electronic Submission Template And Resource (eSTAR)

For Early Submission Requests Draft Version 0.1 (XXXX-XX-XX)

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

Introduction

This template is intended for use in constructing product submissions that are submitted before the premarket submission/application. This template is also intended to be a resource of medical device premarket regulations.

This template is only used for constructing, not submitting, your 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 and/or feedback?
A: Questions and feedback regarding this template can be sent to eSubPilot@fda.hhs.gov.

Q: What if I have several devices in one 510(k)?
A: When a question asks about a device, consider the question as it applies to any device within the submission.

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.

Q: Is eSTAR compatible with Mac computers?
A: Yes. However, Mac computers will add hidden dot files (e.g., ".Trashes") to thumb drives by default. These dot

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

0.1 (XXXX-XX-XX): Initial beta release.

Application/Submission Type

Take care in providing answers and data to all of the questions in your submission. Any false or misleading statements may be grounds for FDA to put the application on hold before the review commences. FDA may also put the application on hold if an English translation for any documentation provided is not included.

The content of this template complements the FDA reviewer's smart template used in reviewing submissions, and therefore this template will provide the reviewers what they are expecting. This may reduce the number of inconsistencies and omissions in your application/submission documents, and therefore the number of additional information requests the FDA may send to you.

Request for Feedback	(•) Request for Information (513g) ( ) Pre-Sub Written Feedback (Q-Sub)
Request for Determination	( ) Accessory Request - New Accessory (Q-Sub) ( ) Accessory Request - Existing Accessory (Q-Sub) ( ) Determination Meeting (Q-Sub) ( ) Agreement Meeting (Q-Sub) ( ) Expedited Programs Entrance Request (Q-Sub) ( ) Study Risk Determination (Q-Sub)
Request for Meeting	( ) Expedited Prog Interaction Submission (Q-Sub) ( ) Pre-Sub Meeting (Q-Sub) ( ) Informational Meeting (Q-Sub) ( ) PMA 100-Day Meeting (Q-Sub) ( ) Submission Issue Request (Q-Sub)

Show Application Introduction

Application Sub-Type	(•) New Application/Submission ( ) Additional Information

Cover Letter / Letters of Reference

Add Attachment	Attach your Cover Letter	?
Add Attachment	Attach any Letters of Reference	?

Applicant Information ?

Contact

Title | Last Name | First Name

Email | Phone Number

Occupation Title

Company

Company Name

Address - Line 1

Address - Line 2

City | State | Zip | Country: United States

Add Correspondent/Consultant

Primary Correspondent/Consultant Information

Contact

Title | Last Name | First Name

Email | Phone Number

Occupation Title

Company

Company Name

Address - Line 1

Address - Line 2

City | State | Zip | Country: United States

Add Correspondent/Consultant | Delete Correspondent/Consultant

Product Description

Listing of Product(s)

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

Trade Name	Model Number/Name	Delete Product

In Vitro Diagnostic Assay and Instrument Information

Product(s) in this submission include	☐ Instrument (IVD) ☐ Assay (IVD) ☐ Neither, product is not an IVD

General Product Characteristics

Is the product a General Wellness product?	
Does the product meet the definition of a device?	
Is the product subject to the Intent to Exempt guidance?	
Is the product life-supporting or life-sustaining?	
Are there any direct or indirect tissue contacting components?	Yes
• Is the product or a component an implant?	
Does the product use software/firmware?	Yes
• Is the product, or does it contain, digital health technology?	Yes
• Is the product a mobile medical app or software as a medical device?	
• Please check the attributes that are applicable to your device.	☐ Cloud Communication ☐ Network connection (active or not) ☐ Wireless communication in any form ☐ USB/serial ports/removable media ☐ Software upgrades (this includes patches) ☐ None of the above
Is the product or a component packaged as sterile?	
The product/system uses or is... (choose all that apply)	☐ a single use device(s), non-sterile or packaged as sterile ☐ a single use device(s), terminal/end user sterilized ☐ a reusable single patient use product(s) ☐ a reusable multi-patient use product(s)
The environment of use of the product/system includes... (choose all that apply)	☐ Professional Healthcare Facility ☐ Home Environment ☐ Magnetic Resonance (MR) Environment ☐ Transport (Ambulatory) Environment ☐ Other Environment
Is the product a combination product?	Yes

• If a Request for Designation (RFD) number exists, please provide the RFD number that established that the device or combination product being submitted here was assigned to CDRH.	
Is the product electrical (battery or wall powered)?	Yes, it is mains powered only.
• Does the product/system include wireless technology?	
Please check the attributes that are applicable to your product. If none apply, keep all unchecked.	☐ Medical Counter Measures Device ☐ Nanotechnology ☐ Reprocessed Single Use Device ☐ Animal-Derived Material(s)

Description

Please provide a Product Description Summary below, and ensure it includes an explanation of how the product functions, the scientific concepts that form the basis for the product, and the significant physical and performance characteristics of the product, such as product design, material used, and physical properties.

