

STATUS: eSTAR INCOMPLETE

This eSTAR is incomplete and will not be reviewed if submitted. You will be notified by an eSTAR 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

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

Hover

Text

FAQ

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 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 [IMDRF Table of Contents N9](#) chapter number. **If you need to number the attachments, we recommend using the IMDRF chapter numbers.**

Version History

Application/Submission Type

Application Jurisdiction

☒ US FDA

If none of the attachments to a question are relevant to the question or if an inaccurate response is provided to any question, the submission may be put on an early Technical Screening hold, which would request correction of these inadequacies. Examples of responses that would place the submission on a Technical Screening hold include: stating "0" wireless functions are used, but wireless functions are used by the device, improperly indicating device(s) changes are appropriate for a Special 510(k), improper citation of attachments or page numbers in text boxes, stating "N/A" in text boxes that are applicable. An example of an irrelevant attachment includes providing attachments to the software description question none of which contains a software description. FDA may also put the submission on hold if a legible English (i.e. not broken 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.

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

Verification

If you want to save the data in this eSTAR in XML format, you can click the Export Data button to the left. Attachments will not be included in the generated XML file.

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.

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 FDA. This process is known as establishment registration.

Registration and Listing

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), De Novo, PMA, PDP, HDE). The owner/operator cannot list the device until the premarket submission has been cleared, granted, or approved to market in the United States.

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.

Please submit this eSTAR PDF for review to the Center for Devices and Radiological Health (CDRH) 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 center. You do not need to send any documentation in physical form using mail couriers. If you encounter an issue or wish to contact us regarding the Electronic Registration and Listing System known as the FDA Unified Registration and Listing System (FURLS)/Device Registration and Listing Module (DRLM), please send an email to reglist@cdrh.fda.gov.

For CBER-regulated medical devices or for combination products where CBER is the lead center, 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](#).