PRECEDIUM *drafting assistance*

LANDSCAPE BRIEF

Landscape brief: QIH

QIH · Automated Radiological Image Processing Software

PRODUCT CODE
QIH

DEVICE TYPE
Automated Radiological Image Processing Software

CLASS / REGULATION
Class II · 21 CFR 892.2050

PREPARED FOR
Example report

RECORD READ
2026-11-17

338	190	140	2
FDA decisions	companies	median review, days	devices with a recall

ABOUT THIS DOCUMENT

- REAL EXAMPLE of the Landscape brief, $249. Get yours at precedium.com/services/landscape-brief/
- Made from the FDA's public record as Device Evidence publishes it (read 2026-11-17): the FDA register, 510(k) summaries read and checked page by page, and openFDA's recall data. No language model wrote any part of it.
- Every figure is traced to that record, and every passage to the page of the FDA summary it is quoted from; the sources appendix lists each one.
- It covers product code QIH. It uses no document from Example report and makes no statement about any particular device of theirs.
- Not regulatory or investment advice. This brief describes the FDA's public record of one product code as Device Evidence publishes it. It makes no statement about whether the FDA will clear any device, about any route a device should take, or about the prospects of any company.

Contents

01 At a glance 3
02 Devices most like yours 3
03 The record in numbers 6
04 Decisions by year 7
05 Review time by submission type 7
06 What the cleared devices showed 7
07 Where the predicates come from 10
08 Most cited predicates in this code 10
09 Most frequent applicants 11
10 The leading applicants, profiled 11
11 Devices with an authorized change-control plan 12
12 Clinical uses in this code 14
13 The 15 most recent decisions 15
14 Recalls listed against devices in this code 16

Appendix: every decision in QIH 17
15 Questions the record raises 38
16 Sources and method 38
17 Get this landscape brief for your device 38

Appendix: sources 40

01 At a glance

338 FDA decisions in product code QIH, from 2019-11-13 to 2026-10-19 (338 by 510(k)).[1]

306 of them are on the FDA's AI-enabled device list.

Decisions per year went from 2 in 2019 to 94 in 2025.

190 different companies hold them; the most frequent, Siemens Medical Solutions USA, Inc., holds 13.

A 510(k) in this code took a median of 140 days from receipt to decision; one in four took more than 211 days, one in ten more than 265.

The predicate cited most often by later summaries: K153736, 3mensio Workstation (Pie Medical Imaging BV), cited by 6.

2 cleared devices have an FDA recall listed against them.

The earliest decision in the code: K191171, EchoGo Core (Ultromics, Ltd.), 2019-11-13.

25 devices in this code hold an FDA-authorized change-control plan (PCCP).

Median 510(k) review went from 145 days in 2020 to 132 in 2026 (years with at least five reviews).

Of the 302 AI-device summaries held, 213 (71%) state a validation sample size, 100 (33%) data from more than one site and 9 (3%) prospectively collected data.

133 of 262 confirmed predicate links point to devices in QIH itself; 123 point to LLZ. A predicate was a median 2.4 years old when cited.

In the last ten years a Special 510(k) took a median of 29 days (n=41) against 151 for a Traditional (n=296).

The cleared device whose indications are closest to the device described: K211611, QIR Suite (Casis Cardiac Simulation & Imaging Software). The ten closest are listed below.

02 Devices most like yours

The device described: *"AI software that automatically segments the left and right ventricles on cardiac MRI and calculates volumes, ejection fraction and myocardial mass for review by a physician."*

Ranked by how many of the key words in the description appear in each device's indications for use statement, quoted from its 510(k) summary; a device whose summary names only a different imaging type counts at half weight. A word count, not a judgement of equivalence: read each statement before choosing a predicate.

Device	Applicant	Decided	Imaging type	Your key words in its indications
K211611 QIR Suite	Casis Cardiac Simulation & Imaging Software	2022-09-30	MRI, CT	45%

Device	Applicant	Decided	Imaging type	Your key words in its indications
K241038 Cardiac CT Function Software Application	Circle Cardiovascular Imaging	2024-06-07	CT (differs)	45%
K240791 ADAS 3D	Adas3D Medical S.L.	2024-09-09	MRI, CT	18%
K253969 ADAS 3D	Adas3D Medical S.L.	2026-06-29	MRI, CT	18%
K200621 Caption Interpretation Automated Ejection Frac...	Caption Health	2020-07-22	ultrasound (differs)	36%
K210747 Caption Interpretation Automated Ejection Frac...	Caption Health	2022-01-19	ultrasound (differs)	36%
K233676 Us2.v2	Eko.Ai Pte Ltd. D/B/A Us2.Ai	2024-04-01	ultrasound, ECG (differs)	36%
K240786 AutoChamber	HeartLung Corporation	2024-10-10	CT (differs)	36%
K241222 Ventripoint Medical System Plus (VMS+) 4.0	Ventripoint Diagnostics , Ltd.	2025-02-26	ultrasound (differs)	36%
K203256 Imbio RV/LV Software	Imbio, LLC	2021-03-09	CT (differs)	27%

THEIR INDICATIONS, AS STATED

K211611, QIR Suite: "The software has been validated for use on adult patients. QIR Suite comprises QIR-MR for analysis of MR images. QIR-MR is composed of a viewer and analysis modules, and uses user inputs, standard algorithms, and/or automated deep learning detection..."[2]

K241038, Cardiac CT Function Software Application: "CT Function includes manual and semi-automatic heart segmentation of 2 chambers (LV and RV) and calculation of cardiac function metrics including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and..."[3]

K240791, ADAS 3D: "ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease. ADAS 3D processes MR and CT images. The quality and the resolution of the medical images determines the accuracy of the data produced by ADAS 3D."[4]

K253969, ADAS 3D: "ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease. ADAS 3D processes MR and CT images. The quality and the resolution of the medical images determines the accuracy of the data produced by ADAS 3D."[5]

K200621, Caption Interpretation Automated Ejection Fraction Software: "The Caption Interpretation Automated Ejection Fraction software is used to process previously acquired transthoracic cardiac

ultrasound images, to store images, and to manipulate and make measurements on images using an ultrasound device, personal computer,..."[6]

THE THREE CLOSEST, IN DETAIL

What each device's own 510(k) summary shows: the predicates it cites (confirmed links), the kinds of testing it reports, and for a device on the FDA's AI list, how many of the thirteen evidence elements its summary states.

Device	Its predicates	Testing it reports	AI evidence stated
K211611 QIR Suite	K163076 Segment CMR	Software	2 of 13: Reference standard, Performance comparator
K241038 Cardiac CT Function Software Application	none confirmed	Bench / non-clinical performance, Software	3 of 13: Reference standard, Performance comparator, Multiple collection sites
K240791 ADAS 3D	K230803 ADAS 3D	none confirmed	2 of 13: Reference standard, Performance comparator

EVIDENCE GRID: WHAT THE CLOSEST DEVICES' SUMMARIES STATE

For each of the closest devices on the FDA's AI list, whether its 510(k) summary states each kind of evidence, with the page to read. A dash means the summary does not state it; that is not proof the work was not done.

