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Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

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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

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration 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. Identify all comments with the docket number FDA-2021-D-0872. Comments may not be acted upon by the Agency until the document is next revised or updated.

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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 510(k) Electronic Submission Template 6
VI. Electronic Submission Template Waivers, Exemptions, and Timing 11
A. Waivers and Exemptions From Electronic Submission Requirements 11
B. When Electronic Submissions Will Be Required 12

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Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

This guidance represents 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 guidance document to introduce submitters of premarket notification (510(k)) submissions 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 510(k) electronic submissions to FDA. This 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.[1] This guidance facilitates 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[2]) 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 Cosmetic Act"[3] (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

[1] 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.
[2] https://www.govinfo.gov/content/pkg/PLAW-115publ52/html/PLAW-115publ52.htm.
[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-medical-devices-electronic-format-submissions-under-section-745ab.

submissions and corresponding timetables for implementation. This guidance provides such information for 510(k) 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 guidance on FDA's interpretation of the statutory requirement for electronic submissions solely in electronic format. Therefore, to the extent that this 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. 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 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 guidance contains both binding and nonbinding provisions. Insofar as this guidance provides "standards," "timetable," or "criteria for waivers" and "exemptions" pursuant to section 745A(b) of the FD&C Act, it has binding effect.

For those provisions not identified as binding, the contents of this document do not have the force and effect of law. This document, other than the binding provisions, 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.[4]

In addition, in the Medical Device User Fee Amendments of 2017 (MDUFA IV) Commitment Letter[5] 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.

In September 2018, as a first step in the transition to 510(k) electronic submissions solely in electronic format, FDA launched the "Quality in 510(k) Review Program Pilot"[6] for the submission of Traditional and Abbreviated 510(k)s for certain devices using the eSubmitter electronic submission template. The eSubmitter template was developed by FDA as an optional free tool consisting of a collection of questions, text, logic, and prompts that guides a user through preparation of a 510(k) submission in electronic format. Upon completion, the resulting submission package would contain the structured and unstructured data of a complete 510(k)[7] submission. The pilot helped facilitate the production of well-organized submissions, however, as of May 30, 2021, FDA concluded the Quality in 510(k) Review Program Pilot, along with use of the eSubmitter electronic submission template for preparation of a 510(k) submission in electronic format.

In February 2020, to support the next step in transition to 510(k) electronic submissions solely in electronic format, CDRH developed and has piloted the use of the electronic Submission Template And Resource (eSTAR) electronic submission template through launching the eSTAR Pilot Program.[8] CBER began piloting the use of eSTAR in June 2022.[9] Based on the experience with the eSubmitter software, FDA developed eSTAR to include similar benefits as eSubmitter,

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[4] See section 745A(b)(3)(B) of the FD&C Act.

[5] 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.

[6] Information on the Quality in 510(k) Review Program Pilot is available at: https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots#quik.

[7] The 510(k) regulations at 21 CFR 807.87 to 807.100 provide greater detail regarding the specific information that each premarket notification submission must contain. For example, the submission must include proposed labeling (21 CFR 807.87(e)), a statement regarding the similarities and differences between the device and others of comparable type (21 CFR 807.87(f)), supporting data (21 CFR 807.87(f) and 807.100(b)(2)(ii)(B)), and FDA may request any additional information necessary to determine whether the device is substantially equivalent when the information provided is insufficient to enable such a determination (21 CFR 807.87(m)).

[8] 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.

[9] See Notice and request for comments, 87 FR 36861 (June 21, 2022), available at https://www.federalregister.gov/documents/2022/06/21/2022-13210/improving-510k-submission-preparation-and-review-center-for-biologics-evaluation-and-research.

as well as additional benefits. Similar to eSubmitter, eSTAR includes the following benefits: automation (e.g., form construction, autofilling); content and structure that is complementary to CDRH internal review templates; integration of multiple resources (e.g., guidances, databases); guided construction for each submission section; automatic verification; and it is free to use. In contrast to eSubmitter, eSTAR incorporates additional benefits, including: use of a familiar software application, Adobe Acrobat Pro, and not a proprietary application that requires training; more dynamic functionality, such as support for images and messages with hyperlinks; supporting the creation of Supplements and certain Amendments; mobile device compatibility for certain dynamic PDF features; ability for the submitter to add comments to the PDF after flattening the dynamic version, for the purposes of helping submission preparation; and that eSTAR content and logic fully mirrors the internal templates used by reviewers to review devices, therefore supporting completeness of the submission content and facilitating more efficient review. During the transition time up to the point when 510(k) electronic submissions will be required (see Section VI.B below), anyone can voluntarily use eSTAR for 510(k) submissions. As described below, eSTAR is the only electronic submission template currently available to enable 510(k) electronic submissions.

