Contains Nonbinding Recommendations

Draft – Not for Implementation

Electronic Submission Template for Medical Device Q-Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on May 29, 2025.

You should submit comments and suggestions regarding this draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs at 301-796-5640 or eSubPilot@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.



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

GRZAN
DRAFT

Preface

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an email request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number GUI00007041 and complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., WO71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

GRZAN
DRAFT

Table of Contents

I. Introduction 1
II. Background 2
III. Scope 4
IV. Significant Terminology 4
V. Current Electronic Submission Template Structure, Format, and Use 5
A. Structure of the Current Q-Sub Electronic Submission Template 6
VI. Electronic Submission Template Waivers, Exemptions, and Timing 9
A. Waivers and Exemptions From Electronic Submission Requirements 9
B. When Electronic Submissions Will Be Required 10

DRAFT
GRZAN

Electronic Submission Template for Medical Device Q-Submissions

Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) is issuing this draft guidance document to introduce submitters of Q-Submissions (Q-Subs) to the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) to the current resources and associated content developed and made publicly available to support certain Q-Sub electronic submissions to FDA, specifically Pre-Submissions (Pre-Subs).[1] This draft guidance is intended to represent one of several steps in meeting FDA's commitment to the development of electronic submission templates to serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process.[2] When finalized, this guidance will also facilitate the implementation of the FDA's mandate under section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), amended by section 207 of the FDA Reauthorization Act of 2017 (FDARA) (Pub. L. 115-52) to provide further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.

FDA's guidance document "Providing Regulatory Submissions for Medical Devices in Electronic Format — Submissions Under Section 745A(b) of the Federal Food, Drug, and

[1] A Pre-Sub includes a formal written request from a submitter for feedback from FDA prior to an intended premarket submission that is provided in the form of a formal written response or, if the submitter chooses, formal written feedback followed by a meeting. For additional information regarding the Q-Submission Program, refer to FDA's guidance document "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"

[2] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download and 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/158308/download

Cosmetic Act" (hereafter referred to as the "745A(b) device parent guidance") provides a process for the development of templates to facilitate the preparation, submission, and review of regulatory submissions for medical devices solely in electronic format. As described in the 745A(b) device parent guidance, FDA plans to implement the requirements of section 745A(b)(3) of the FD&C Act with individual guidances specifying the formats for specific submissions and corresponding timetables for implementation. When finalized, this guidance will provide such information for Q-Sub electronic submissions solely in electronic format.

In section 745A(b)(3) of the FD&C Act, Congress granted explicit statutory authorization to FDA to specify in guidance the electronic submissions requirement by providing standards, criteria for waivers and exemptions, and a timetable for such submissions. Accordingly, to the extent that this document provides such requirements under section 745A(b)(3) of the FD&C Act, indicated by the use of mandatory words, such as must or required, this guidance is not subject to the usual restrictions in section 701(h) of the FD&C Act and FDA's good guidance practices (GGPs) regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d).

This document provides draft guidance on FDA's interpretation of the statutory requirement for electronic submissions solely in electronic format. Therefore, to the extent that this draft guidance describes recommendations that are not "standards," "timetable," or "criteria for waivers" and "exemptions" under section 745A(b)(3) of the FD&C Act, this document does not create or confer any rights for or on any person and does not operate to bind FDA or the public, but does represent the Agency's current thinking on this topic, once final. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff listed on the title page of this draft guidance.

To comply with the GGP regulations and make sure that regulated entities and the public understand that guidance documents are nonbinding, FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. This draft guidance, when finalized, will contain both binding and nonbinding provisions. Insofar as this draft guidance provides "standards," "timetable," or "criteria for waivers" and "exemptions" pursuant to section 745A(b) of the FD&C Act, it will have a binding effect when final.