Device	Sample size	Sites	Prospective	Reference standard	Study design	Performance	Demographics
K211611 QIR Suite	-	-	-	p. 8	-	-	-
K241038 Cardiac CT Function Software Application	-	p. 11	-	p. 11	-	-	-
K240791 ADAS 3D	-	-	-	p. 14	-	-	-
K253969 ADAS 3D	-	-	-	p. 17	-	-	-
K200621 Caption Interpretation Automated Ejection Frac...	-	-	-	p. 6	p. 6	p. 6	-
K210747 Caption Interpretation Automated	p. 6	p. 5	-	p. 6	p. 6	-	-

Device	Sample size	Sites	Prospective	Reference standard	Study design	Performance	Demographics
Ejection Frac...							
K233676 Us2.v2	p. 8	-	-	p. 8	p. 8	-	p. 8
K241222 Ventripoint Medical System Plus (VMS+) 4.0	p. 7	-	-	p. 7	p. 6	-	-
K203256 Imbio RV/LV Software	-	-	-	-	p. 7	-	-

Not on the FDA's AI list, so not in the grid: K240786.

03 The record in numbers

Measure	Value
FDA decisions with product code QIH	338
by 510(k)	338
On the FDA's AI-enabled device list	306
Earliest / most recent decision	2019-11-13 / 2026-10-19
Distinct applicants	190
510(k) review, receipt to decision (days): median / 75th / 90th percentile	140 / 211 / 265 (n=338)
Devices with an FDA recall listed against them	2

All figures from the FDA register as Device Evidence publishes it.[1]

Review time is calendar days from the FDA's received date to its decision date; it includes time on hold.

04 Decisions by year

Year	Decisions	Median 510(k) review, days	
2019	2	196 (n=2)	|
2020	11	145	||||
2021	19	125	|||||
2022	25	134	|||||||
2023	45	151	|||||||||||
2024	64	142	|||||||||||||||
2025	94	152	||||||||||||||||||||||||
2026	78	132	|||||||||||||||||||

05 Review time by submission type

510(k)s decided in the last ten years, by the submission type the FDA records.[1]

Submission type	510(k)s	Median days	75th percentile
Traditional	296	151	222
Special	41	29	65
Abbreviated	1	117	-

A Special 510(k) is for a change to the submitter's own cleared device; an Abbreviated one leans on guidance documents and standards. Calendar days from receipt to decision, including time on hold.

06 What the cleared devices showed

How the 302 summaries of AI-list devices in QIH describe their performance evidence: how many state each of the thirteen elements Device Evidence reads.[1]

Evidence element	Summaries stating it	Share
Performance comparator	223 of 302	74%

Evidence element	Summaries stating it	Share
Validation sample size	213 of 302	71%
Reference standard	211 of 302	70%
Study design	190 of 302	63%
Age distribution	132 of 302	44%
Sex breakdown	114 of 302	38%
Multiple collection sites	100 of 302	33%
Race or ethnicity breakdown	53 of 302	18%
Sensitivity	36 of 302	12%
Specificity	27 of 302	9%
Prospective collection	9 of 302	3%
AUC	4 of 302	1%
Patient outcomes	0 of 302	0%

Counted from what each summary states. A summary can omit what the full submission contained, so a low share is a floor, not proof the evidence was missing. The devices' own sentences, with pages, are in the testing precedent report.

Evidence element, by when decided	2016-2020 (13)	2021-2023 (88)	2024 on (201)
Validation sample size	31%	65%	76%
Age distribution	0%	43%	47%
Sex breakdown	0%	32%	43%
Race or ethnicity breakdown	0%	13%	21%
Study design	31%	65%	64%
Sensitivity	15%	15%	10%
Specificity	8%	11%	8%
AUC	0%	1%	1%
Reference standard	31%	60%	77%
Performance comparator	31%	68%	79%
Multiple collection sites	0%	28%	37%
Prospective collection	0%	3%	3%

Evidence element, by when decided	2016-2020 (13)	2021-2023 (88)	2024 on (201)
Patient outcomes	0%	0%	0%

TESTING REPORTED

Kind of testing	Summaries reporting it	Share
Software	at least 196 of 331	59%
Bench / non-clinical performance	at least 94 of 331	28%
Usability / human factors	at least 77 of 331	23%
Cybersecurity	at least 23 of 331	7%
Clinical data	at least 22 of 331	7%
Electrical safety	at least 6 of 331	2%
Electromagnetic compatibility	at least 4 of 331	1%
Biocompatibility	at least 1 of 331	<1%

Standard cited	Summaries
IEC 62304	63 of 331
IEC 62366-1	37 of 331
IEC 62366	10 of 331
IEC 82304-1	6 of 331
IEC 81001-5-1	4 of 331
AAMI 57	2 of 331
IEC 60601-1	2 of 331
IEC 60601-1-2	2 of 331
IEC 62366-2	1 of 331
ISO 10993-1	1 of 331

Each line is a passage in a cleared summary that reports this kind of testing for the device itself: a statement that it was tested, or the standard it meets as listed in the summary. Testing the summary attributes to the predicate, another device or an earlier submission, or reports as not performed, is left out (every line read against its page twice, D-095 to D-098). A share counts summaries that report the kind; a summary can leave out testing that was done, so each share is a floor: 'at least this many report it', never 'only this many did'.

07 Where the predicates come from

239 summaries in QIH cite a confirmed predicate, 262 links in all. 133 (51%) point to a device in QIH; the rest to other product codes.[1]

Predicate's product code	Links
QIH (this code)	133
LLZ	123
JAK	2
LNH	2
KPS	1
QKB	1

When cited, a predicate was a median 2.4 years old; 14 of 262 were more than ten years old.

08 Most cited predicates in this code

How many later summaries name each device as their predicate. From summaries decided 2016 onwards; confirmed links only.

Predicate	Device	Applicant	Decided	Cited by
K153736	3mensio Workstation	Pie Medical Imaging BV	2016-05-27	6
K203256	Imbio RV/LV Software	Imbio, LLC	2021-03-09	5
K191647	QLAB Advanced Quantification Software	Philips Health Care	2019-12-20	4
K210053	LVivo Software Application	Dia Imaging Analysis, Ltd.	2021-02-05	4
K220497	CoLumbo	Smart Soft Healthcare AD	2022-06-23	4
K233925	Relu Creator	Relu BV	2024-06-13	4
K170981	NeuroQuant	Cortechs Labs, Inc.	2017-09-07	3
K192109	KOALA	Ib Lab GmbH	2019-11-05	3
K193290	AI-Rad Companion Brain MR	Siemens Medical Solutions USA, Inc.	2020-06-17	3
K210187	Overjet Dental Assist	Overjet, Inc.	2021-05-19	3

09 Most frequent applicants

Applicant	Decisions	Share
Siemens Medical Solutions USA, Inc.	13	4%
Dia Imaging Analysis, Ltd.	10	3%
Ischemaview, Inc.	6	2%
Shanghai United Imaging Healthcare Co., Ltd.	6	2%
Clarius Mobile Health Corp.	5	1%
Overjet, Inc.	5	1%
Siemens Healthcare GmbH	5	1%
Aidoc Medical , Ltd.	4	1%
Ceevra, Inc.	4	1%
Circle Cardiovascular Imaging, Inc.	4	1%

Counted by company: spellings of one name (capitals, punctuation, Inc. or Ltd.) are counted together under the spelling used most often. A parent and its subsidiaries file under different names and are counted separately.

