

eSTAR: CDRH's PDF Template for Premarket Submissions

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Learning Objectives

- Define what is eSTAR
- Identify how to download eSTAR
- Describe how to enter data into eSTAR
- Describe how to submit eSTAR to FDA
- Define the eSTAR review timeline

What is eSTAR?

electronic Submission Template And Resource

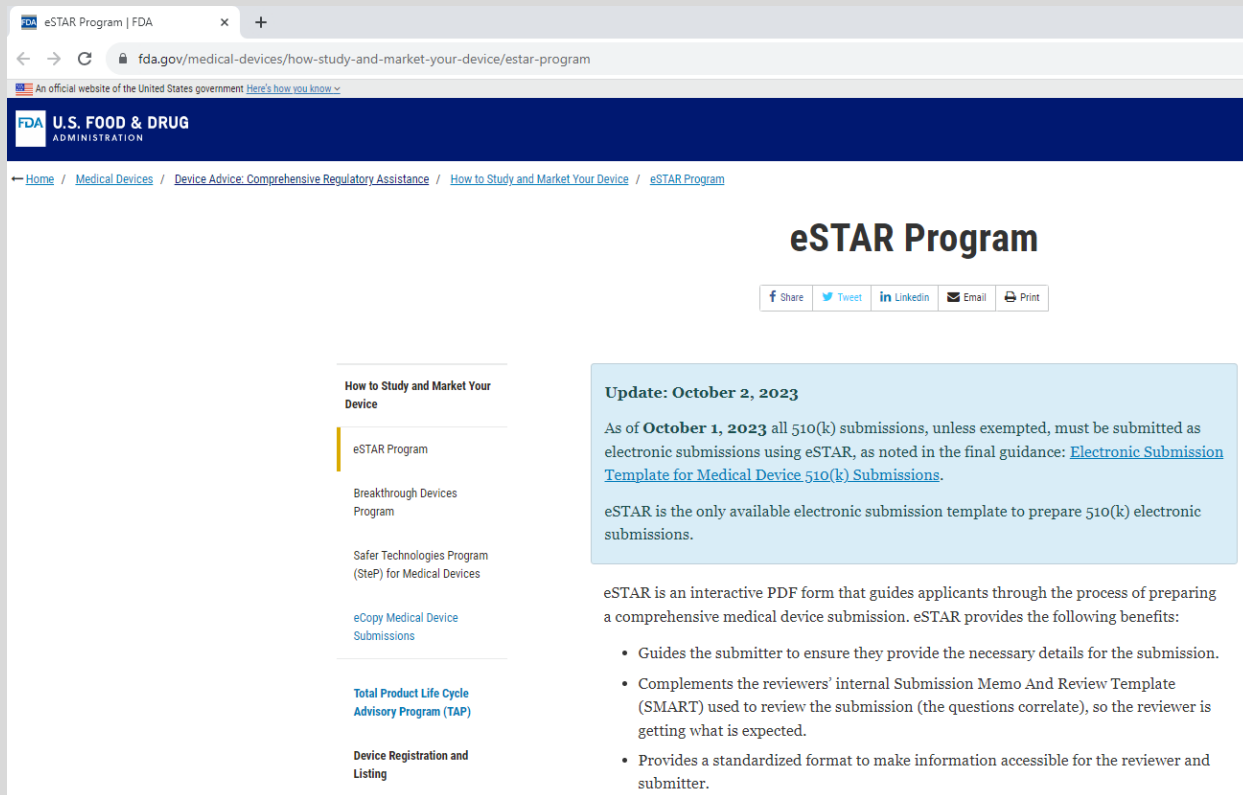
- Dynamic PDF submission template
- Contains resources for submission preparation

Why eSTAR?

- Enhances submission quality
- Improves CDRH's premarket review efficiency

How to Download eSTAR

Download eSTAR?



