U.S. FOOD & DRUG ADMINISTRATION

Session II. Promoting Transparency

FDA's Role in Promoting Transparency Through Labeling and Public Facing Documents

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Robert Ochs, PhD
Deputy Office Director for Radiological Health
FDA | CDRH | OPEQ | OHT7: Office of In Vitro Diagnostics and Radiological Health

Presentation Topics

- Background
  - FDA Premarket Review
- Sources of Information
  - Medical Device Labeling
  - FDA Public Databases
- Discussion Topics
  - Current Challenges
  - Transparency Principles for Discussion

Background - Premarket Review

- FDA conducts a premarket review for mid- to high-risk AI/ML-enabled devices
- Evaluation of safety and effectiveness based on:
  - Intended use
  - Device description / design
  - Performance assessment
  - Labeling
  - *and more…e.g., human factors, software quality, cybersecurity as applicable*

Background - Premarket Review

- The study design and performance must support the intended use of the AI/ML device, taking into consideration…
  - Safety and effectiveness of the device
  - Generalizability to the intended use population (e.g., acquisition hardware, patient demographics, disease variations)
  - Best practices in study design and statistics (e.g., data independence, pre-specified endpoints, sources of bias)
  - *and more…*

- Does the labeling contain sufficient information to support safe and effective use?

- What is labeling, and what information is available to users in the device labeling?

Medical Device Labeling

- Labels and other written, printed, or graphic matters on or accompanying the device

- All medical devices have some of the same general requirements, unless exempted by regulation

- Additional labeling requirements depend on the submission type and/or are enacted as part of “special controls” (device-type specific risk mitigation)

Medical Device Labeling

- Premarket submissions include proposed labeling that describes:
  - The device
  - Intended use
  - Directions for use (which may include relevant information based on performance testing)

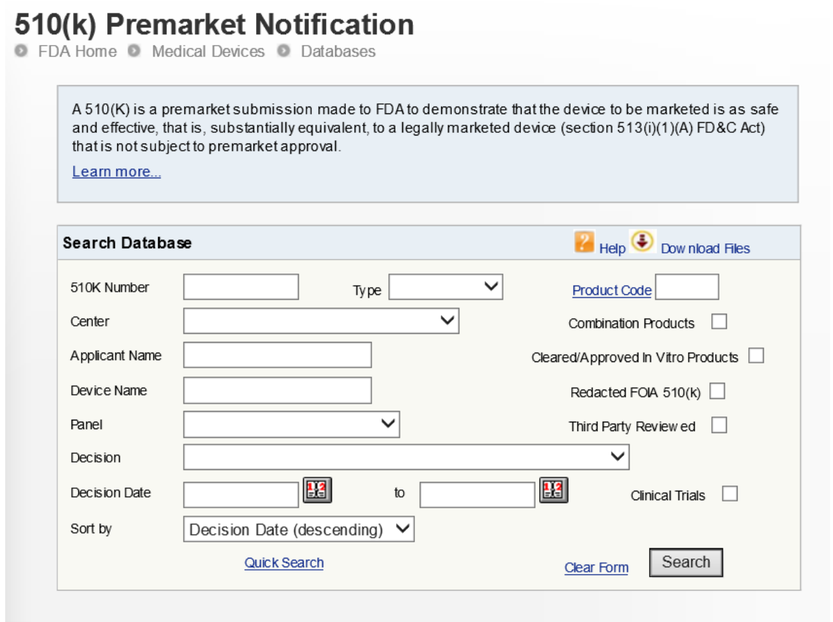
Medical Device Labeling

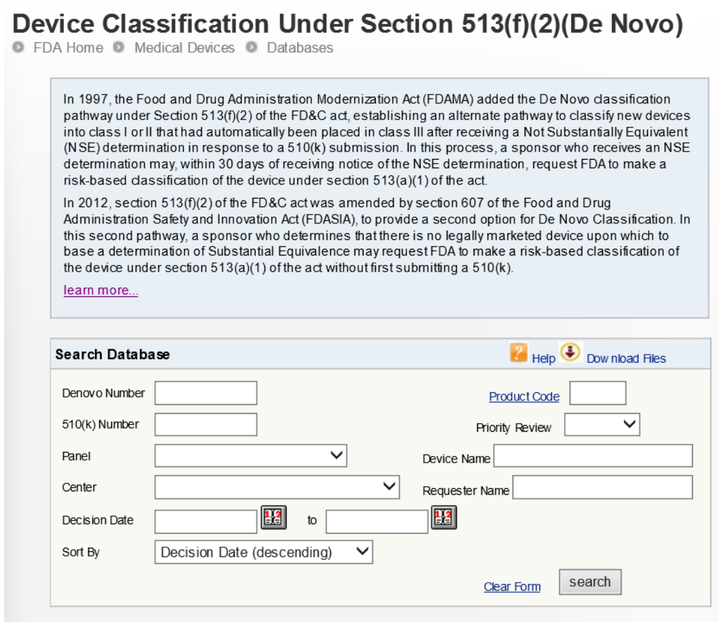
- For AI/ML-enabled devices:
  - Operation/workflow
  - Identification of compatible hardware/software (inputs/outputs)
  - Details of the validation, including dataset characteristics, sub-analyses stratified by relevant confounders
  - Other information to help users understand its use, requirements, limitations, and generalizability

- What information on AI/ML-enabled devices is available from FDA's public databases?