10 The leading applicants, profiled

The 10 most frequent applicants in QIH: when they filed, how long their 510(k)s took, how many of their devices are on the FDA's AI list, and the predicates their own summaries cite most.[1]

Company	Decisions	First / latest	Median 510(k) days	On AI list	Predicates they cite most
Siemens Medical Solutions USA, Inc.	13	2020-07-30 / 2026-09-25	95	12	K201202 MI View&GO (2); K110494 SYNGO MBF (1); K180336 syngo.MR Applications (1)
Dia Imaging Analysis, Ltd.	10	2020-06-23 / 2025-03-17	127	10	K200232 LVivo Software Application (2); K222970 LVivo IQS (2); K202546 LVivo Seamless (1)
Ischemaview, Inc.	6	2023-02-01 / 2026-09-21	88	5	K203256 Imbio RV/LV Software (1); K213165 Rapid (1); K223396 Rapid RV/LV (1)

Company	Decisions	First / latest	Median 510(k) days	On AI list	Predicates they cite most
Shanghai United Imaging Healthcare Co., Ltd.	6	2020-06-01 / 2026-04-22	232	6	K183170 uWS-CT (1); K233186 uOmnispace.MR (1); K233209 uOmnispace.CT (1)
Clarius Mobile Health Corp.	5	2023-01-23 / 2026-03-02	108	5	K210747 Caption Interpretation Automated Ejection Frac... (1)
Overjet, Inc.	5	2024-02-23 / 2026-04-10	107	5	K200572 Planmeca Romexis (1); K222054 Denti.AI Auto-Chart (1); K233925 Relu Creator (1)
Siemens Healthcare GmbH	5	2022-04-15 / 2026-04-10	140	5	K193290 AI-Rad Companion Brain MR (1); K222428 Syngo Dynamics (Version VA40F) (1); K230561 Syngo Carbon Space VA30A (1)
Aidoc Medical , Ltd.	4	2023-11-08 / 2024-11-22	123	4	K211222 qER-Quant (1); K241112 BriefCase-Quantification (1)
Ceevra, Inc.	4	2023-04-25 / 2026-08-25	103	3	K173274 Ceevra Reveal 2.0 (1); K222676 Ceevra Reveal 3 (1); K243933 Ceevra Reveal 3+ (1)
Circle Cardiovascular Imaging, Inc.	4	2022-07-28 / 2025-10-27	208	4	K082628 CMR42 CARDIAC MRI IMAGING SYSTEM, 2.1.23 (1); K111373 CT42 CARDIAC COMPUTED TOMOGRAPHY (CT) SOFTWARE (1); K141480 CVI42 (1)

11 Devices with an authorized change-control plan

25 devices with primary product code QIH are on the FDA's list of devices with an authorized Predetermined Change Control Plan (PCCP): a plan, authorized with the submission, for how the model may change after clearance.[7]

Number	Device	Company	Decided
K261623	ECHOPAC SOFTWARE ONLY / ECHOPAC PLUG-IN (V211)	GE MEDICAL SYSTEMS ULTRASOUND AND PRIMARY CARE...	2026-09-16
K260811	HEARTVUE.PROTON	HEARTVUE.AI, INC.	2026-08-26
K261595	CEEVRA REVEAL 4	CEEVRA, INC.	2026-08-25
K260980	CMANGIO® V2.0	CUREMETRIX INC.	2026-07-30
K261210	CLEERLY PLAQUE	CLEERLY, INC.	2026-07-29
K260973	INFEROPERATE SUITE	BEIJING INFERVISION HEALTHCARE MEDICAL TECHNOL...	2026-07-07
K253786	SYNGO.CT CORONARY COCKPIT	SIEMENS MEDICAL SOLUTIONS USA, INC.	2026-06-25
K260406	BRAINOMIX 360 HYPERDENSITY	BRAINOMIX LIMITED	2026-06-12
K260234	MSK GO	SMART ALFA TEKNOLOJI SAN. VE TIC. A.S.	2026-05-21
K254131	BAC	DEEPHEALTH, INC.	2026-05-21
K253689	SYNGO DYNAMICS (VA41F)	SIEMENS HEALTHCARE GMBH	2026-04-10
K253593	CLARIUS EJECTION FRACTION AI	CLARIUS MOBILE HEALTH CORP.	2026-03-02
K252235	PVAD IQ SOFTWARE	ULTRASIGHT LTD.	2025-12-18
K250369	AXIAL3D INSIGHT	AXIAL MEDICAL PRINTING LIMITED	2025-09-18
K250237	INFEROPERATE SUITE	BEIJING INFERVISION HEALTHCARE MEDICAL TECHNOL...	2025-09-15
K243685	MAMMOSCREEN BD	THERAPIXEL	2025-08-22
K251456	BRIGHTHEART VIEW CLASSIFIER	BRIGHTHEART	2025-06-05
K250226	CLARIUS MEDIAN NERVE AI	CLARIUS MOBILE HEALTH CORP.	2025-05-08
K243684	BRIGHTHEART VIEW CLASSIFIER	BRIGHTHEART	2025-05-07
K243853	CLARIUS PROSTATE AI	CLARIUS MOBILE HEALTH CORP.	2025-04-16
K242551	SYNGO DYNAMICS (VERSION VA41D)	SIEMENS HEALTHCARE GMBH	2025-04-03
K241684	OVERJET CHARTING ASSIST	OVERJET, INC	2024-08-27
K240953	AI PLATFORM 2.0 (AIP002)	EXO IMAGING	2024-08-05
K234009	ACORN 3D SOFTWARE (AC-SEG-4009); ACORN 3DP MOD...	MIGHTY OAK MEDICAL	2024-07-12

Number	Device	Company	Decided
K233030	BONEMRI	MRIGUIDANCE B.V	2024-03-01

An authorized PCCP is a fact about a submission, not a rating of the device. Its own summary describes the plan's scope.

12 Clinical uses in this code

What the 258 indications statements held for QIH are for, by body area and by task.[1]

A keyword grouping of each device's name and indications statement: a device can fall in several groups, and 5 fall in none. It sorts the record; it does not classify any device for the FDA.