The screenshot shows the FDA's eSTAR Program page. The browser address bar displays the URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>. The page header includes the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". Below the header is a navigation breadcrumb: [Home](#) / [Medical Devices](#) / [Device Advice, Comprehensive Regulatory Assistance](#) / [How to Study and Market Your Device](#) / [eSTAR Program](#). The main heading is "eSTAR Program". To the right of the heading are social media sharing buttons for Facebook, Twitter, LinkedIn, Email, and Print. On the left side, there is a sidebar with a "How to Study and Market Your Device" section containing links to "eSTAR Program", "Breakthrough Devices Program", "Safer Technologies Program (SteP) for Medical Devices", "eCopy Medical Device Submissions", "Total Product Life Cycle Advisory Program (TAP)", and "Device Registration and Listing". The "eSTAR Program" link is highlighted. The main content area features an "Update: October 2, 2023" section stating that as of October 1, 2023, all 510(k) submissions must be submitted electronically using eSTAR, with a link to the "Electronic Submission Template for Medical Device 510(k) Submissions". Below this, it states that eSTAR is the only available electronic submission template for 510(k) submissions. Further down, it describes eSTAR as an interactive PDF form that guides applicants through the submission process and lists three benefits: guiding the submitter, complementing the SMART template, and providing a standardized format.

eSTAR Program

Share Tweet LinkedIn Email Print

How to Study and Market Your Device

- eSTAR Program**
- Breakthrough Devices Program
- Safer Technologies Program (SteP) for Medical Devices
- eCopy Medical Device Submissions
- Total Product Life Cycle Advisory Program (TAP)
- Device Registration and Listing

Update: October 2, 2023

As of **October 1, 2023** all 510(k) submissions, unless exempted, must be submitted as electronic submissions using eSTAR, as noted in the final guidance: [Electronic Submission Template for Medical Device 510\(k\) Submissions](#).

eSTAR is the only available electronic submission template to prepare 510(k) electronic submissions.

eSTAR is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission. eSTAR provides the following benefits:

- Guides the submitter to ensure they provide the necessary details for the submission.
- Complements the reviewers' internal Submission Memo And Review Template (SMART) used to review the submission (the questions correlate), so the reviewer is getting what is expected.
- Provides a standardized format to make information accessible for the reviewer and submitter.

Download eSTAR?

Current eSTAR Versions¹:

eSTAR PDF Template (you MUST right-click and download)	This eSTAR template may be used to submit to CDRH:	Content is approved for collection under OMB numbers ² :
Non-In Vitro Diagnostic eSTAR Version 4	510(k) and De Novo medical device submissions for Non-In Vitro Diagnostic devices	0910-0120, 0910-0844
In Vitro Diagnostics eSTAR Version 4	510(k) and De Novo medical device submissions for In Vitro Diagnostic devices	0910-0120, 0910-0844
Early Submission Requests eSTAR (PreSTAR) Beta Version	Pre-Submissions (a type of Q-Submission) for Non-In Vitro and In Vitro Diagnostic devices. ³	0910-0756

How to Enter Data into eSTAR

Tip #1 for eSTAR Data Entry

- DO
 - Use Adobe Acrobat Pro
 - May use FoxIt PDF Reader or PDF-XChange Editor
- DON'T
 - Don't use web browsers
 - Don't use Adobe Acrobat Reader

Tip #2 for eSTAR Data Entry

Read and follow instructions on page 1 of eSTAR

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 an *in vitro* medical device premarket application/submission, and in being a resource of *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.

Understand eSTAR Before Data Entry

How to Enter Data into eSTAR

Application Purpose

(Choose 510(k) if you are submitting a Dual 510(k) and CLIA Waiver by Application.)



- ☒ Premarket Notification 510(k)
- ☐ De Novo
- ☐ Premarket Application PMA

?

Show Application Introduction

Application Type

(Choose Abbreviated if you are submitting a Safety & Performance based submission.)



- ☒ Traditional
- ☐ Abbreviated
- ☐ Special

Show Application Type Introduction

Is this a Dual 510(k) and CLIA Waiver by Application (Dual Submission)?



?

Application Sub-Type

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



- ☐ New Application/Submission
- ☐ Additional Information

?

How to Enter Data into eSTAR

Cover Letter / Letters of Reference

Add Attachment

Attach your Cover Letter

Add attachment

?

Open Attachment

Cover Letter.docx

Delete Attachment

Add Attachment

Attach any Letters of Reference

?

Applicant Information

?

Contact

Title

Mr.

▼

Last Name

Smith

Enter Text

First Name

John

Email

John.Smith@ABC.com

Phone Number

(123) 456-7890

Occupation Title

Regulatory Affairs Specialist

How to Enter Data into eSTAR

Is the device life-supporting or life-sustaining?	No	?
Are there any direct or indirect tissue contacting components?	No	?
Does the device use software/firmware?	Yes	?
<ul style="list-style-type: none"> Is the device, or does it contain, digital health technology? 	Yes	?
<ul style="list-style-type: none"> Please check the attributes that are applicable to your device. 	<input type="checkbox"/> Cloud Communication <input checked="" type="checkbox"/> Network connection (active or not) <input checked="" type="checkbox"/> Wireless communication in any form <input type="checkbox"/> USB/serial ports/removable media <input checked="" type="checkbox"/> Software upgrades (this includes patches) <input type="checkbox"/> None of the above	?