III. Scope

This guidance describes the technical standards associated with preparation of the electronic submission template for 510(k)s that enable submission of the 510(k) electronic submission solely in electronic format. 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, as required by regulation or essential to FDA's substantive review of the 510(k) submission. This guidance is not intended to specify the user-interface and detailed content of the eSTAR, but instead is limited to establishing the 510(k) 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.[10]

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.[11] An electronic copy is not considered to be an electronic submission, as defined below.

[10] See FDA's website on the eSTAR program at https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program.

[11] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

eSubmitter: A freely available FDA software program[12] that contains electronic submission templates, including the eSubmitter electronic submission template that was available for preparing 510(k) eSubmissions from September 2018, through May 2021, and is no longer available for use to prepare 510(k) submissions.

Electronic Submission (eSubmission): The submission package produced by an electronic submission template[13] that contains the data of a 'complete' submission.

eSTAR (electronic Submission Template And Resource): An electronic submission template[14] 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 510(k) submissions 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 the respective premarket submission type and device to facilitate submission preparation and enhance consistency, quality, and efficiency in the premarket review process.[15]

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 510(k) 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' 510(k) submission. eSTAR is highly automated, includes integrated databases (e.g., FDA product codes,[16] FDA-recognized voluntary consensus standards[17]), 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

[12] https://www.fda.gov/industry/fda-esubmitter.
[13] See 84 FR 68334 and the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.
[14] The 510(k) eSTAR 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.
[15] https://www.fda.gov/media/102699/download.
[16] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm.
[17] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.

collect and assemble content in the 510(k) submission as an electronic submission that closely follows the content of the "SMART" 510(k) review memo template[18] used by CDRH reviewers.

Given that an electronic submission properly prepared with an electronic submission template should represent a complete submission,[19] eSTAR submissions are not anticipated to undergo a refuse to accept (RTA) process. The CDRH Portal will automatically verify that the eSTAR is complete, and therefore we do not expect to receive incomplete 510(k) eSTARs. 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 Software Description attachment is included in response to the Software Description question if software is applicable to the submission). The technical screening process is anticipated to occur within 15 days of FDA receiving the 510(k) eSTAR. FDA intends to only begin the technical screening for 510(k) electronic submissions where the appropriate user fee has been paid. If the eSTAR does not pass technical screening, FDA will notify the submitter via email[20] and identify the incomplete information, and the 510(k) will be placed and remain on hold until a complete replacement eSTAR is submitted to FDA. If a replacement eSTAR is not received within 180 days of the date of technical screening deficiency notification, FDA will consider the 510(k) to be withdrawn and the submission will be closed in the system. The technical screening review time does not impact the review clock for files that pass the technical screening. For a submission that passes technical screening, the review clock starts on the day the submission was received by FDA.

A. Structure of the current 510(k) Electronic Submission Template

In Table 1 below, is a high-level overview of the structure of the current electronic submission template for 510(k)s,[21] including a summary of the anticipated submission content provided by the submitter in each section:[22]

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[18] For more information on the "SMART" 510(k) review memo template, please see "FDA Has Taken Steps to Strengthen The 510(k) Program" available at https://www.fda.gov/media/118500/download or "Improve 510(k) Submission Quality" available at https://www.accessdata.fda.gov/scripts/fdatrack/view/track_project.cfm?program=cdrh&id=CDRH-ODE-Improve-510k-Submission-Quality.

[19] After a submitter completes 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.

[20] For additional information about email communications with CBER, please see the "SOPP 8119: Use of Email for Regulatory Communications," available at https://www.fda.gov/media/108992/download.

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

[22] Throughout completion of the eSTAR, submitters can add attachments as unstructured data, including but not limited to documents, PDFs, images, and videos that the submitter believes are pertinent to the review of their device. In addition, eSTAR will prompt for any documents that are needed. For example, when the use of clinical testing to support the submission is affirmatively indicated, eSTAR will automatically prompt for the attachment of clinical testing documents and any applicable financial certifications or disclosure statements. These attachments appear within the applicable bookmark of the eSTAR PDF when viewed by the submitter or FDA.