Body area	Devices	Share
Bone, joint and spine	60	23%
Heart	58	22%
Brain and head	48	19%
Blood vessels	37	14%
Abdomen and pelvis	28	11%
Lung and chest	28	11%
Breast	25	10%
Teeth and jaw	20	8%
Eye	1	<1%

Task	Devices	Share
Segmentation and measurement	190	74%
Viewing and communication	107	41%
Detection	77	30%
Planning and guidance	69	27%
Image enhancement	32	12%
Diagnosis and scoring	28	11%
Triage and notification	1	<1%

THE MOST COMMON COMBINATIONS

Body area	Task	Devices
Heart	Segmentation and measurement	49
Bone, joint and spine	Segmentation and measurement	42
Brain and head	Segmentation and measurement	39
Blood vessels	Segmentation and measurement	33
Heart	Viewing and communication	30
Bone, joint and spine	Planning and guidance	25
Blood vessels	Viewing and communication	23
Brain and head	Viewing and communication	22
Lung and chest	Segmentation and measurement	22
Abdomen and pelvis	Segmentation and measurement	20
Bone, joint and spine	Viewing and communication	19
Brain and head	Detection	18

13 The 15 most recent decisions

Number	Device	Applicant	Decided
K262147	CINA-Aneurysm+	Avicenna.Ai	2026-10-19
K262134	NeuroDR	Deep Reasoning Ai, Inc.	2026-10-07
K261733	Ligence Heart	UAB Ligence	2026-10-07
K260523	QGuideCT (1.0)	Medis Medical Imaging Systems BV	2026-10-05
K260055	syngo.CT Brain Quantification	Siemens Medical Solutions USA, Inc.	2026-09-25
K262390	BoneXpert	Visiana	2026-09-22
K261368	Rapid Platform (R6.7)	Ischemaview, Inc.	2026-09-21
K261623	EchoPAC Software Only / EchoPAC Plug-in (v211)	GE Medical Systems Ultrasound and Primary Care...	2026-09-16
K261677	Artificial Intelligence Renal Assessment (AIRA...	Aramis Global AI Consultancies, LLC	2026-09-15

Number	Device	Applicant	Decided
K260879	4DM	INVIA, LLC	2026-09-10
K261795	Quicktome Software Suite	Omniscient Neurotechnology Pty, Ltd.	2026-09-10
K251417	ReVISION 2	Argus Cognitive, Inc.	2026-09-09
K260525	NextMR Spine	MRI2CT, Inc.	2026-09-04
K260811	Heartvue.Proton	Heartvue.ai, Inc.	2026-08-26
K261595	Ceevra Reveal 4	Ceevra, Inc.	2026-08-25

14 Recalls listed against devices in this code

2 recall events against 2 devices: Class II 2. Class I is the most serious.

Number	Device	Recalls	Most recent initiated
K250330	3mensio Workstation	1	2026-05-07
K200621	Caption Interpretation Automated Ejection Frac...	1	2021-05-19

EACH RECALL, IN THE FDA'S WORDS

K250330 3mensio Workstation · Class II · initiated 2026-05-07 · Z-2767-2026:"User measurement value reported by diagnostic bioimaging software intended to measure/visualize cardiovascular structures may be larger (0.8% to 34.4%) than the actual anatomical dimension, if all the following occur: affected software is used, and the user has access only to 3D Echo OR Mitral 3D..."

K200621 Caption Interpretation Automated Ejection Frac... · Class II · initiated 2021-05-19 · Z-2111-2021: "The firm is aware of a issue with ultrasound software that results in unintended video frames being included. This could lead to an incorrect automated ejection fraction (AutoEF) and image quality score (IQS) estimates."

From openFDA's device recall and enforcement data, joined on the submission number. A recall is listed against the submission, not necessarily the model a reader has in mind.[8]

Appendix: every decision in QIH

All 338 FDA decisions with product code QIH, newest first.[1]

Type is the submission type the FDA records. Days are calendar days from receipt to decision, for 510(k)s. Flags: AI = on the FDA's AI-enabled device list; R = an FDA recall is listed against it; P = an authorized change-control plan.

Number	Device	Applicant	Decided	Type	Days	Flags
K262147	CINA-Aneurysm+	Avicenna.Ai	2026-10-19	Traditional	116	-
K262134	NeuroDR	Deep Reasoning Ai, Inc.	2026-10-07	Traditional	104	-
K261733	Ligence Heart	UAB Ligence	2026-10-07	Traditional	134	-
K260523	QGuideCT (1.0)	Medis Medical Imaging Systems BV	2026-10-05	Traditional	230	-
K260055	syngo.CT Brain Quantification	Siemens Medical Solutions USA, Inc.	2026-09-25	Traditional	260	-
K262390	BoneXpert	Visiana	2026-09-22	Traditional	71	-
K261368	Rapid Platform (R6.7)	Ischemaview, Inc.	2026-09-21	Traditional	147	-
K261623	EchoPAC Software Only / EchoPAC Plug-in (v211)	GE Medical Systems Ultrasound and Primary Care...	2026-09-16	Traditional	124	P
K261677	Artificial Intelligence Renal Assessment (AIRA...	Aramis Global AI Consultancies , LLC	2026-09-15	Traditional	117	-
K260879	4DM	INVIA, LLC	2026-09-10	Traditional	177	-
K261795	Quicktome Software Suite	Omniscient Neurotechnology Pty, Ltd.	2026-09-10	Traditional	104	-
K251417	ReVISION 2	Argus Cognitive, Inc.	2026-09-09	Traditional	490	-

Number	Device	Applicant	Decided	Type	Days	Flags
K260525	NextMR Spine	MRI2CT, Inc.	2026-09-04	Traditional	199	-
K260811	Heartvue.Proton	Heartvue.ai, Inc.	2026-08-26	Traditional	167	P
K261595	Ceevra Reveal 4	Ceevra, Inc.	2026-08-25	Traditional	103	P
K260584	BoneMRI	Mriguidance B.V.	2026-08-21	Traditional	182	-
K262127	DS Core CBCT Anatomy	Dentsply Sirona	2026-08-21	Traditional	58	-
K261641	Lower Limb AI (LLAI)	AI Planning Logic, Inc.	2026-08-18	Traditional	92	-
K253794	Prostate Core	Lucida Medical, Ltd.	2026-08-10	Traditional	255	-
K252571	mdprostate	Mediaire GmbH	2026-08-07	Traditional	358	-
K253902	RealGUIDE	3DIEMME SRL	2026-08-04	Traditional	242	-
K253835	Affinity	Hermes Medical Solutions AB	2026-07-31	Traditional	242	-
K260980	cmAngio® V2.0	Curemetrix, Inc.	2026-07-30	Traditional	127	P
K261210	Cleerly Plaque	Cleerly, Inc.	2026-07-29	Traditional	106	P
K260192	DIANA	ROPCA ApS	2026-07-24	Traditional	183	-
K261349	SwiftMR	Airs Medical, Inc.	2026-07-24	Traditional	91	-
K254096	VELMENI for DENTISTS (V4D) 3D	Velmeni, Inc.	2026-07-23	Traditional	216	-
K261535	Hi-D Imaging 4TAVR	Hi-D Imaging AG	2026-07-20	Special	73	-
K260206	SkeletonPlanner	UPlanner B.V. - Presurgeo	2026-07-15	Traditional	173	-
K260973	InferOperate Suite	Beijing Infervision Healthcare Medical Technol...	2026-07-07	Traditional	105	P