For those provisions not identified as binding, the contents of this document are not intended to have the force and effect of law. This document, other than the binding provisions when finalized, is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

Section 745A(b) of the FD&C Act, amended by section 207 of FDARA, requires that pre-submissions and submissions for devices under sections 510(k), 513(f)(2)(A), 515(c), 515(d), 515(f), 520(g), 520(m), or 564 of the FD&C Act or section 351 of the Public Health Service Act, and any supplements to such pre-submissions or submissions, including appeals of those submissions, be submitted in electronic format specified by FDA beginning on such date as specified by FDA in final guidance. It also mandates that FDA issue draft guidance not later than October 1, 2019, and a final guidance not later than 1 year after the close of the public comment period, providing for further standards for the submission by electronic format, a timetable for establishment of these further standards, and criteria for waivers of and exemptions from the requirements.[3]

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter[4] from the Secretary of Health and Human Services to Congress, FDA committed to developing "electronic submission templates that will serve as guided submission preparation tools for industry to improve submission consistency and enhance efficiency in the review process" and "[by] FY [fiscal year] 2020, the Agency will issue a draft guidance document on the use of the electronic submission templates." In addition, the MDUFA IV Commitment Letter states that "[n]o later than 12 months after the close of the public comment period, the Agency will issue a final guidance." The 745A(b) device parent guidance was intended to satisfy the final guidance documents referenced in section 745A(b)(3) of the FD&C Act and the MDUFA IV Commitment Letter. The Medical Device User Fee Amendments of 2022 (MDUFA V) Commitment Letter affirmed FDA's commitment to the continued development of electronic submission templates for a variety of premarket submission types.[5]

In February 2020, CDRH piloted the use of the electronic Submission Template And Resource (eSTAR) electronic submission template by launching the eSTAR Pilot Program.[6] Since that time, the development and availability of eSTAR templates, and new versions of those templates, has expanded and currently available templates and versions can be found on FDA's website.[7]

During the transition time, up to the point when Pre-Sub electronic submissions will be required (see Section VI.B below), anyone can voluntarily use eSTAR for submission of Pre-Subs. As described below, eSTAR is the only electronic submission template currently available to enable Pre-Sub electronic submissions.

[3] See section 745A(b)(3)(B) of the FD&C Act.
[4] See 163 CONG. REC. S4729-S4736 (daily ed. August 2, 2017) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/102699/download
[5] See 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/158308/download
[6] See Notice and request for comments, 85 FR 11371 (Feb. 27, 2020), available at https://www.federalregister.gov/d/2020-03945. The FDA eSTAR website is available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[7] See FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program

III. Scope

This guidance describes the technical standards associated with preparation of the electronic submission template for Q-Subs that enable submission of the electronic Q-Sub solely in electronic format. Currently, Pre-Subs are the only type of Q-Sub available for electronic submission. This guidance document will be updated accordingly as other Q-Sub types are implemented within the eSTAR program. The electronic submission template includes the information and guided prompts FDA believes will best facilitate the collection and assembly of the necessary elements of a 'complete' submission.[8] This guidance is not intended to specify the user-interface and detailed content of the eSTAR, but instead is limited to establishing the Q-Sub electronic format and standards for complying with section 745(A)(b)(3) of the FD&C Act. FDA intends to implement new versions of eSTAR as relevant policies change. FDA also has an ongoing process to collect and consider public comments and stakeholder feedback, which is described on FDA's website.[9]

IV. Significant Terminology

For the purpose of this document, the following significant terminology is described:

eCopy: An electronic copy is a duplicate device submission in electronic format of the previously required paper copy submission sent to FDA.[10] An electronic copy is not considered to be an electronic submission, as defined below.

Electronic Submission (eSubmission): The submission package produced by an electronic submission template[11] that contains the data of a 'complete'[12] submission.

eSTAR (electronic Submission Template And Resource): An electronic submission template[13] built within a structured dynamic PDF that guides a user through construction of an eSubmission. eSTAR is the only type of electronic submission template that is currently available to facilitate the preparation of Q-Subs as eSubmissions. For simplicity, the electronic submission created with this electronic submission template is often referred to as an eSTAR.

Electronic submission template: A guided submission preparation tool for industry. An electronic submission template walks industry through the relevant contents and components for

[8] See the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"
[9] See FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
[10] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions"
[11] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions"
[12] See the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"
[13] The PreSTAR can be downloaded for free on FDA's website at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program

the respective premarket submission type and device to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.[14]

PreSTAR: As of the date of issuance of this guidance document, PreSTAR includes only Pre-Sub and 513(g) content, but is a version of eSTAR that will capture other submission types in the future.

