

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

The FDA encourages the development of innovative, safe, and effective medical devices, including devices that incorporate Artificial Intelligence and Machine Learning (AI/ML).

The AI/ML-Enabled Medical Device List is a resource intended to identify AI/ML-enabled medical devices that are authorized for marketing in the United States.

Contents of the AI-Enabled Medical Devices List:

- The devices in this list have met the FDA's applicable premarket requirements, including a focused review of the device's overall safety and effectiveness, which includes an evaluation of study appropriateness for the device's intended use and technological characteristics.
- The list provides a direct link to the FDA's database entry of each listed medical device that incorporates AI/ML. The database entry contains releasable information such as summaries of safety and effectiveness. Note, the summaries are not all inclusive and do not include most of the information that may be submitted in an application.
- The list is not a comprehensive resource of medical devices that incorporate AI/ML. Instead, the list includes medical devices that incorporate AI/ML across medical disciplines, primarily based on information provided in the summary descriptions of their marketing authorization document.

This list will continue to be updated periodically.

Send questions or feedback on this list to digitalhealth@fda.hhs.gov (<mailto:digitalhealth@fda.hhs.gov>).

AI/ML-Enabled Medical Devices List

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.

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Date of Final Decision	Submission Number	Device	Company	Panel (lead)	Primary Product Code
09/27/2024	K240369	CAC (gated) Algorithm	BunkerHill Health	Radiology	JAK
09/27/2024	K241480	JBS-LVO	JLK, Inc.	Radiology	QAS

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09/27/2024	K240993 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240993)	encevis (2.1)	AIT Austrian Institute of Technology GmbH	Neurology	OMB
09/24/2024	K242292 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242292)	uAI Easy Triage ICH	Shanghai United Imaging Intelligence Co., Ltd.	Radiology	QAS
09/23/2024	K240013 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240013)	EchoGo Heart Failure (2.0)	Ultromics Limited	Cardiovascular	QUO
09/20/2024	K240036 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240036)	PIUR tUS Infinity	PIUR Imaging GmbH	Radiology	QIH
09/13/2024	K240929 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240929)	Sleep Apnea Notification Feature (SANF)	Apple Inc.	Anesthesiology	QZW
09/12/2024	K241582 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241582)	Aplio i900/i800/i700 Diagnostic Ultrasound System, Software V7.0 (TUS-AI900, TUS-AI800, TUS-AI700)	Canon Medical Systems Corporation	Radiology	IYN
09/12/2024	K241280 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241280)	Constellation (CON-001)	Q Bio, Inc.	Radiology	QIH
09/12/2024	K240942 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240942)	CINA-CSpine	Avicenna.AI	Radiology	QAS
09/11/2024	K241380 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241380)	FETOLY-HEART	Diagnoly	Radiology	IYN
09/10/2024	K240094 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240094)	LumiNE US; Lumi	Augmedit B.V.	Radiology	QIH
09/09/2024	K240697 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240697)	See-Mode Augmented Reporting Tool, Thyroid (SMART-T)	See-Mode Technologies Pte. Ltd.	Radiology	QDQ
09/09/2024	K241681 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241681)	Overjet Image Enhancement Assist	Overjet Inc	Radiology	QIH
09/09/2024	K240791 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240791)	ADAS 3D	Adas3D Medical S.L	Radiology	QIH

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09/06/2024	K240411 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240411)	uAI Portal	Shanghai United Imaging Intelligence Co., Ltd.	Radiology	QIH
09/05/2024	K233998 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233998)	TRAQinform IQ	AIQ Global, Inc.	Radiology	LLZ
09/04/2024	K233977 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233977)	Velacur	Sonic Incytes	Radiology	IYO
08/30/2024	K242275 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242275)	syngo.via MI Workflows; Scenium; syngo MBF	Siemens Medical Solutions USA, Inc.	Radiology	QIH
08/30/2024	K242300 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242300)	MI View&GO	Siemens Medical Solutions USA, Inc.	Radiology	QIH
08/30/2024	K241847 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241847)	Imbio PHA (4.0.0)	Imbio, Inc	Radiology	QIH
08/30/2024	K241585 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241585)	uMI Panorama	Shanghai United Imaging Healthcare Co.,Ltd.	Radiology	KPS
08/30/2024	K240003 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240003)	Velmeni for Dentists (V4D)	Velmeni Inc.	Radiology	MYN
08/29/2024	K233826 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233826)	Kosmos	EchoNous, Inc.	Radiology	IYN
08/27/2024	K241684 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241684)	Overjet Charting Assist	Overjet, Inc	Radiology	QIH
08/22/2024	K241098 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241098)	NeuroQuant	CorTechs Labs, Inc.	Radiology	QIH
08/21/2024	K240290 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240290)	AiMIFY (1.x)	Subtle Medical, Inc.	Radiology	LLZ
08/20/2024	K240200 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240200)	HYDROS Robotic System; HYDROS TRUS Probe; HYDROS Handpiece	Procept BioRobotics	General and Plastic Surgery	PZP