Number	Device	Applicant	Decided	Type	Days	Flags
K253969	ADAS 3D	Adas3D Medical S.L.	2026-06-29	Traditional	200	AI
K253628	Auto-Seg (SO-0012), Spine Auto-Seg (SO-0012)	Agada Medical, Ltd.	2026-06-29	Traditional	222	AI
K253786	syngo.CT Coronary Cockpit	Siemens Medical Solutions USA, Inc.	2026-06-25	Traditional	211	AI P
K260316	CMN Capillary Function with Oncology Virtual E...	Cercare Medical A/S	2026-06-22	Traditional	143	AI
K261713	Synapse PACS (7.6.0)	FUJIFILM Healthcare Americas Corporation	2026-06-18	Special	27	AI
K260300	WatchMate Software	Anumana, Inc.	2026-06-15	Traditional	136	AI
K253172	MediAI-OA	Crescom Co., Ltd.	2026-06-15	Traditional	262	AI
K253690	LungMaps	Siemens Healthineers AG	2026-06-15	Traditional	206	AI
K260406	Brainomix 360 Hyperdensity	Brainomix Limited	2026-06-12	Traditional	123	AI P
K260322	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Mod...	Mighty Oak Medical	2026-06-11	Traditional	132	AI
K260497	DEEPVESSEL Plaque	Keya Medical Technology Co., Ltd.	2026-06-04	Traditional	111	AI
K260077	OrthoGrid Hip AI® 4.0	OrthoGrid Systems, Inc.	2026-05-29	Traditional	137	AI
K261405	ANDI 2.2	Imeka Solutions, Inc.	2026-05-28	Special	29	AI
K260324	Vitrea CT Transcatheter Aortic Valve Replaceme...	Canon Medical Informatics, Inc.	2026-05-22	Traditional	112	AI
K260234	MSK Go	Smart Alfa Teknoloji San.	2026-05-21	Traditional	115	AI P

Number	Device	Applicant	Decided	Type	Days	Flags
		Ve Tic. A.S.				
K254131	BAC	DeepHealth, Inc.	2026-05-21	Traditional	150	AI P
K261273	Neurophet AQUA	Neurophet., Inc.	2026-05-15	Special	28	AI
K254120	SubtleHD-CT (1.x)	Subtle Medical, Inc.	2026-05-15	Traditional	147	AI
K261289	UNiD™ Spine Analyzer (SW3002)	Medicrea International S.A.S. (Medtronic)	2026-05-15	Special	25	AI
K252563	Neurophet SCALE PET	Neurophet., Inc.	2026-05-15	Traditional	274	AI
K260032	Morph	BeauBrain Healthcare, Inc.	2026-05-13	Traditional	127	AI
K254189	Synapse 3D Base Tools (V7.2)	Fujifilm Corporation	2026-04-30	Traditional	128	AI
K254184	syngo Application Software	Siemens Medical Solutions USA, Inc.	2026-04-29	Traditional	127	AI
K260785	DS Core CBCT Anatomy	Dentsply Sirona	2026-04-23	Traditional	44	AI
K253077	uOmnispace.MR	Shanghai United Imaging Healthcare Co., Ltd.	2026-04-22	Traditional	211	AI
K252332	Folliscan	Mim Fertility	2026-04-20	Traditional	269	AI
K253502	Critical Care Suite with Enteric Tube Position...	Ge Medical Systems, LLC	2026-04-14	Traditional	166	AI
K252708	Relu Cloud	Relu BV	2026-04-10	Traditional	226	AI
K253930	Overjet Iris Intelligent Imaging System	Overjet, Inc.	2026-04-10	Traditional	122	AI
K253689	syngo Dynamics (VA41F)	Siemens Healthcare GmbH	2026-04-10	Traditional	140	AI P

Number	Device	Applicant	Decided	Type	Days	Flags
K254015	CoLumbo C-Spine	Smart Soft Healthcare AD	2026-04-01	Traditional	107	AI
K254207	AiORTA - Plan v2.0	ViTAA Medical Solutions, Inc.	2026-03-30	Traditional	91	AI
K253775	SwiftMR	Airs Medical, Inc.	2026-03-26	Traditional	120	AI
K253614	EchoNavigator R5.0	Philips Medical Systems Nederland B.V.	2026-03-17	Traditional	119	AI
K253944	Data Analysis Facilitation Suite (DAFS)	Voronoi Health Analytics Incorporated	2026-03-16	Traditional	96	AI
K252261	InferCare RECIST	Beijing Infervision Healthcare Medical Technol...	2026-03-13	Traditional	235	AI
K253551	VELYS™ Hip Navigation	Depuy Ireland UC	2026-03-06	Traditional	112	AI
K252538	CEPHX3D	Orca Dental AI , Ltd.	2026-03-05	Traditional	205	AI
K253593	Clarius Ejection Fraction AI	Clarius Mobile Health Corp.	2026-03-02	Traditional	105	AI P
K253535	Ligence Heart	Ligence Uab	2026-02-27	Traditional	106	AI
K260217	AI Platform 2.2 (AIP002)	Exo Imaging	2026-02-24	Special	32	AI
K252084	AI4CMR v2.0	Ai4medimaging Medical Solutions S.A.	2026-02-11	Special	224	AI
K254016	MI View&GO	Siemens Medical Solutions USA, Inc.	2026-02-10	Special	57	AI
K252496	Neurophet AQUA AD Plus	Neurophet., Inc.	2026-01-29	Traditional	174	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K252091	Surgical Reality Viewer	Medicalvr B.V.	2026-01-29	Traditional	210	AI
K253735	AV Vascular	Philips Medical Systems Nederland B.V.	2026-01-22	Traditional	59	AI
K253057	AI-Rad Companion Brain MR	Siemens Healthcare GmbH	2026-01-22	Traditional	122	AI
K252634	Imagine® Enterprise Suite	Softlink International Private Limited	2026-01-16	Traditional	149	AI
K253532	TruSPECT Processing Station	Spectrum Dynamics Medical, Ltd.	2025-12-30	Special	47	AI
K252856	PeekMed web	Peek Health, S.A.	2025-12-22	Traditional	104	AI
K252029	AI-CVD	HeartLung Corporation	2025-12-19	Traditional	172	AI
K252670	Alzevita	TOPIA MEDTECH LIMITED	2025-12-19	Traditional	116	AI
K252235	PVAD IQ Software	Ultrasight , Ltd.	2025-12-18	Traditional	154	AI P
K250914	MediAI-BA	Crescom Co., Ltd.	2025-12-18	Traditional	266	AI
K252922	Neosoma Brain Mets	Neosoma, Inc.	2025-12-17	Traditional	93	AI
K251763	IRISeg	Intuitive Surgical, Inc.	2025-12-16	Traditional	190	AI
K251514	Overjet CBCT Assist	Overjet, Inc.	2025-12-05	Traditional	203	AI
K252103	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Mod...	Mighty Oak Medical	2025-12-02	Traditional	152	AI
K251078	AutoDensity	Eos Imaging	2025-11-14	Traditional	220	AI
K252452	PeekMed web	Peek Health, S.A.	2025-11-12	Traditional	100	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K250330	3mensio Workstation	Pie Medical Imaging BV	2025-11-03	Traditional	271	AI R
K250337	AiORTA - Plan	ViTAA Medical Solutions, Inc.	2025-10-30	Traditional	266	AI
K251027	cvi42 Coronary Plaque Software Application	Circle Cardiovascular Imaging, Inc.	2025-10-27	Traditional	208	AI
K251059	Syngo Carbon Clinicals (VA41)	Siemens Healthineers AG	2025-10-24	Traditional	203	AI
K250288	TeraRecon Cardiovascular.Calcification.CT	Terarecon,Inc.	2025-10-23	Traditional	265	AI
K252298	ANDI 2.0	Imeka Solutions, Inc.	2025-10-22	Traditional	91	AI
K252665	brAIn™ Shoulder Positioning	Avatar Medical	2025-10-20	Traditional	56	AI
K252214	AIAS Cephalon	Metamorphosis GmbH	2025-10-07	Traditional	84	AI
K252007	BlineSlide	Deep Breathe, Inc.	2025-10-06	Traditional	101	AI
K250023	SMART PCFD	Disior, Ltd.	2025-09-29	Traditional	269	AI
K252105	Ligence Heart	Ligence Uab	2025-09-26	Traditional	85	AI
K251527	Brain WMH	Quantib B.V.	2025-09-25	Traditional	129	AI
K251483	SwiftSight-Brain	Airs Medical, Inc.	2025-09-23	Traditional	132	AI
K251987	Rapid Aortic Measurements	Ischemaview, Inc.	2025-09-23	Traditional	88	AI
K250369	Axial3D Insight	Axial Medical Printing Limited	2025-09-18	Traditional	220	AI P
K250237	InferOperate Suite	Beijing Infervision Healthcare Medical Technol...	2025-09-15	Traditional	231	AI P

