US FDA Update

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Overview

- International Harmonization Strategic Plan
- Electronic Export Certificates
- 510(k) Program Updates
- Breakthrough Devices Program Update

US FDA/CDRH International Harmonization Strategic Plan

CDRH International Harmonization Strategic Plan

- Recognizes the importance of globally harmonized medical device regulatory policy and practices.
- Outlines specific strategies and activities towards international harmonization, convergence, and reliance over the next 4 years.
- Commits to publishing annual assessments of the international harmonization activities
- CDRH looks forward to public comment and feedback to improve our approach and efforts to provide patients in the United States and globally with safe, effective high-quality medical devices in an increasingly global regulatory environment.

CDRH International Harmonization Draft Strategic Plan 2023 (fda.gov)

CDRH International Harmonization Strategic Plan

Strategy 1	Increase engagements in international harmonization, convergence, and reliance efforts
Strategy 2	Create a mechanism for CDRH to share best practices with trusted partners
Strategy 3	Assess the extent of CDRH implementation of IMDRF technical documents
Strategy 4	Support creation of a forum to engage with stakeholders to identify opportunities for regulators to leverage one another's approach to decision making
Strategy 5	Participate in outreach activities to encourage harmonization, convergence, and reliance

Electronic Export Certificates

Electronic Export Certificates

- Export certificates are often required by importing countries as one of the requirements to market a medical device.
- FDA does not require export certificates to export human medical devices/products that can be legally marketed in the U.S.
- Importing countries often require additional steps:
  - Apostille-U.S. Department of State
  - Legalization- Embassies

Electronic Export Certificate Issuance

- U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) announced in a letter to manufacturers on July 10, 2023 the transition to electronic versions of all export documents:
    - Certificate to Foreign Government,
    - Certificate of Exportability Section 801(e)(1) or 802,
    - Non-Clinical Research Use Only Certificate,
    - Certificate to Foreign Government for Device Not Exported from the United States, and
    - Export Permit Letter.

- Requests received by December 15, 2023, will be issued as paper certificates
- Beginning January 2, 2024, all export documents will be issued electronically

- The electronic certificates (e-certificates) for human medical devices/products will be issued as a downloadable PDF through the CDRH Export Certification Application and Tracking System (CECATS).