Table 1: Structure of the current eSTAR 510(k) Electronic Submission Template

Information Requested	Description
Submission Type	Identification of key information that may be useful to FDA in the initial processing and review of the 510(k) submission, including content from current Form FDA 3514, Section A.[23]
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.
Pre-Submission Correspondence & Previous Regulator Interaction	Information on prior 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, or De Novo classification request.
Consensus Standards[24]	Identification of voluntary consensus standard(s) used, if applicable. This includes both FDA-recognized and non-recognized consensus standards.

[23] https://www.fda.gov/media/72421/download.
[24] https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.

Information Requested	Description
Device Description[25]	Identification of listing number if listed with FDA. Descriptive information for the device, including a description of the technological characteristics of the device including materials, design, energy source, and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A). 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 device is intended to be marketed with accessories. Identification of any applicable device-specific guidance document(s) or special controls for the device type as provided in a special controls document (or alternative measures identified that provide at least an equivalent assurance of safety and effectiveness) or in a device-specific classification regulation, and/or performance standards. *See* "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[26]
Proposed Indications for Use (Form FDA 3881)[27]	Identification of the proposed indications for use of the device. The term indications for use, as defined in 21 CFR 814.20(b)(3)(i), 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.[28]
Classification[29]	Identification of the classification regulation number that seems most appropriate for the subject device, as applicable.

[25] FDA's regulations require manufacturers to include in their 510(k)s "[a] description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 CFR 807.92(a)(4); *see also* 21 CFR 807.87(f).

[26] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.

[27] https://www.fda.gov/media/124401/download.

[28] We have a long-standing policy of applying the definition of indications for use in the PMA regulation at 21 CFR 814.20(b)(3)(i) in the same way in the 510(k) context.

[29] 21 CFR 807.87(c).

Information Requested	Description
Predicates and Substantial Equivalence[30]	Identification of a predicate device (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt and limitations to exemption are exceeded, or statement that the predicate is a preamendments device). The submission should include a comparison of the predicate and subject device and a discussion why any differences between the subject and predicate do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)]. A reference device should also be included in the discussion, if applicable. *See* "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."[31]
Design/Special Controls, Risks to Health, and Mitigation Measures	Applicable to Special 510(k) submissions only. Identification of the device changes and the risk analysis method(s) used to assess the impact of the change(s) on the device and the results of the analysis. Risk control measures to mitigate identified risks (e.g., labeling, verification). *See* "The Special 510(k) Program."[32]
Labeling[33]	Submission of proposed labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). Generally, if the device is an *in vitro* diagnostic device, the labeling must also satisfy the requirements of 21 CFR 809.10. Additionally, the term "labeling" generally includes the device label, instructions for use, and any patient labeling. *See* "Guidance on Medical Device Patient Labeling."[34]
Reprocessing	Information for assessing the reprocessing validation and labeling, if applicable. *See* "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."[35]

[30] 21 CFR 807.87(f) and FD&C Act section 513(i)(1)(A).
[31] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[32] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program.
[33] 21 CFR 807.87(e).
[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.
[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.

Information Requested	Description
Sterility	Information on sterility and validation methods, if applicable. *See* "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile."[36]
Shelf Life	Summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life[37] (e.g., mechanical properties, coating integrity, pH, osmolality), if applicable.
Biocompatibility	Information on the biocompatibility assessment of patient contacting materials, if applicable. *See* "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"[38]
Software/Firmware	Submission of applicable software documentation, if applicable. *See* "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."[39]
Cybersecurity/Interoperability	Submission of applicable information regarding the assessment of cybersecurity, if applicable. *See* "Content for Premarket Submissions for Management of Cybersecurity in Medical Devices"[40] and "Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices."[41]
Electromagnetic Compatibility (EMC), Electrical, Mechanical, Wireless and Thermal Safety	Submission of the EMC, Electrical, Mechanical, Wireless and Thermal Safety testing for your device or summarize why testing is not needed. *See* "Electromagnetic Compatibility (EMC) of Medical Devices"[42] and "Radio Frequency Wireless Technology in Medical Devices."[43]

[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.
[37] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices.
[38] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.
[39] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[41] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.
[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices.
[43] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.