Number	Device	Applicant	Decided	Type	Days	Flags
K244002	AngioWaveNet	Angiowave Imaging, Inc.	2025-09-10	Traditional	258	AI
K251072	Segmentron Viewer	DGNCT, LLC	2025-09-09	Traditional	155	AI
K251656	Careverse CoronaryDoc (Careverse CoronaryDoc)	Careverse Technology Pte. , Ltd.	2025-09-04	Traditional	97	AI
K252539	Tempus Pixel	Arterys, Inc.	2025-09-03	Special	22	AI
K243859	PRAEVAorta®2	Nurea	2025-08-29	Traditional	256	AI
K250947	VistaSoft 4.0 and VisionX 4.0	Durr Dental SE	2025-08-27	Traditional	152	-
K243685	MammoScreen BD	Therapixel	2025-08-22	Traditional	266	AI P
K252362	GBrain MRI	Galileo Cds, Inc.	2025-08-22	Special	24	AI
K251837	Salix Coronary Plaque (V1.0.0)	Artrya Limited	2025-08-20	Traditional	65	AI
K251747	VEA Align; spineEOS	Eos Imaging	2025-08-15	Traditional	70	AI
K250755	DS Core Diagnosis	Dentsply Sirona, Inc.	2025-08-12	Traditional	153	AI
K251629	UNiD™ Spine Analyzer	Medicrea International S.A.S. (Medtronic)	2025-08-07	Traditional	71	AI
K243919	Voxel Dosimetry (00859873006226)	Hermes Medical Solutions AB	2025-07-30	Traditional	222	AI
K251342	EchoPAC Software Only / EchoPAC Plug-in	GE Medical Systems Ultrasound and Primary Care...	2025-07-16	Traditional	77	AI
K251096	PeekMed web	Peek Health, S.A.	2025-07-14	Traditional	95	AI
K251766	TumorSight Viz	SimBioSys, Inc.	2025-07-08	Special	29	AI
K251528	syngo.via MI Workflows; Scenium; syngo MBF	Siemens Medical Solutions USA, Inc.	2025-07-03	Traditional	45	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K243779	Bunkerhill Abdominal Aortic Quantification (AAQ)	BunkerHill Health	2025-07-01	Traditional	204	AI
K250670	EchoConfidence (USA)	Mycardium AI Limited	2025-06-30	Abbreviated	117	AI
K243647	Synapse PACS (7.5)	FUJIFILM Healthcare Americas Corporation	2025-06-30	Traditional	216	AI
K250484	PIUR tUS inside	Piur Imaging GmbH	2025-06-30	Traditional	131	AI
K243633	Brainlab Elements (7.0); Brainlab Elements Ima...	Brainlab AG	2025-06-13	Traditional	200	AI
K250354	Viz Subdural+, Viz SUBDURAL PLUS	Viz. Ai, Inc.	2025-06-10	Traditional	123	AI
K251009	Cirrus Resting State fMRI Software	Sora Neuroscience , Inc.	2025-06-06	Traditional	66	AI
K251456	BrightHeart View Classifier	Brightheart	2025-06-05	Special	24	AI P
K243810	TraumaCad Neo (1.1)	Brainlab , Ltd.	2025-06-04	Traditional	175	AI
K243005	AudaxCeph Cephalogram Analysis Software	Audax D.O.O.	2025-05-30	Traditional	246	AI
K243863	Opulus™ Lymphoma Precision	Roche Molecular Systems, Inc.	2025-05-30	Traditional	164	AI
K250367	CoLumboX	Smart Soft Healthcare AD	2025-05-28	Traditional	107	AI
K243378	Rapid MLS	Ischemaview, Inc.	2025-05-28	Traditional	210	AI
K250005	Clever One	Ewoosoft Co., Ltd.	2025-05-23	Traditional	141	AI
K243989	Second Opinion® 3D	Pearl, Inc.	2025-05-23	Traditional	148	AI
K243762	Synapse 3D Base Tools (V7.0)	Fujifilm Corporation	2025-05-21	Traditional	166	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K242624	Medical Image Post-processing Software (uOmnis...	Shanghai United Imaging Healthcare Co., Ltd.	2025-05-14	Traditional	253	AI
K243230	Second Opinion® BLE	Pearl, Inc.	2025-05-09	Traditional	213	AI
K250226	Clarius Median Nerve AI	Clarius Mobile Health Corp.	2025-05-08	Traditional	101	AI P
K243684	BrightHeart View Classifier	Brightheart	2025-05-07	Traditional	159	AI P
K250328	UltraExtend NX CUW-U001S V2.0 Ultrasound Image...	Canon Medical Systems Corporation	2025-04-30	Traditional	84	AI
K242500	LARALAB	Laralab GmbH	2025-04-16	Traditional	237	AI
K243853	Clarius Prostate AI	Clarius Mobile Health Corp.	2025-04-16	Traditional	121	AI P
K250416	GBrain MRI	Galileo Cds, Inc.	2025-04-11	Traditional	57	AI
K250754	cmAngio® (V1.6)	Curemetrix, Inc.	2025-04-10	Special	29	AI
K241982	DeepFoqus (DeepFoqus-Accelerate)	Foqus Technologies, Inc.	2025-04-04	Traditional	273	AI
K242551	syngo Dynamics (Version VA41D)	Siemens Healthcare GmbH	2025-04-03	Traditional	219	AI P
K241984	Hi-D Imaging 4TAVR	Hi-D Imaging AG	2025-04-02	Traditional	268	AI
K242166	TribusConnect	Tribusmed Beheer BV	2025-03-31	Traditional	250	AI
K243038	Salix Central	Artrya Limited	2025-03-27	Traditional	181	AI
K241961	Vent Creativity Knee v1.0 (Hermes)	Vent Creativity	2025-03-20	Traditional	260	AI
K250042	PeekMed web	Peek Health, S.A.	2025-03-19	Traditional	70	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K243689	AVIEW	Coreline Soft Co., Ltd.	2025-03-19	Special	110	AI
K243862	LVivo Software Application	Dia Imaging Analysis, Ltd.	2025-03-17	Special	91	AI
K242338	Cleerly LABS (v2.0)	Cleerly, Inc.	2025-03-07	Special	212	AI
K243331	LVivo Seamless	Dia Imaging Analysis, Ltd.	2025-03-06	Special	133	AI
K243933	Ceevra Reveal 3+	Ceevra, Inc.	2025-03-04	Traditional	74	AI
K243235	LVivo Software Application	Dia Imaging Analysis, Ltd.	2025-03-03	Traditional	144	AI
K241922	Myomics	Phantomics, Inc.	2025-02-28	Traditional	242	AI
K241222	Ventripoint Medical System Plus (VMS+) 4.0	Ventripoint Diagnostics , Ltd.	2025-02-26	Traditional	301	AI
K242607	ScanDiags Ortho L-Spine MR-Q	Scandiags AG	2025-02-21	Traditional	171	AI
K243696	AVIEW CAC	Coreline Soft Co., Ltd.	2025-02-14	Special	77	AI
K243250	SubtleHD (1.x)	Subtle Medical, Inc.	2025-02-12	Traditional	120	AI
K241659	Ultrasound Workspace (UWS 6.0)	Philips Ultrasound, LLC	2025-02-10	Traditional	245	AI
K241593	BoneMetrics (US)	Gleamer Sas	2025-02-05	Traditional	247	AI
K243158	TeraRecon Aorta.CT (1.1.0)	Terarecon,Inc.	2025-01-23	Traditional	115	AI
K243350	Rapid Neuro3D	Ischemaview, Inc.	2025-01-22	Traditional	86	AI
K242334	Ezra Flash	Ezra Ai, Inc.	2025-01-02	Traditional	148	AI
K241696	Ortho AI	Ortho Ai, LLC	2025-01-02	Traditional	204	AI
K242270	OrthoNext Platform System	Orthofix Srl	2024-12-19	Traditional	140	AI
K243705	Saige-Density (2.5.0)	DeepHealth, Inc.	2024-12-19	Special	20	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K240793	MSKai	Mskai	2024-12-16	Traditional	269	AI
K242461	IRISeg	Intuitive Surgical, Inc.	2024-12-10	Traditional	113	AI
K241543	DrAid™ for Liver Segmentation	Vinbrain Joint Stock Company	2024-12-06	Traditional	189	AI
K240680	CDM Insights	Oxford Brain Diagnostics, Ltd.	2024-12-06	Traditional	270	AI
K240645	Sonix Health	Ontact Health Co., Ltd.	2024-11-27	Traditional	265	AI
K242203	BriefCase-Quantification	Aidoc Medical , Ltd.	2024-11-22	Traditional	119	AI
K242359	Strain AI (SAI001)	Exo, Inc.	2024-11-20	Traditional	103	AI