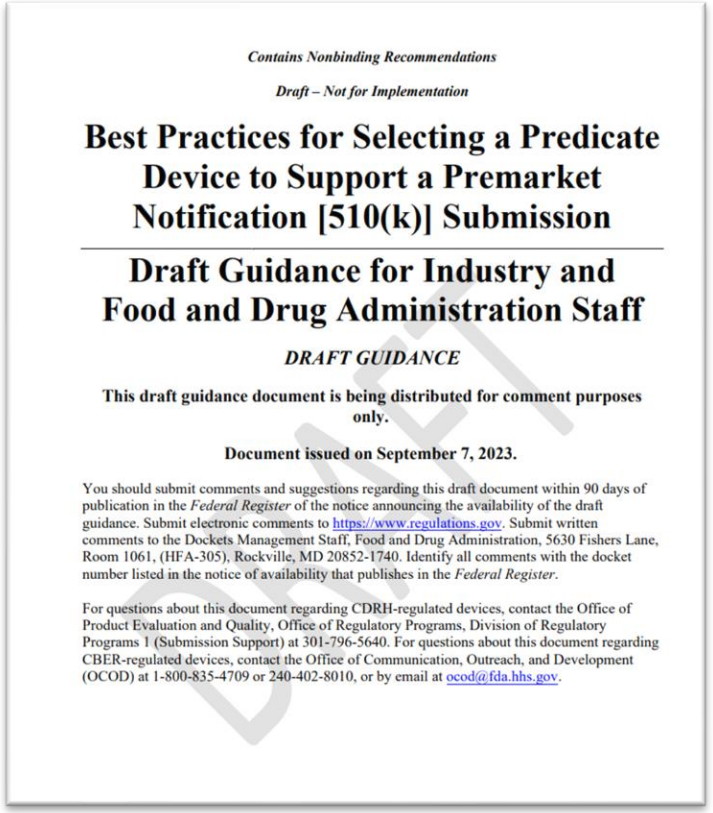
Electronic Export Certificate Issuance

- **Old process**
  - Starting January 2, 2024, Exports Certificates and documents will no longer be:
    - Printed on security paper
    - Mailed
- **Unchanged process**
    - Still requested in CDRH Export Certificate Application and Tracking System (CECATS)
- **New Process**
  - If granted after review by FDA:
    - Requester receives an email with instructions
    - One time access to print or save a PDF within 45 days
- **To validate:**
  - Access the FDA Export Certificate Validator (FECV) website
    - Enter certificate number
    - And the expiration date
  - FDA will add a unique Quick Response (QR) code to the e-certificate

510(k) Program Updates

Draft Guidance:
Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

- Outlines best practices in selecting a predicate device in 510(k) submissions to enhance the predictability, consistency, and transparency of the 510(k) Program.
- Developed in response to public feedback, and to continue to modernize the framework for 510(k) review.
- Proposes factors for consideration for choosing a predicate device, including selecting a predicate device that was cleared using well-established methods, meets or exceeds expected safety and performance, is without unmitigated use-related or design-related safety issues, and is without an associated design-related recall.
- FDA believes use of these best practices will encourage the evolution of safer and more effective medical devices in the 510(k) Program over time.



Contains Nonbinding Recommendations

Draft – Not for Implementation

Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission

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 7, 2023.

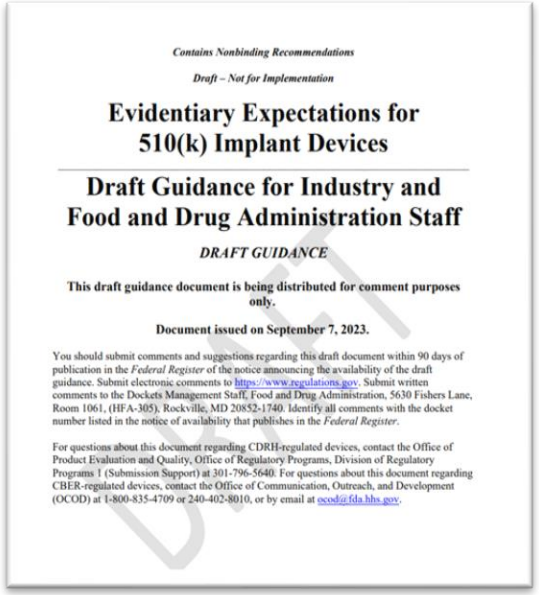
You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management 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 the Office of Product Evaluation and Quality, Office of Regulatory Programs, Division of Regulatory Programs 1 (Submission Support) at 301-796-5640. 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.

DRAFT

Draft Guidance: Evidentiary Expectations for 510(k) Implant Devices

- Outlines current recommendations for implant devices subject to 510(k)
- Developed in response to public feedback, and to continue to modernize the framework for 510(k) review
- Provides recommendations for general considerations including indications for use, intended duration of implantation, and anticipated patient and physician experience
- Provides recommendations for non-clinical issues relevant to implants, such as:
  - Biocompatibility
  - Sterility and Shelf Life
  - Reprocessing and Cleaning
  - Software and Cybersecurity
  - Electrical Safety and Electromagnetic Compatibility
  - MR Compatibility
  - Animal Testing