FDA Public Databases

- FDA posts information on authorized medical devices
- The format, content, and details depends on the submission type and underlying regulatory requirements



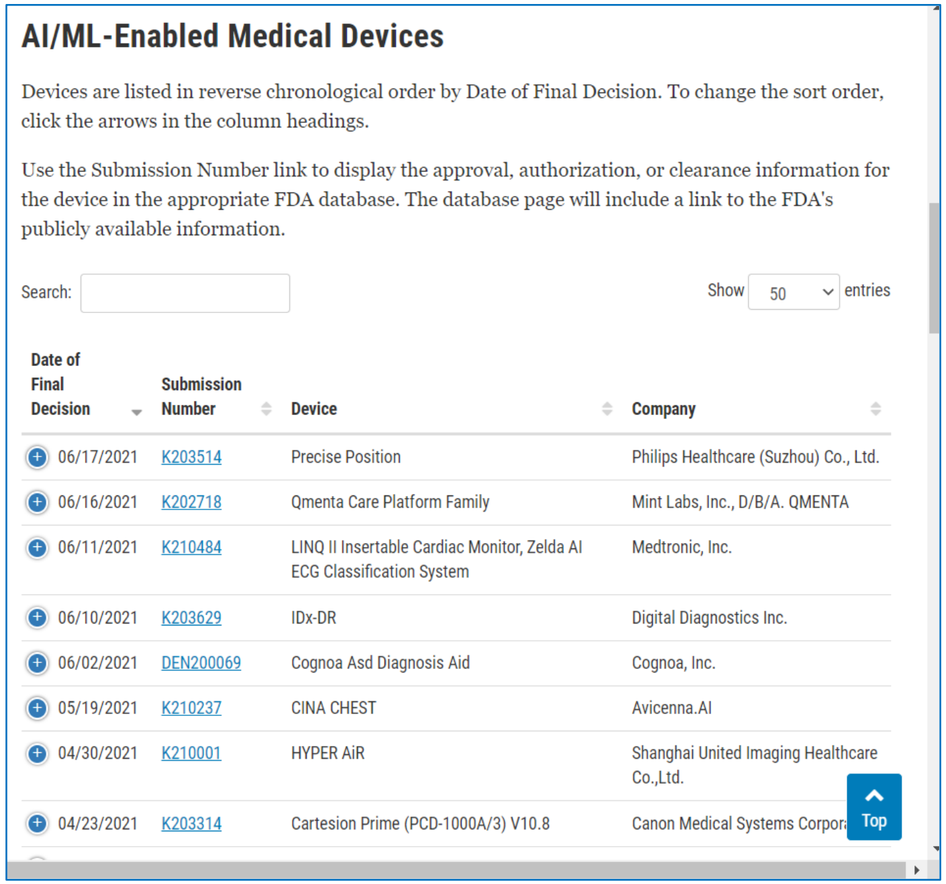


FDA Public Databases - Overview

Database	Documents	Overview
510(k)	Decision Letter Indications for Use 510(k) Summary/Statement	A brief summary of the device, intended use, and summary of the performance testing relied upon for the decision.
De Novo	Reclassification Order FDA Decision Summary	Regulatory definition of the new device-type classification, including any special controls. The Decision Summary includes the device description, intended use, review of performance testing, etc. for the authorized device.
PMA	Approval Order Summary of Safety & Effectiveness Labeling	Detailed summary of information submitted for the device, including device description, performance testing, and copies of labeling.

FDA's List of AI/ML-Enabled Devices

- Public list of authorized AI/ML-enabled medical devices with key information (e.g., device and company name, link to summary)
- Increases transparency about these devices and the FDA's work in AI/ML-enabled devices
- ~300 devices (through June 2021)



AI/ML-Enabled Medical Devices

Devices are listed in reverse chronological order by Date of Final Decision. To change the sort order, click the arrows in the column headings.

Use the Submission Number link to display the approval, authorization, or clearance information for the device in the appropriate FDA database. The database page will include a link to the FDA's publicly available information.

Search: Show 50 entries

Date of Final Decision	Submission Number	Device	Company
06/17/2021	K203514	Precise Position	Philips Healthcare (Suzhou) Co., Ltd.
06/16/2021	K202718	Qmenta Care Platform Family	Mint Labs, Inc., D/B/A. QMENTA
06/11/2021	K210484	LINQ II Insertable Cardiac Monitor, Zelda AI ECG Classification System	Medtronic, Inc.
06/10/2021	K203629	IDx-DR	Digital Diagnostics Inc.
06/02/2021	DEN200069	Cognoa Asd Diagnosis Aid	Cognoa, Inc.
05/19/2021	K210237	CINA CHEST	Avicenna.AI
04/30/2021	K210001	HYPER AiR	Shanghai United Imaging Healthcare Co.,Ltd.
04/23/2021	K203314	Cartesion Prime (PCD-1000A/3) V10.8	Canon Medical Systems Corpora

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[Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices]

Transparency Challenges

- Device labeling
  - Is not posted online by FDA, except for Original and Panel Track PMAs
  - May not be easy to find or readily available to all end-users

- FDA's public databases
  - The information will vary based on the submission type
  - The information reflects the performance at authorization, and not real-world performance

- Lack of a standard template for reporting on AI/ML-enabled devices

Transparency Principles for Discussion

- Users should be provided ready access to clear, relevant information that is appropriate for the intended audience (e.g., clinicians or patients), including:
  - The intended use and indications for use
  - The basis for decision-making when available
  - Performance of the model for appropriate subgroups
  - Characteristics of the data used to train and test the model
  - Acceptable inputs
  - Known limitations
  - User interface interpretation
  - Clinical workflow integration of the model
  - Device modifications and updates from real-world performance monitoring
  - User are provided a means to communicate concerns to the developer

Summary

- FDA conducts an in-depth premarket review of AI/ML-enabled devices
- Device labeling includes information on the intended use, performance, generalizability, limitations, etc.
- FDA public databases provide information on authorized devices
- More can be done to develop and implement best practices for promoting transparency


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