K241312	TeraRecon Cardiac.Chambers.MR (1.0.0)	Terarecon,Inc .	2024-11-05	Traditional	180	AI
K241108	RemedyLogic AI MRI Lumbar Spine Reader	Remedy Logic, Inc.	2024-10-30	Traditional	191	AI
K242215	Neurophet AQUA (V3.1)	Neurophet., Inc.	2024-10-25	Traditional	88	AI
K243189	TumorSight Viz	SimBioSys, Inc.	2024-10-25	Special	25	AI
K242781	cvi42 Software Application	Circle Cardiovascular Imaging, Inc.	2024-10-15	Special	29	AI
K240786	AutoChamber	HeartLung Corporation	2024-10-10	Traditional	202	-
K241430	EchoMeasure	Icardio.Ai	2024-10-10	Traditional	142	AI
K240553	LVivo Software Application	Dia Imaging Analysis, Ltd.	2024-10-04	Special	219	AI
K241561	MammoScreen BD	Therapixel	2024-10-02	Traditional	124	AI
K240943	LungVision	Bodyvision Medical , Ltd.	2024-10-01	Traditional	179	AI
K240036	PIUR tUS Infinity	Piur Imaging GmbH	2024-09-20	Traditional	259	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K241280	Constellation (CON-001)	Q Bio, Inc.	2024-09-12	Traditional	128	AI
K240094	LumiNE US; Lumi	Augmedit B.V.	2024-09-10	Traditional	242	AI
K241681	Overjet Image Enhancement Assist	Overjet, Inc.	2024-09-09	Traditional	90	AI
K240791	ADAS 3D	Adas3D Medical S.L.	2024-09-09	Traditional	171	AI
K240411	uAI Portal	Shanghai United Imaging Intelligence Co., Ltd.	2024-09-06	Traditional	207	AI
K241847	Imbio PHA (4.0.0)	Imbio, Inc.	2024-08-30	Special	65	AI
K242275	syngo.via MI Workflows; Scenium; syngo MBF	Siemens Medical Solutions USA, Inc.	2024-08-30	Special	29	AI
K242300	MI View&GO	Siemens Medical Solutions USA, Inc.	2024-08-30	Special	28	AI
K241684	Overjet Charting Assist	Overjet, Inc.	2024-08-27	Traditional	77	AI P
K241098	NeuroQuant	Cortechs Labs, Inc.	2024-08-22	Traditional	122	AI
K240740	qCT LN Quant	Qure.Ai Technologies	2024-08-16	Traditional	151	AI
K241211	CoLumbo	Smart Soft Healthcare	2024-08-15	Traditional	107	AI
K242054	OptimMRI (v2)	Rebrain, Sas	2024-08-12	Special	28	AI
K233822	i2Contour	Mrimath, LLC	2024-08-08	Traditional	251	AI
K240953	AI Platform 2.0 (AIP002)	Exo Imaging	2024-08-05	Traditional	119	AI P
K234009	Acorn 3D Software (AC-SEG-4009); Acorn 3DP Mod...	Mighty Oak Medical	2024-07-12	Traditional	206	AI P
K233457	RUS	Hutom, Inc.	2024-07-12	Traditional	266	AI
K241329	SubtleSYNTH (1.x)	Subtle Medical, Inc.	2024-07-11	Traditional	62	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K240736	SMART Bun-Yo-Matic X-Ray	Disior, Ltd.	2024-07-02	Traditional	106	AI
K240582	VEA Align; spineEOS	Eos Imaging	2024-06-25	Traditional	116	AI
K233196	Medihub Prostate	JLK, Inc.	2024-06-21	Traditional	267	AI
K240642	SMART Bun-Yo-Matic CT	Disior, Ltd.	2024-06-20	Traditional	106	AI
K241083	SIS System	Surgical Information Sciences, Inc.	2024-06-14	Traditional	56	AI
K233925	Relu Creator	Relu BV	2024-06-13	Traditional	183	AI
K234042	EFAI Bonesuite XR Bone Age Pro Assessment Syst...	Ever Fortune.Ai, Co., Ltd.	2024-06-07	Traditional	169	AI
K241038	Cardiac CT Function Software Application	Circle Cardiovascular Imaging	2024-06-07	Traditional	52	AI
K240769	LVivo IQS	Dia Imaging Analysis, Ltd.	2024-05-24	Special	64	AI
K233209	uOmnispace.CT	Shanghai United Imaging Healthcare Co., Ltd.	2024-05-17	Traditional	232	AI
K241112	BriefCase-Quantification	Aidoc Medical, Ltd.	2024-05-15	Special	23	AI
K232331	InVision Precision LVEF (LVEF)	InVision Medical Technology Corporation	2024-04-25	Traditional	265	AI
K233186	uOmnispace.MR	Shanghai United Imaging Healthcare Co., Ltd.	2024-04-17	Traditional	202	AI
K240172	Preview Shoulder	Genesis Software Innovations	2024-04-04	Special	73	AI
K233676	Us2.v2	Eko.Ai Pte Ltd. D/B/A Us2.Ai	2024-04-01	Traditional	137	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K233211	AVIEW CAC	Coreline Soft Co., Ltd.	2024-03-29	Traditional	183	AI
K231690	iCAS-LV	Highrad , Ltd.	2024-03-01	Traditional	266	AI
K233030	BoneMRI	Mriguidance B.V.	2024-03-01	Traditional	158	AI P
K231683	inHEART Models	Inheart, Sas	2024-02-29	Traditional	265	AI
K232613	CT Cardiomegaly	Innolitics, LLC	2024-02-28	Traditional	184	AI
K233590	Overjet Charting Assist	Overjet, Inc.	2024-02-23	Traditional	107	AI
K232363	Viz HDS, Viz Volume Plus, Viz ICH+	Viz. Ai, Inc.	2024-02-05	Traditional	182	AI
K232698	NemoScan	Software Nemotec S.L.	2024-01-18	Traditional	135	AI
K233512	Rapid (6.0)	Ischemaview, Inc.	2024-01-16	Special	76	AI
K231324	DASI Dimensions (V1.0)	Dasi Simulations	2024-01-08	Traditional	245	AI
K231917	VEA Align	Eos Imaging	2024-01-05	Traditional	190	AI
K231130	TumorSight Viz	SimBioSys, Inc.	2023-12-26	Traditional	250	AI
K231929	iQ-solutions	Sydney Neuroimaging Analysis Centre Pty, Ltd.	2023-12-18	Traditional	171	AI
K232231	QP-Brain®	Quibim S.L.	2023-12-13	Traditional	139	AI
K232096	Transpara Density 1.0.0	Screenpoint Medical B.V.	2023-12-11	Traditional	151	AI
K223757	Bonelogic	Disior, Ltd.	2023-12-08	Traditional	358	AI
K232440	Adravision Perio	Adra Corporation	2023-12-05	Traditional	113	AI
K233568	Ceevra Reveal 3+	Ceevra, Inc.	2023-12-05	Special	29	AI
K232856	Syngo Carbon Clinicals	Siemens Healthcare GmbH	2023-12-01	Traditional	77	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K232000	syngo.via MI Workflows; Scenium; syngo MBF	Siemens Medical Solutions USA, Inc.	2023-11-28	Traditional	146	AI
K232501	AI Platform (AIP001)	Exo, Inc.	2023-11-17	Traditional	92	AI
K232841	Axial3D Insight	Axial Medical Printing Limited	2023-11-15	Special	62	AI
K232257	Clarius Bladder AI	Clarius Mobile Health Corp.	2023-11-13	Traditional	108	AI
K232083	BriefCase-Quantification	Aidoc Medical , Ltd.	2023-11-13	Traditional	123	AI
K230534	BriefCase-Quantification	Aidoc Medical , Ltd.	2023-11-08	Traditional	254	AI
K231955	aprevo® Digital Segmentation	Carlsmed, Inc.	2023-11-03	Traditional	123	AI
K232305	AI-Rad Companion Brain MR	Siemens Medical Solutions U.S.A.	2023-10-23	Traditional	83	AI
K230209	Sonix Health	Ontact Health Co., Ltd.	2023-10-20	Traditional	268	AI
K232367	cmAngio® V1.0	Curemetrix, Inc.	2023-10-05	Traditional	58	AI
K231398	VUNO Med-DeepBrain	Vuno, Inc.	2023-10-04	Traditional	142	AI
K230045	HipCheck	Stryker Corp.	2023-09-29	Traditional	266	AI
K231149	qXR-CTR	Qure.Ai Technologies	2023-09-22	Traditional	154	AI
K223621	DeepXray	Alpha Intelligence Manifolds, Inc.	2023-09-08	Traditional	277	AI
K230913	ANDI	Imeka Solutions, Inc.	2023-07-25	Traditional	116	AI
K230150	OptimMRI	Rebrain, Sas	2023-07-21	Traditional	183	AI
K230039	uOmnispace	Shanghai United	2023-07-20	Traditional	195	AI