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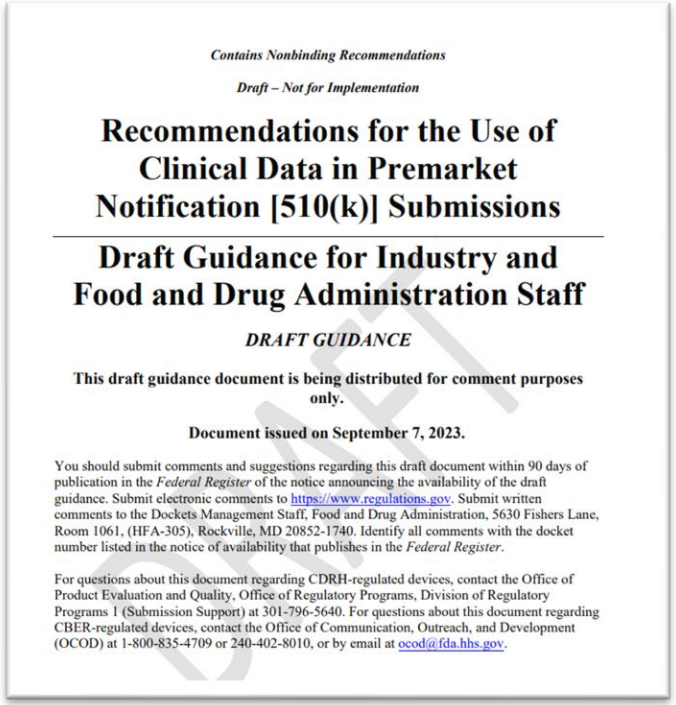
DRAFT

Draft Guidance: Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

- Clarifies and provides additional context for situations when clinical data may be necessary to demonstrate substantial equivalence (SE), including when:
  - There are differences in the indications for use
  - There are differences in the technological characteristics
  - The SE cannot be determined by non-clinical testing
  - There are newly identified or increased risks for the predicate device



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Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions

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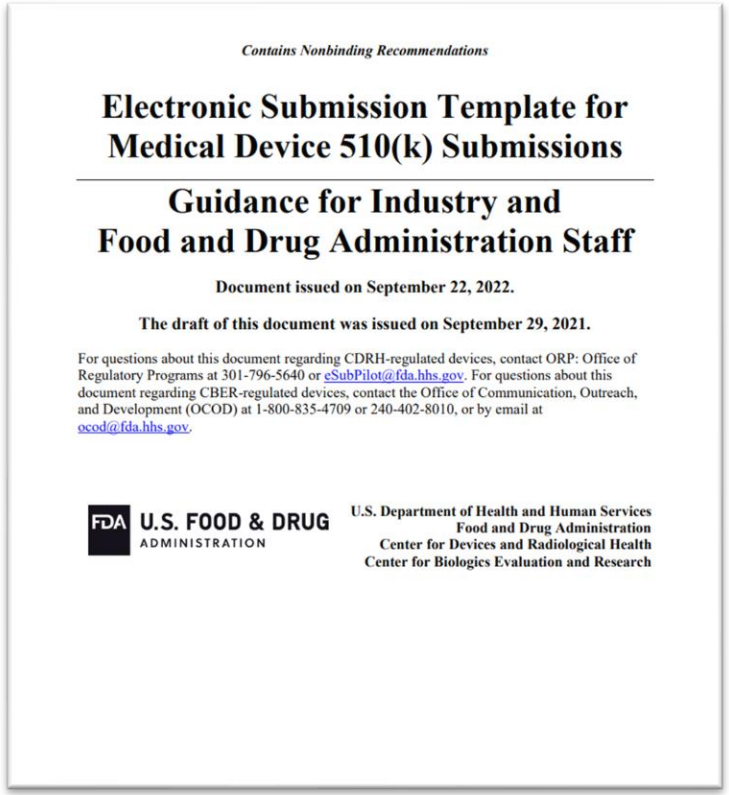
Final Guidance: Electronic Submission Template for Medical Device 510(k) Submissions

- 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 an electronic format (eSTAR)

- Beginning October 1, 2023, all 510(k) submissions, unless exempted, must be submitted as electronic submissions using eSTAR



Contains Nonbinding Recommendations

Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 22, 2022.

The draft of this document was issued on September 29, 2021.

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.