Choose from
drop down lists

Click Checkbox

Tip #3 for eSTAR Data Entry

Fill in the template from beginning to end

Show Application Introduction

Application Type

(Choose Abbreviated if you are submitting a Safety & Performance based submission.)



☒ Traditional

☐ Abbreviated



☐ Special

How to Enter Data into eSTAR



General Device Characteristics		
Is the device life-supporting or life-sustaining?	No	?
Are there any direct or indirect tissue contacting components?	No	?
Does the device use software/firmware?	Yes	?
• Is the device, or does it contain, digital health technology?	Yes	?
• Please check the attributes that are applicable to your device.	<input type="checkbox"/> Cloud Communication <input checked="" type="checkbox"/> Network connection (active or not) <input checked="" type="checkbox"/> Wireless communication in any form <input type="checkbox"/> USB/serial ports/removable media <input checked="" type="checkbox"/> Software upgrades (this includes patches) <input type="checkbox"/> None of the above	?
Is the device or a component packaged as sterile?	No	?
The device/system uses or is... (choose all that apply)	<input checked="" type="checkbox"/> a single use device(s), non-sterile or packaged as sterile <input type="checkbox"/> a single use device(s), terminal/end user sterilized <input type="checkbox"/> a reusable single patient use device(s) <input type="checkbox"/> a reusable multi-patient use device(s)	?
Is the device electrical (battery or wall powered)?	Yes, it is mains powered only.	?
• Does the device/system include wireless technology?	Yes	?

→ Biocompatibility

→ Software/firmware

→ Cybersecurity

→ Sterility

→ Reprocessing

→ EMC

→ Wireless

Tip #4 for eSTAR Data Entry

Be sure the eSTAR status changes to “eSTAR COMPLETE” once you finish



electronic Submission Template And Resource (eSTAR)

For In Vitro Diagnostic Medical Devices

Version 4.3 (2023-10-02)

→ **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.



electronic Submission Template And Resource (eSTAR)

For In Vitro Diagnostic Medical Devices

Version 4.3 (2023-10-02)



STATUS: eSTAR COMPLETE

How to Enter Data into eSTAR

Verification

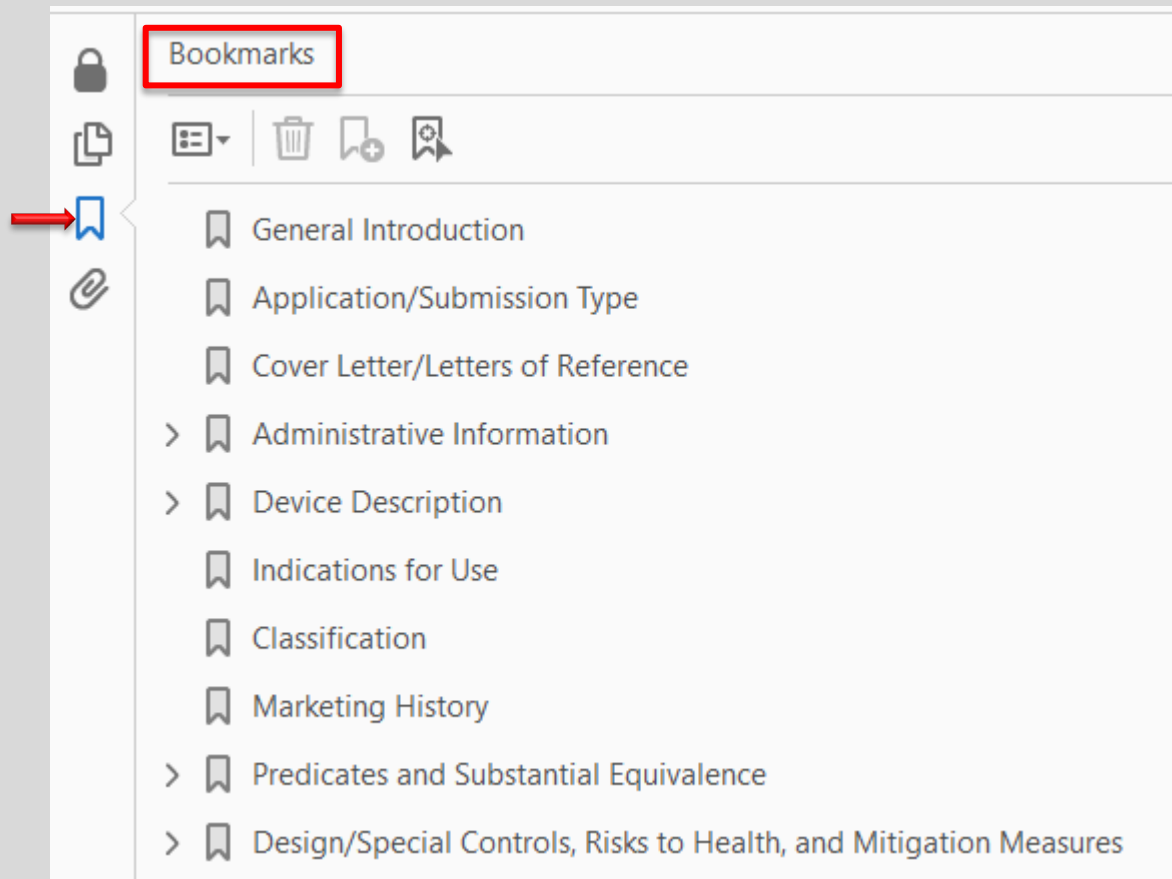
The following sections are complete:

Cover Letter / Letters of Reference
 Administrative Information
 Indications for Use
 Classification
 Predicates and Substantial Equivalence
 Biocompatibility
 Software/Firmware & Cybersecurity/Interoperability
 EMC, Wireless, Electrical, Mechanical, and Thermal Safety
 References
 Additional Information Response

The following sections are incomplete:

Application/Submission Type
 Device Description
 Labeling
 Reprocessing, Sterility, and Shelf-Life
 Performance Testing
 Administrative Documentation

Use Bookmarks as Table of Contents



Unique Features in IVD eSTAR

- Dual 510(k)/CLIA Waiver Option
- Detailed Performance Testing List
- Labeling Requirements

Unique Features in IVD eSTAR

- 🔖 Performance Testing
 - 🔖 Analytical Performance
 - 🔖 Comparison Studies
 - 🔖 Clinical Studies
 - 🔖 Reference Range
 - 🔖 Animal Testing
 - 🔖 Accuracy
 - 🔖 Performance Testing Summary
 - 🔖 Guidance Adherence

IVD
vs.
nIVD

- 🔖 Performance Testing
 - 🔖 Bench Testing
 - 🔖 Animal Testing
 - 🔖 Clinical Testing
 - 🔖 Guidance Adherence

How to Submit eSTAR to FDA

How to Submit eSTAR

Delivery Directions

Please submit this eSTAR PDF for review using the [CDRH Portal](#) unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to [Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products](#) for information on how to submit to CBER through the [Electronic Submission Gateway](#).

<https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal>

How to Submit Responses to FDA's Additional Information Requests

- Either eCOPY (if original 510(k) was submitted before 10/1/2023) or eSTAR is acceptable
- If using eSTAR:

Show Application Type Introduction	
Application Sub-Type <i>(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)</i>	<input type="radio"/> New Application/Submission <input checked="" type="radio"/> Additional Information
Please enter the parent application/submission number.	<input type="text" value="K220000"/>

Additional Information Response

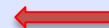


Is this a response to an Additional Information request?

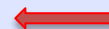
Yes

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 or Technical Screening holds, you should replace the deficiencies below with those from the latest Additional Information or Technical Screening 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

How to submit Additional Information (AI) responses

eSTAR Review Timeline

eSTAR Review Timeline

- eSTAR review timeline same as eCOPY
- Within 15 days Technical Screening (TS) to verify:
 - responses are accurate and
 - at least one relevant attachment per attachment-type question

Knowledge Check

Which type(s) of premarket submission can be prepared using eSTAR now?

- ☒ 510(k)
- ☒ De Novo
- ☐ PMA
- ☒ Pre-submission

Knowledge Check

Which of the following types of attachments are NOT acceptable to eSTAR?

- ☐ compressed file (e.g., .zip)
- ☐ macro-enabled file (e.g., .docm)
- ☐ executable file (e.g., .exe)
- ☒ All of the above

Summary

- Dynamic PDF submission template
- Uploading directly to CDRH Portal
- Review timeline same as eCOPY

Questions