Structured data: Data and content that are captured in the fields, dropdown boxes, checkboxes, etc., within the electronic submission template.

Unstructured data: Data and content that are submitted as attachments to the electronic submission template.

V. Current Electronic Submission Template Structure, Format, and Use

The electronic submission template, eSTAR, is the only currently available electronic submission template at this time to facilitate the preparation of Q-Sub electronic submissions. eSTAR consists of a collection of questions, text, logic, and prompts within a template that guides a user through construction of a 'complete' Q-Sub[15] submission. eSTAR is highly automated, includes integrated databases (e.g., FDA product codes, FDA-recognized voluntary consensus standards), and includes targeted questions designed to collect specific data and information from the submitter. eSTAR also includes applicable links to regulations, relevant guidances, and other resources for the submitter's reference. Finally, eSTAR is structured to collect and assemble content in the Q-Sub as an electronic submission that closely follows the content of the "SMART" Q-Sub review memo template, an internal review tool used by FDA reviewers.

Given that an electronic submission properly prepared with an electronic submission template should represent a complete submission,[16] eSTAR submissions are not anticipated to undergo a refuse to accept (RTA) process. However, FDA intends to employ a virus scanning and technical screening process for an eSTAR. A technical screening process is a process for verifying that eSTAR responses accurately describe the device(s) (e.g., there are, in fact, no tissue contacting components if indicated as such) and that there is at least one relevant attachment per each applicable attachment-type question (e.g., a Product Description attachment is included in response to the Product Description question).[17] For Pre-Subs, the technical screening process is

[14] https://www.fda.gov/media/102699/download

[15] See the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program"

[16] After submitters complete all necessary sections in their eSTAR file correctly, the status message at the top of the PDF will indicate "eSTAR Complete" to represent a complete submission.

[17] For Pre-Subs, given that an eSubmission properly prepared with an eSTAR should represent a complete submission as described in the Pre-Sub Acceptance Checklist in the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program," the technical screening process ensures that the content within the Pre-Sub Acceptance Checklist has been submitted.

anticipated to occur within 15 calendar days of FDA receiving the Pre-Sub eSTAR. If the Pre-Sub eSTAR does not pass technical screening, FDA will notify the submitter via email and identify the incomplete information, and the Pre-Sub will be placed and remain on hold until additional information is submitted to FDA. If a response (i.e., an updated eSTAR with additional information in the applicable sections) is received within the 180-day timeframe, this will be logged in as an amendment to the Q-Sub. If a response is not received within 180 days of the date of technical screening deficiency notification, FDA will consider the Pre-Sub to be withdrawn and the submission will be closed in the system. Upon receipt of the newly submitted information, the review clock will restart at day 0, and FDA staff will conduct the technical screening again, following the same procedure, within the first 15 days of the restarted review clock, to assess whether the new information makes the submission complete. When a submission passes technical screening (whether it is the first technical screening or multiple have occurred), the review clock continues for the rest of the review process. At this time, FDA will notify the requester electronically and the submission proceeds to substantive review.

A. Structure of the Current Q-Sub Electronic Submission Template

Table 1 below shows a high-level overview of the structure of the current electronic submission template for Pre-Subs,[18] the only Q-Sub type for which eSTAR is currently available, including a summary of the anticipated submission content provided by the submitter in each section:[19]

Table 1: Structure of the current eSTAR Pre-Sub Electronic Submission Template[20]

Information Requested	Description
Submission Type	Identification of key information that may be useful to FDA in the initial processing and review of the Q-Submission, including content from current Form FDA 3514, Section A.[21]
Cover Letter / Letters of Reference	Attach a cover letter and any documents that refer to other submissions.
Applicant Information	Information on the applicant and correspondent, if applicable, consistent with content from current Form FDA 3514, Sections B and C.

[18] As indicated above, FDA intends to employ a technical screening process to verify that electronic submission template responses accurately describe the device.

