

US FDA Update

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U.S. Food and Drug Administration

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Patients are at the Heart of What We Do



Center for Devices and Radiological Health (CDRH) Vision

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance

CDRH Core Pillars

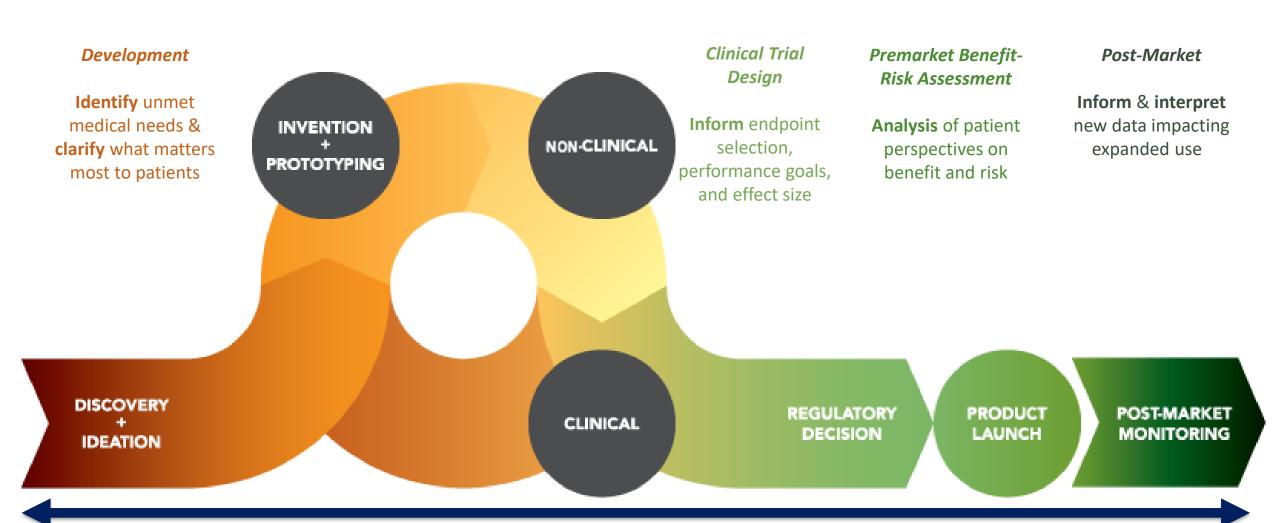






Patient-Centered Development & Evaluation







Real-World Evidence Program

Use of Real-World Data & Evidence in place of conventional clinical trial data to reduce time to answer device questions



Total Product Life Cycle Advisory Program (TAP) Pilot Update



Engage in a teleconference within 14 days for 90% of requests for interaction

Written feedback on all other requested topics within 40 days for 90% of requests

100% of key quantitative performance metrics met



Digital Health Innovation



Regulatory Accelerator – Curated resources to support development of medical device software

Resource Index



Visual guide to FDA tools and resources available throughout the process of bringing a device to market

Early Orientation



Best practices for engaging early with the FDA on marketing submissions on medical device software

Guidance Navigator



Resource for identifying guidances that may be applicable to a device across the development life cycle

AI in Medical Devices



Contains Nonbinding Recommendations

Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 4, 2024.

The draft of this document was issued on April 3, 2023.

For questions about this document regarding CDRH-regulated devices, contact the Digital Health

regarding CBER-regulated of Development (OCOD) at 1-For questions about this doc Drug Evaluation and Resear questions about this docume Combination Products by en

FDA U.S. FOOD

Artificial Intelligence-Enabled Device
Software Functions: Lifecycle
Management and Marketing
Submission Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

Contains Nonbinding Recommendations

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 policy. Fou 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 quadrace as listed on the tile page.

I. Introduction

FDA has long promoted a total product life cycle (TPLC) approach to the oversight of medical devices, including artificial intelligence (A)) enabled devices, and has committed to developing guidinoses and resources for such an approach. Some recent efforts include developing guiding principles for good machine learning practice (GMLP) and transparency for machine learning enabled devices, to help promite safe; effective, and high-quility machine learning models; and discussions of device transparency for users. ² This guidance intends to continue these efforts, by providing lifecycle management and marketing submission recommendations consistent with a TPLC approach for A-mahelded edveces.