Add Attachment	Comprehensive Product Description and Principles of Operation Documentation
Add Attachment	Product Pictures, Illustrations, Schematics, and/or Diagrams. Attach a justification if the product does not have a physical form.

Accessories

Is the product intended to be marketed with accessories?	Yes
Add Accessory	List all of the accessories to be marketed with the subject device.

Please include a description of each accessory (see help text for the information we request be included). Please also provide the submission number if the accessory was previously cleared, granted or approved (or a statement that it was not).

Add Attachment	Please attach Accessory Pictures, Illustrations, Schematics, and/or Diagrams

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Submission Number *(if known)*

Device Name

Indications for Use *(Describe)*

Hover over each field on this page to view help text. It is recommended that you also include age, sex, gender, race and/or ethnicity information for which your device(s) is indicated in your Indications for Use, if applicable.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Classification

Select your proposed classification for the subject device, and in the blank field below, provide a justification for why it should be so classified. You may type in the proposed product code directly, 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). ?

Medical Specialty	
Regulation	
Product Code	
Associated Product Code(s)	?

Justification for Classification

Labeling

Please submit proposed labels, labeling, and advertisements sufficient to describe the product, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings may be supplied. We also strongly recommend you consult standard AAMI ANSI ES60601-1 Section 7 for applicable labeling that may be important for your product if it is electrical (consult ISO 14708-1 instead for implantable components).

General Labeling

If a symbols glossary was used, please specifically cite the attachment and page number where it is located in the labeling (type "N/A" if not used). Be aware that if a glossary was not used, the symbols should be described in adjacent text (if applicable, see Help Text).		?
What is the Magnetic Resonance (MR) safety status for the product(s) in the submission?		?

Package Labeling

Add Attachment	Please attach copies of packaging that demonstrate the labeling of any applicable packaging used in the transportation of the product. This includes, but is not limited to, the product packaging and sterile packaging.	?

Package Insert / Instructions for Use

Add Attachment	Please attach copies of the User Instructions, Inserts, Directions for Use and/or Instructions for Use that are intended for use with your product. This includes instructions that may be downloaded or viewed on a website.	?

Other Labeling

Add Attachment	Choose the attachment type in the dropdown for each attachment. Click the help text button to the right for an explanation of each option.	?

Specific Labeling

Please specifically cite the attachment and page number where the Indications for Use exists in the labeling.		
Please specifically cite the attachment and page number where the name and place of business of the manufacturer, packer, or distributor is located.		?

References

Is literature referenced in the submission? ?

Administrative Documentation

Add Attachment	Executive Summary	?
Add Attachment	Please attach your User Fee form here. Please be sure to submit your user fee payment at least three (3) business days before submitting, to ensure the payment is processed and your submission is not placed on user fee hold.	?
Please enter in the User Fee Payment Identification Number.		?

Show User Fee Introduction

Verification

The following sections are complete:	The following sections are incomplete:
Application/Submission Type	Cover Letter / Letters of Reference
Classification	Administrative Information
Labeling	Product Description
References	Indications for Use
	Administrative Documentation

Export Data	You can export the data in this eSTAR in XML format by clicking the Export Data button to the left. Attachments are not included.
Import Data	You can import the XML data of another eSTAR into this eSTAR by clicking the Import Data button to the left, and choosing the XML file. Attachments will not be imported.

Registration and Listing

Owners or operators of places of business (also called establishments or facilities) that are involved in the production and distribution of medical devices intended for use in the United States (U.S.) are required to register annually with the FDA. This process is known as establishment registration.

Congress has authorized FDA to collect an annual establishment registration fee for device establishment registrations. A detailed list of all those establishment types that have to pay the registration fee can be found at the Who Must Register, List and Pay the Fee website. There are no reductions in annual establishment registration fees for small businesses or any other group.

Most establishments that are required to register with the FDA are also required to list the devices that are made there and the activities that are performed on those devices. If a device requires premarket approval or notification before being marketed in the U.S., then the owner/operator should also submit the FDA premarket submission number (510(k), PMA, PDP, HDE). If a device is exempt from 510k requirements, either by regulation or by FDA determination (e.g. via a 513(g) submission), the owner/operator should still follow registration and listing requirements.

Registration and listing provides FDA with the location of medical device establishments and the devices manufactured at those establishments. Knowing where devices are made increases the nation's ability to prepare for and respond to public health emergencies.

For details about registering and listing your device, please see the Device Registration and Listing website. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System (FURLS), please send an email to reglist@cdrh.fda.gov.

Delivery Directions

You only need to mail this eSTAR PDF with embedded attachments on a CD, DVD, or USB Drive (SD cards are not accepted) with a printed cover letter to our Document Control Center. As an example, an acceptable submission package would consist of a printed cover letter accompanying a USB drive with only this eSTAR PDF on it. **The submission does not need to be eCopy compliant, nor does the eSTAR PDF need to be zipped and placed in a MISC FILES folder.**