FDA U.S. FOOD & DRUG ADMINISTRATION

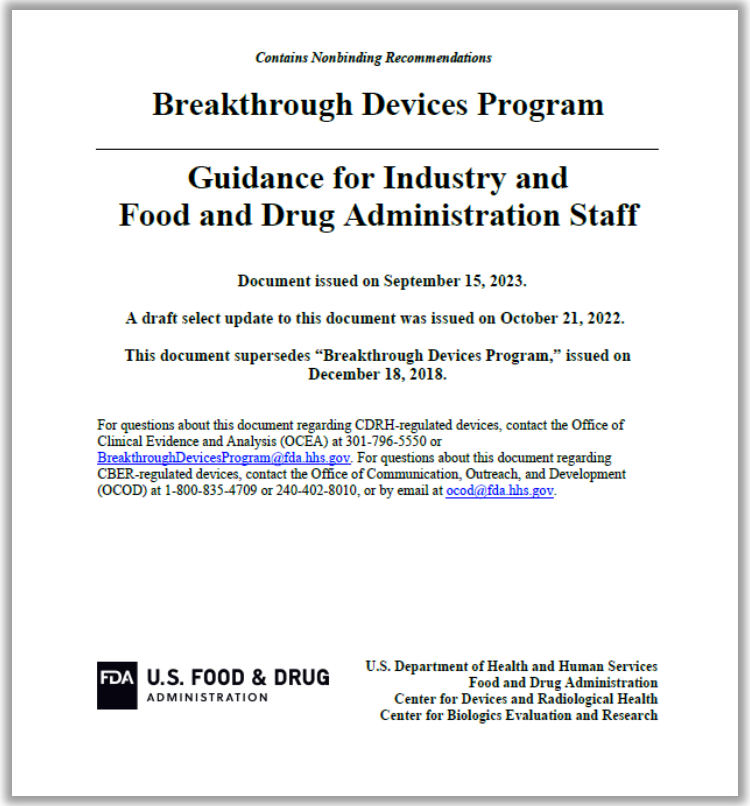
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Breakthrough Devices Program Update

Updated Guidance: Breakthrough Devices Program

- Clarifies Breakthrough Device designation eligibility:
  - Devices that benefit populations impacted by inequities in health or health care
  - Devices that address disparities in accessibility to care
  - Non-addictive medical products intended to treat pain or addiction

- 831 designations granted as of June 30
  - 77 reported marketing authorizations



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Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 15, 2023.

A draft select update to this document was issued on October 21, 2022.

This document supersedes "Breakthrough Devices Program," issued on December 18, 2018.

For questions about this document regarding CDRH-regulated devices, contact the Office of Clinical Evidence and Analysis (OCEA) at 301-796-5550 or BreakthroughDevicesProgram@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.

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U.S. Department of Health and Human Services
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FDA
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ADMINISTRATION

IMDRF International Medical Device Regulators Forum

Software as a Medical Device (SaMD) Update

US FDA & Health Canada Co-chairs

September 2023

Ongoing Work

Goal: To refine the previously published SaMD documents to improve international alignment and ensure ongoing consistency, predictability, and transparency by:

- **Publishing a new document related to:**
  - Enhancing focus on better characterizing the device to inform downstream risk considerations
    - Drafted document includes discussion of how to clearly characterize medical device software to improve consistent understanding of these devices by regulators globally
    - Drafted document includes considerations for identifying and understanding medical devices software risks based upon information-based hazards

Progress and Planned Milestones

- June-July 2022: Identification of WG members and co-chair coordination meeting
- August 2022: Survey to WG members re: proposals for changes to existing documents
- September 2022: WG kick-off meeting, meeting every two weeks
- April 2023: 3 x half-day virtual WG meeting
- **November 2023: Planned submission of draft document to IMDRF MC**
- December 2023: Public consultation of document(s)*
- January 2024: 3/4-day WG meeting
- March 2024: Final document(s) submitted to IMDRF MC
- **May 2024: Publish final technical document(s)***

* Pending IMDRF MC Approval

IMDRF International Medical Device Regulators Forum

Thank you/Questions

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