Information Requested	Description
Performance Testing	For non-in vitro diagnostic devices: Provide information on the non-clinical and clinical test reports submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence. *See* "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions."[44] For in vitro diagnostic devices: Provide analytical performance, comparison studies, reference range/expected values, and clinical study information.
References	Inclusion of any literature references, if applicable.
Administrative Documentation	Inclusion of additional administrative forms applicable to the submission, including but not limited to a general summary of submission/executive summary (recommended), a Truthful and Accuracy Statement,[45] and a 510(k) Summary[46] or statement.[47]
Amendment/Additional Information (AI) response	Inclusion of responses to Additional Information requests.[48]

VI. Electronic Submission Template Waivers, Exemptions, and Timing

All 510(k) submissions, including original submissions for Traditional, Special, and Abbreviated 510(k)s, and subsequent Supplements and Amendments (amendments include add-to-files and appeals),[49] and any other subsequent submissions to an original submission unless exempted below in Section VI.A of this guidance, are required to be submitted as electronic submissions. A 510(k) submission that is not provided as an electronic submission as described in Section V above, will not be received unless an exemption from the electronic submission requirements or a waiver with respect to that submission applies.

A. Waivers and Exemptions From Electronic Submission Requirements

[44] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.
[45] 21 CFR 807.87(l).
[46] 21 CFR 807.92.
[47] 21 CFR 807.93.
[48] While the responses to FDA additional information requests 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).
[49] References to supplements and amendments are generally meant to capture the various submission types that typically occur in association with a 510(k) file that is undergoing review or has received a final decision.

Above, FDA identified that 510(k) submissions are subject to electronic submission requirements. 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 510(k)s below.

Exemptions

At this time, FDA is exempting the following 510(k) submissions/information from the 510(k) electronic submission requirements:

- Interactive review responses;[50]
- Amendments:[51]
    - Appeals/requests for supervisory review;[52]
    - Substantive summary requests;
    - Change in correspondent amendments;
    - Amendments after final decision (i.e., add-to-files); and
- Withdrawal requests.[53]

Waivers

At this time, FDA has not identified any particular circumstances appropriate for a waiver of the 510(k) electronic submission requirements and does not intend to grant requests for waiver. Given the widespread availability of software to enable use of the current 510(k) eSTAR PDF (available to download on FDA's website), all submitters should have the ability to provide a 510(k) eSTAR.[54]

B. When Electronic Submissions Will Be Required

As described in the 745A(b) device parent guidance, this guidance specifies the corresponding timetable(s) for implementation of 510(k) electronic submissions. FDA is identifying October 1, 2023 as the date on which the 510(k) electronic submission requirements will take effect. This

[50] 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 (see "Amendment/Additional Information (AI) Response" category in Table 1 above).

[51] These 510(k) amendments remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions.

[52] 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 510(k) appeals by electronic format, the timetable for establishment of such further standards, and any criteria for a waiver from such requirements.

[53] As 510(k) supplements, submission withdrawal requests remain subject to any applicable eCopy requirements. For more information, see the FDA guidance "eCopy Program for Medical Device Submissions" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/ecopy-program-medical-device-submissions. FDA recommends that withdrawal requests be submitted electronically via email or to the CDRH Portal.

[54] While use of the eSTAR will be required starting on October 1, 2023, there are currently known technical reasons that preclude electronic submission via the CDRH Portal and impacted submissions will need to 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

date includes a transition period of a minimum of one year prior to the requirement that all 510(k) submissions be provided as electronic submissions. During the transition period, eSTARs may be used voluntarily for 510(k) submissions. At this time, eSTAR is the only electronic submission template available to prepare a complete 510(k) electronic submission using the guided prompts for the collection of structured and unstructured data. As instructed at the website for the eSTAR Program (under the heading, "How to prepare a submission using eSTAR"[55]), the electronic submission must be submitted using FDA's electronic portal when submitted to CDRH, or via FDA's Electronic Submission Gateway[56] when submitted to CBER. FDA only intends to accept 510(k) submissions saved to a form of electronic storage media and mailed to FDA if they are received by FDA before October 1, 2023.

[55] https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program#prepare.
[56] https://www.fda.gov/industry/electronic-submissions-gateway.