



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

510(k) Premarket Notification

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A 510(K) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act) that is not subject to premarket approval.

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510K Number	<input type="text"/>	Type	<input type="text"/>	Product Code	<input type="text"/>
Center	<input type="text"/>	Combination Products	<input type="checkbox"/>		
Applicant Name	<input type="text"/>	Cleared/Approved In Vitro Products	<input type="checkbox"/>		
Device Name	<input type="text"/>	Redacted FOIA 510(k)	<input type="checkbox"/>		
Panel	<input type="text"/>	Third Party Review ed	<input type="checkbox"/>		
Decision	<input type="text"/>				
Decision Date	<input type="text"/>	to	<input type="text"/>	Clinical Trials	<input type="checkbox"/>
Sort by	Decision Date (descending)				

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Device Classification Under Section 513(f)(2)(De Novo)

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In 1997, the Food and Drug Administration Modernization Act (FDAMA) added the De Novo classification pathway under Section 513(f)(2) of the FD&C act, establishing an alternate pathway to classify new devices into class I or II that had automatically been placed in class III after receiving a Not Substantially Equivalent (NSE) determination in response to a 510(k) submission. In this process, a sponsor who receives an NSE determination may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the act.

In 2012, section 513(f)(2) of the FD&C act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA), to provide a second option for De Novo Classification. In this second pathway, a sponsor who determines that there is no legally marketed device upon which to base a determination of Substantial Equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the act without first submitting a 510(k).

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Denovo Number	<input type="text"/>	Product Code	<input type="text"/>
510(k) Number	<input type="text"/>	Priority Review	<input type="text"/>
Panel	<input type="text"/>	Device Name	<input type="text"/>
Center	<input type="text"/>	Requester Name	<input type="text"/>
Decision Date	<input type="text"/>	to	<input type="text"/>
Sort By	Decision Date (descending)		

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Premarket Approval (PMA)

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Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

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Applicant	<input type="text"/>	Product Code	<input type="text"/>	PMA Number	<input type="text"/>
Device	<input type="text"/>			Expedited Review	<input type="text"/>
Decision Date	<input type="text"/>	to	<input type="text"/>	Docket Number	<input type="text"/>
Advisory Committee	<input type="text"/>			Cleared/Approved IVD Products	<input type="checkbox"/>
Supplement Type	<input type="text"/>			Combination Products	<input type="checkbox"/>
Sort by	Decision Date (Descending)			Center	<input type="text"/>

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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 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, Zeldia 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 Corporation

[Top](#)



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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