Powered, Dental
<p>The primary product code of your device indicates a device specific guidance document is available to aid you in preparing a comprehensive submission. The document entitled "Guidance Document on Dental Handpieces" is available at the link below. If you have any questions about applicability of this guidance, please contact the CDRH review Office.</p> <p>https://www.fda.gov/regulatory-information/search-fda-guidance-documents/dental-handpieces-premarket-notification-510k-submissions</p>	
Associated Product Code(s)	EGS

- If instructions call out another section - match responses between all sections
- Check that responses are selected consistently with information in text boxes

Guidance provided in Classification section



Consistent Responses

Guidance and Special Controls Adherence
<p>In the text box below, please address or provide information demonstrating compliance with any applicable special controls, requirements in a device specific classification regulation, or adherence to device specific guidance recommendations for the Performance Testing. For each specific special control, regulation, or guidance recommendation applicable to your device: Please list the special control, regulation, or recommendation and cite the attachment(s) and page number(s) where it was addressed. Please use the primary product code you provided in the Classification section above to determine whether a device specific guidance exists for your device. Type "N/A" if no device specific guidance, regulation, or special controls exist for your device type. If you type "N/A," and special controls, a regulation, or a device specific guidance exists that requests information covered by this review section, the time-line for review of your file may be affected.</p>
N/A

Utilize Help Text

Inaccurate Response → TS Hold



Consistency
with Help Text

Device Description

Listing of Device(s) ?

Add Device

Provide the Product Trade Name and (optionally) Model Number/Name

Trade Name

Model Number/Name

Delete Device

Assay and Instrument Information

Device(s) in this submission include

(If this is a software only submission, please see Help Text)

☐ Instrument
 ☒ Assay

Is there an instrument associated with your assay(s)?

?

?

Help Text

- Use Help Text to assist eSTAR responses to indicate what is to be cleared in the submission
- Select all appropriate items
- Fill out each section accurately

Please consider your entire test system and select the content that needs premarket authorization in this submission. For example, if there is an instrument associated with your assay, and FDA has never reviewed the instrument information before, you should select both instrument and assay options here.

If this is a software only submission, please select "Instrument" as your device type.

If part of your test system has been previously cleared or granted by FDA, please reference FDA's guidance entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" to determine whether the previously cleared or granted device should be included in this submission.

Resources

[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](#)

Check Attachments

Irrelevant Attachment → TS Hold

Device Characteristics Comparison

Test		Wingdings 1	Wingdings 2	Wingdings 3
a	A	☺	☹	☺
b	B	☺	☹	☺
c	C	☺	☹	☺
d	D	☺	☹	☺
e	E	☺	☹	☺
f	F	☺	☹	☺
g	G	☺	☹	☺
h	H	☺	☹	☺
i	I	☺	☹	☺
j	J	☺	☹	☺
k	K	☺	☹	☺
l	L	☺	☹	☺
m	M	☺	☹	☺
n	N	☺	☹	☺
o	O	☺	☹	☺
p	P	☺	☹	☺
q	Q	☺	☹	☺
r	R	☺	☹	☺
s	S	☺	☹	☺

- Non-English document with no translation provided
- Blank document
- Document can't be opened

Check attachments:

- > Uploaded as intended
- > Include content that is appropriate for that section
- > Content is consistent with the file name

Consistency between eSTAR responses and attachments



Knowledge Check

Which of the following statements is **NOT** true?

- A. You must submit a new 510(k) using eSTAR format.
- B. If your submission is not accepted for review (TS Hold), you will always receive an AI type letter (TSIC letter).
- C. If your submission is not accepted for review (TSIC), you will always receive the checklist and the RTA addendum.
- D. You can submit and track your submission in the CDRH Portal.

Final Notes and Resources

Resources



Slide Number	Cited Resource	URL
6	510(k) Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
13, 14	Q-Submission	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
13	513(g)	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic
13	Device Determination	www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
13	Device Classification	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device

Other Resources



Resource	URL
FDA Guidance: 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
FDA Guidance: Electronic Submission Template for Medical Device 510(k) Submissions	www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-submission-template-medical-device-510k-submissions
FDA Guidance: Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions	www.fda.gov/regulatory-information/search-fda-guidance-documents/developing-and-responding-deficiencies-accordance-least-burdensome-provisions
FDA Guidance: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals
FDA Guidance: 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

Other Resources



Resource	URL
eSTAR Program (Device Advice)	www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program
CDRH Portal (FDA Web – Resources for You)	www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal

Summary

- The 510(k) Program has several updates
- An applicant has options to communicate with CDRH before and during 510(k) review
- The 510(k) Program has procedures for responding to interactive and TS/AINN requests for information
- Some best practices may help with eSTAR content development

Questions



Your Call to Action

Use the available tools and tips when communicating with CDRH and developing your next 510(k) eSTAR!