[19] Throughout completion of the eSTAR, submitters can add attachments as unstructured data, including but not limited to documents, PDFs, images, and videos that the submitters believe are pertinent to the review of their device. In addition, eSTAR will prompt for any documents that are needed or may be optionally provided.

[20] The MDUFA V Commitment Letter states that "Pre-Submissions will be accepted in accordance with the Pre-Submission acceptance checklist described in FDA's guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program." FDA intends to replace the Pre-Sub Acceptance Checklist in Appendix 1 of the guidance titled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" with the Pre-Sub eSTAR template elements in Table 1 of this draft guidance, once finalized.

[21] https://www.fda.gov/media/72421/download

Information Requested	Description
Pre-Submission Correspondence & Previous Regulator Interaction	Information on prior or ongoing submissions for the same device included in the current submission, such as submission numbers for a prior not substantially equivalent (NSE) determination, prior deleted or withdrawn 510(k), Q-Submission, Investigational Device Exemption (IDE) application, premarket approval (PMA) application, humanitarian device exemption (HDE) application, De Novo classification request, requests for information under section 513(g) of the FD&C Act, or requests for emergency use authorization (EUA).
Consensus Standards[22]	Identification of voluntary consensus standard(s) used, if applicable. This includes both FDA-recognized and non-recognized consensus standards.
Submission Characteristics	Information about the overall purpose of the submission, including the applicant's goals for the outcome of the interaction with FDA, the intended submission to be submitted in the future, and identification of topic categories the Q-Sub questions fall under. Meeting information, if applicable. This includes meeting type, proposed length of meeting, identification of three (3) or more preferred meeting dates[23] and times, draft meeting agenda with estimated time for each agenda item, list of planned attendees and each attendee's position/title and affiliation, identification of non-U.S. citizens attending the meeting, and any requests for specific FDA staff or subject matter experts.

[22] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program

[23] See 168 CONG. REC. S5194-S5203 (daily ed. September 28, 2022) (Food and Drug Administration User Fee Reauthorization), also available at https://www.fda.gov/media/158308/download

Information Requested	Description
Product Description	Identification of listing number if listed with FDA. Descriptive information for the product, including a description of the technological characteristics of the device including materials, design, energy source, and other device features. Descriptive information also includes a description of the principle of operation for achieving the intended effect and the proposed conditions of use, such as surgical technique for implants, anatomical location of use, user interface, how the device interacts with other devices, and/or how the device interacts with the patient. Information on whether the product is intended to be marketed with accessories. If a Request for Designation (RFD) number exists, provide the RFD number that established that the device or combination product being submitted was assigned to CDRH or CBER.[24]
Device Uses / Proposed Indications for Use	Identification of the proposed indications for use of the device that describes the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.[25]
Classification[26]	Identification of the proposed classification regulation number that seems most appropriate for the subject product, as applicable.
Labeling	As applicable, submission of proposed labeling in sufficient detail to describe the product, its intended use, and directions for its use. The term "labeling" generally includes the device label, instructions for use, and any patient labeling. See "Guidance on Medical Device Patient Labeling."
References	Inclusion of any literature references, if applicable.
Pre-Submission Questions[27] (for Pre-Subs only)	Inclusion of questions related to the review topics identified in the Submission Characteristics section, and, if applicable, supporting documentation.

[24] See 21 CFR 860.220(a)(3)).
[25] See 21 CFR 814.20, 21 CFR 807.92(a)(5), and 21 CFR 860.220(a)(5).
[26] See 21 CFR 807.87(c).
[27] See the FDA guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" for examples of questions that support productive Pre-Sub interactions.

Information Requested	Description
Amendment/Additional Information (AI) response	Inclusion of responses to Additional Information requests or a Technical Screening hold. Inclusion of a summary of information not requested by FDA that does not include new requests for feedback, such as clarifications or corrections to documents already submitted in the parent Q-Sub, documents that were referenced but were inadvertently excluded, etc.[28] For Pre-Subs, meeting minutes or presentation slides should be submitted as an eCopy.[29]

VI. Electronic Submission Template Waivers, Exemptions, and Timing

Upon finalization of this draft guidance, all Pre-Subs, including Originals, Supplements, and Amendments, unless exempted below in Section VI.A of this guidance, will be required to be submitted as electronic submissions as of the implementation date. A Pre-Sub that is not provided as an electronic submission as of that date and as described in Section V above, will not be received unless an exemption from the electronic submission requirements applies.