This guidance provides recommendations on the contents of marketing submissions for devices that include A—reabled device software functions including documentation and information that will support FDA's review. To support the development of appropriate documentation for FDA's assessment of devices, this guidance also provides recommendations for the chaigs and

See FDA's website on Good Mechine Learning Practice for Medical Device Development: Guidine Principles
See FDA's website on Interception of Medical Learning-Enabled Medical Devices: Guidine Principles
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See FDA's website on Interception of Medical Learning-Enabled Medical Devices: The Medical Devices of Medical De

FDA's Digital Health Advisory Committee

Authorized AI/ML-Enabled Medical Devices*

Over 1,200 AI-enabled devices have been authorized by FDA

Date of Final Decision	•	Submission Number	\$	Device	\$	Company \$	Panel (lead)	\$	Primary Product Code	\$
05/30/2025		K251406		BriefCase-Triage		Aidoc Medical, Ltd.	Radiology		QAS	
05/30/2025		K250236		Swoop® Portable MR Imaging® System (V2)		Hyperfine, Inc.	Radiology		LNH	
05/30/2025		K243863		Opulus™ Lymphoma Precision		Roche Molecular System	Radiology		QIH	
05/30/2025		K243005		AudaxCeph Cephalogram Analysis Software		Audax d.o.o.	Radiology		QIH	
05/30/2025		K242830		LensHooke X3 PRO Semen Quality Analyzer; LensHooke X3 PRO SE Semen Quality Analyzer	/	Bonraybio Co., LTD.	Hematology		POV	
05/30/2025		DEN240047		Allix5		Clairity, Inc.	Radiology		SEZ	
05/29/2025		K250543		Voluson™ Performance 16; Voluson™ Performance 18		GE Medical Systems Ultr	Radiology		IYN	
05/28/2025		K243378		Rapid MLS		iSchemaview Inc.	Radiology		QIH	

*Updated July 2025









Save Time

Compare documents in context Find and extract information Cross-reference regulations



Tailor Communications

Summarize large communication threads
Accelerate drafting of communications



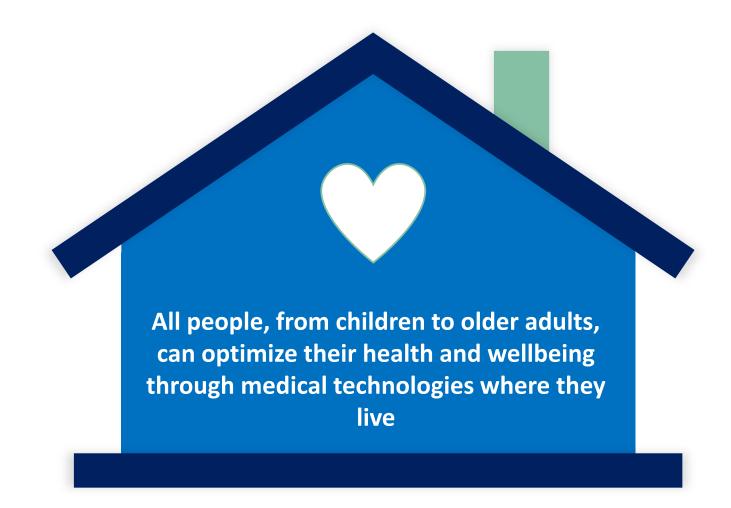
Accelerate Discovery & Understanding

Analyze large files for content Provide context and insights on new topics

Home as a Health Care Hub Initiative



Reimagine the home environment as an integral part of the health care system, with the goal of advancing access to better health outcomes for all people in the U.S.



The Idea Lab



Imagine Home as a Health Care Hub through The Idea Lab









Fueling innovation in home use of medical devices through person-centered design





2025		2026	2027
 Jun Federal Register Notice (FRN) of public meeting, 6/11/25 Public meeting. 8/4/25 30-day docket comment period, 8/4/25-9/4/25 	Oct – Feb Industry negotiation meetings Patient/ consumer consultation meetings	 Mar – Aug Finalize draft agreement Agency, HHS, & OMB Clearance Sept – Jan Brief Congress Publish draft agreement in FRN Seek comment (docket & public meeting) 	Jan • Transmit to Congress by 1/15/27

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CDRH Vision

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