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Electronic Submission Template for Medical Device 510(k) 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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.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 September 29, 2021.

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draft document within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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, Rm. 1061, (HFA-305), Rockville, MD 20852. 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 the 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. FOOD & DRUG ADMINISTRATION

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

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Preface

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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 19006 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., Bldg. 71, 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

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Electronic Submission Template for Medical Device 510(k) 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Draft Guidance for Industry and Food and Drug Administration Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

FDA is issuing this draft 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 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.[1] When final, this draft guidance will also further 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 submissions and corresponding

[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.

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timetables for implementation. When finalized, this draft guidance will provide such information for 510(k) 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 draft guidance, when final, 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 submission 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 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 binding effect when final. For those provisions not identified as binding the contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. 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 the FDARA, requires that pre-submissions and submissions for devices under section 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 the Food and Drug Administration (FDA or the Agency) beginning on such date as specified by FDA in final guidance. It also

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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 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) submissions solely in electronic format, CDRH developed and has piloted the use of the eSTAR electronic submission template through launching the eSTAR Pilot Program.[8] Based on the experience with the eSubmitter software, FDA developed eSTAR to include similar benefits as eSubmitter, as well as additional benefits. Similar to eSubmitter, eSTAR includes the following benefits: Automation (e.g., form construction, auto-filling); content and structure that is complementary to CDRH internal review

[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)). For more information, please see the FDA guidance "Refuse to Accept Policy for 510(k)s" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.

[8] See Notice and request for comments, 85 FR 11371 (Feb. 27, 2020). CBER also intends to pilot eSTAR and will provide appropriate notice regarding that pilot.

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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 beneficial dynamic functionality, such as support for images and messages with hyperlinks; supporting the creation of Supplements and Amendments; availability for use on mobile devices as a dynamic PDF; ability to add comments to the PDF; 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. Although the FDA is currently not accepting requests for participation in the eSTAR Pilot Program, anyone can voluntarily use eSTAR. As described below, eSTAR is the only electronic submission template currently available to enable 510(k) electronic submissions.

III. Scope

This draft guidance describes the technical standards associated with preparation of the electronic submission template for 510(k)s that, when the guidance is finalized, will 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.[9]

IV. Significant Terminology

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

eCopy: An electronic copy is a submission created and submitted on a compact disc (CD), Digital Versatile Disc (DVD), or flash drive and mailed to FDA, and which is a duplicate of the previously required paper copy sent to FDA.[10] An electronic copy is not considered to be an electronic submission, as defined below.

eSubmitter: A freely available FDA software program[11] 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.

[9] See the FDA guidance "Refuse to Accept Policy for 510(k)s" at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[10] 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.
[11] https://www.fda.gov/industry/fda-esubmitter.

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Electronic Submission (eSubmission): The submission package produced by an electronic submission template[12] that contains the data of a 'complete'[13] submission.

eSTAR (electronic Submission Template And Resource): An electronic submission template 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.[14]

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)[15] 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 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.

[12] 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.
[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[14] https://www.fda.gov/media/102699/download.
[15] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.
[16] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm.
[17] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[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)

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Given that an electronic submission properly generated with an electronic submission template should represent a complete submission, eSTAR submissions are not anticipated to undergo a refuse to accept (RTA) process.[19] However, FDA intends to employ a 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 is not complete when submitted, it 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.

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,[20] including a summary of the anticipated submission content provided by the submitter in each section:

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.[21]
Cover Letter	Opportunity to attach a cover letter.
Submitter Information	Information on submitter and correspondent, if applicable, consistent with content from current Form FDA 3514, Sections B and C.
Pre-Submission Correspondence & Previous Regulatory Interaction	Information on prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent (NSE) determination, prior deleted or withdrawn 510(k), Pre-Submission, Investigational Device Exemption (IDE), Premarket approval application (PMA)).

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] For more information on the RTA process, please see "Refuse to Accept Policy for 510(k)s" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks.

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

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

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Information Requested	Description
Consensus Standards[22]	Identification of voluntary consensus standard(s) used, if applicable. This includes both FDA-recognized and non-recognized consensus standards.
Device Description[23]	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)].*[24]
Proposed Indications for Use (Form FDA 3881)[25]	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.[26]
Classification[27]	Identification of the classification regulation number that seems most appropriate for the subject device, as applicable.

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

[23] 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).

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

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

[26] 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.

[27] 21 CFR 807.87(c).

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Information Requested	Description
Predicates and Substantial Equivalence[28]	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 preamendment 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)].*[29]
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.*[30]
Labeling[31]	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.*[32]
Reprocessing	Information for assessing the reprocessing validation and labeling, if applicable. *See Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*[33]
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.*[34]
Shelf Life	Summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life[35] (e.g., mechanical properties, coating integrity, pH, osmolality), if applicable.

[28] 21 CFR 807.87(f) and FD&C Act section 513(i)(1)(A).
[29] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k.
[30] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/special-510k-program.
[31] 21 CFR 807.87(e).
[32] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling.
[33] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling.
[34] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled.
[35] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-life-medical-devices.

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Information Requested	Description
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."*[36]
Software/Firmware	Submission of applicable software documentation, if applicable. *See Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*[37]
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*[38] and *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices.*[39]
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 Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically Powered Medical Devices*[40] *and Radio Frequency Wireless Technology in Medical Devices.*[41]
Performance Testing (Bench/Animal/Clinical)	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.*[42]
References	Inclusion of any literature references, if applicable.
Administrative Documentation	Inclusion of a Truthful and Accuracy Statement[43] and a 510(k) Summary[44] or statement.[45]

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[36] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and.
[37] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices.
[38] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0.
[39] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices.
[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices.
[41] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radio-frequency-wireless-technology-medical-devices-guidance-industry-and-fda-staff.
[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket.
[43] 21 CFR 807.87(k).
[44] 21 CFR 807.92.
[45] 21 CFR 807.93.

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VI. Electronic Submission Template Waivers, Exemptions, and Timing

Upon finalization of this draft guidance, electronic submissions for all 510(k) submissions and subsequent submissions to an original submission, including amendments (amendments include add-to-files and appeals) and supplements 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 it has been exempted from the electronic submission requirements or the electronic submission requirements have been waived with respect to that submission.

A. Waivers and Exemptions From Electronic Submission Requirements

At this time, FDA has not identified any circumstances appropriate for a waiver of or exemption from the 510(k) electronic submission requirements.

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 for 510(k) electronic 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. However, as instructed at the website regarding the eSTAR pilot (under the heading, "How to submit a 510(k) for the eSTAR Pilot Program"[46]), the electronic submission must still be saved to a form of electronic storage media and mailed to FDA. By September 30, 2022 (i.e., the time period through MDUFA IV), FDA intends to identify a specific date on which we will require that 510(k) electronic submissions be provided. We anticipate that from the time we announce a date, there will be a transition period of a minimum of one year prior to requiring that all 510(k) submissions be provided as electronic submissions. When a date is identified, this guidance will be updated and finalized to provide that specific date and set forth the electronic format(s) specified in this guidance that must be used for 510(k) submissions.

[46] https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots#estarprep510k.