A. Waivers and Exemptions From Electronic Submission Requirements

Above, FDA identified that Pre-Subs are subject to electronic submission requirements upon finalization of this draft guidance after the implementation date. However, section 745A(b)(2) of the FD&C Act allows for FDA to set forth criteria for exemptions and waivers from electronic submission requirements. FDA has identified such criteria for Q-Subs below.

Exemptions

Upon finalization of this draft guidance, FDA intends to implement exemptions for the following Pre-Subs/information from the Pre-Sub electronic submission requirements:

- Interactive review responses;[30]

[28] While the responses to FDA additional information requests or a summary of information not requested by FDA are included in this section, submitters should include the actual changes to the information to be reviewed by FDA in the respective section of eSTAR (e.g., updated draft labeling should be included in the Labeling section).

[29] We encourage Pre-Sub amendments containing meeting minutes or presentation slides be submitted as an eCopy via the CDRH Portal.

[30] If the reviewer used interactive review via phone or email, the submitter should reply to the reviewer via email with the requested attachments and additional information. Other responses to requests for additional information must be submitted in eSTAR once this guidance is finalized and specifies an implementation date (see "Amendment/Additional Information (AI) Response" category in Table 1 above).

- Amendments:[31]
  - Appeals/requests for supervisory review[32];
  - Change in correspondent/change of legal entity;
  - Amendments after decision;
  - Meeting minutes;
  - Meeting minutes disagreements;
  - Presentation slides; and
  - Withdrawal requests.

Waivers

At this time, FDA has not identified any particular circumstances appropriate for a waiver of the Pre-Sub electronic submission requirements and does not intend to grant requests for waiver. Given the widespread availability of software to enable use of the current Q-Sub eSTAR PDF (available to download on FDA's website), all submitters should have the ability to provide a Pre-Sub eSTAR.[33]

B. When Electronic Submissions Will Be Required

As described in the 745A(b) device parent guidance, this draft guidance, once finalized, will be used to specify the corresponding timetable(s) for implementation of Pre-Sub electronic submissions. FDA intends to provide a transition period of a minimum of one year from the final guidance issuance prior to requiring that all Pre-Subs be provided as electronic submissions. Currently, and during the transition period, eSTARs may be used voluntarily for Pre-Subs. As instructed at the website for the eSTAR Program (under the heading, "How to prepare a submission using eSTAR"[34]), the electronic submission must be submitted using FDA's electronic portal when submitting to CDRH. You can submit questions pertaining to the preparation of submission in electronic format to CDRH at OPEQSubmissionSupport@fda.hhs.gov. For electronic submissions to CBER, please refer to Regulatory Submissions in Electronic Format for CBER-Regulated Products on how to submit through the Electronic Submissions Gateway. You can submit questions pertaining to the preparation of submission in electronic format to CBER at ESUBPREP@fda.hhs.gov.

[31] These Q-Sub amendments remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions"

[32] Section 745A(b)(3) of the FD&C Act authorizes FDA to also require that appeals be submitted solely in such electronic format as specified by the Agency in guidance. Once FDA develops such a format, FDA intends to update this guidance to specify any further standards for the submission of Q-Sub appeals by electronic format, the timetable for establishment of such further standards, and any criteria for a waiver from such requirements.

[33] There are currently known technical reasons that preclude electronic submission via the CDRH Portal. Those impacted submissions should be mailed to the CDRH Document Control Center (DCC). For a list of the known technical reasons, please refer to FDA's CDRH Portal webpage, available at https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal

[34] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program#prepare

Guidance History*	Date	Description
Level 1 Draft Guidance	May 2025	See Notice of Availability for more information.**

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage.

GRZAN DRAFT