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08/20/2024	K241496 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241496)	Vantage Galan 3T, MRT-3020, V10.0 with AiCE Reconstruction Processing Unit for MR	Canon Medical Systems Corporation	Radiology	LNH
08/19/2024	K241440 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241440)	HealthCCSng	Nano-X AI Ltd.	Radiology	JAK
08/16/2024	K233755 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233755)	HeartKey® Rhythm	B-Secur Limited	Cardiovascular	DQK
08/16/2024	K240740 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240740)	qCT LN Quant	Qure.ai Technologies	Radiology	QIH
08/15/2024	K241211 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241211)	CoLumbo	Smart Soft Healthcare	Radiology	QIH
08/15/2024	K241596 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241596)	uMI Panvivo	Shanghai United Imaging Healthcare Co., Ltd.	Radiology	KPS
08/12/2024	K242054 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K242054)	OptimMRI (v2)	Rebrain, SAS	Radiology	QIH
08/08/2024	K233822 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233822)	i2Contour	MRIMath LLC	Radiology	QIH
08/05/2024	K240953 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240953)	AI Platform 2.0 (AIP002)	Exo Imaging	Radiology	QIH
08/05/2024	K233992 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233992)	Precision AI Surgical Planning System (PAI-SPS)	Precision AI Pty Ltd	Orthopedic	QHE
08/02/2024	K233984 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233984)	Acumen Assisted Fluid Management (AFM) Software Feature	Edwards Lifesciences, LLC	Cardiovascular	QMS
08/01/2024	K240301 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240301)	MammoScreen® (3)	Therapixel	Radiology	QDQ
08/01/2024	K234141 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K234141)	AISAP Cardio V1.0	Aisap	Radiology	POK
08/01/2024	K233731 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233731)	CardIQ Suite	GE Medical Systems SCS	Radiology	JAK

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07/25/2024	K241887 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241887)	GI Genius Module 100 (GGM100.US); GI Genius Module 200 (GGM200.US); ColonPRO 4.0 (CPRO40.US); GI Genius Module 300 (GGM300-US); ColonPRO 4.0 (CPRO40S-US)	Cosmo Artificial Intelligence - AI Ltd	Gastroenterology-Urology	QNP
07/24/2024	K240044 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240044)	CADDIE	Odin Medical Limited	Gastroenterology-Urology	QNP
07/22/2024	K240704 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240704)	ACUSON Sequoia Diagnostic Ultrasound System, ACUSON Sequoia Select Diagnostic Ultrasound System, ACUSON Origin Diagnostic Ultrasound System, ACUSON Origin ICE Diagnostic Ultrasound System	Siemens Medical Solutions, USA, Inc.	Radiology	IYN
07/17/2024	K241121 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241121)	MICSI-RMT	Microstructure Imaging, Inc.	Radiology	LLZ
07/17/2024	K240845 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240845)	Rayvolve	AZmed SAS	Radiology	QBS
07/16/2024	K240944 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240944)	Swoop® Portable MR Imaging® System	Hyperfine, Inc.	Radiology	LNH
07/15/2024	K240285 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240285)	Huxley SANSA Home Sleep Apnea Test (1000-00)	Huxley Medical	Anesthesiology	MNR
07/12/2024	K234009 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K234009)	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Model (AC-101-XX)	Mighty Oak Medical	Radiology	QIH