Number	Device	Applicant	Decided	Type	Days	Flags
		Imaging Healthcare Co., Ltd.				
K231757	Ez3D-i /E3	Ewoosoft Co., Ltd.	2023-07-14	Special	28	AI
K223106	Brainlab Elements Image Fusion, Contouring (4....	Brainlab AG	2023-07-14	Traditional	287	AI
K231668	Spine CAMP™ (1.1)	Medical Metrics, Inc.	2023-07-07	Special	30	AI
K222745	Axial3D Insight	Axial Medical Printing Limited	2023-07-03	Traditional	294	AI
K230497	Bladder AI (AIBV01)	Exo, Inc.	2023-06-22	Traditional	118	AI
K223646	IB Lab LAMA	Ib Lab GmbH	2023-06-16	Traditional	192	AI
K223556	DeepCatch	Medical IP Co., Ltd.	2023-06-16	Traditional	200	AI
K223855	FEops HEARTguideTM, FEops HEARTguideTM ALPACA	Feops NV	2023-06-06	Traditional	165	AI
K230977	SIS System	Surgical Information Sciences, Inc.	2023-05-02	Special	27	AI
K222676	Ceevra Reveal 3	Ceevra, Inc.	2023-04-25	Traditional	231	AI
K223501	ViewFinder Software Version 1.1	Elaitra, Ltd.	2023-04-21	Traditional	151	AI
K213986	CerebralGo Plus	Yukun (Beijing) Technology Co., Ltd.	2023-04-13	Traditional	479	AI
K213272	Formus Hip	Formus Labs, Ltd.	2023-03-31	Traditional	547	AI
K222174	RadioLens v1.0	Synapsica	2023-03-28	Traditional	250	AI
K222036	MPXA-2000	Medipixel, Inc.	2023-03-22	Traditional	254	AI
K230197	BoneMRI v1.6	Mriguidance B.V.	2023-02-22	Special	28	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K223296	Videa Perio Assist	Videahealth, Inc.	2023-02-06	Traditional	103	AI
K222970	LVivo IQS	Dia Imaging Analysis, Ltd.	2023-02-01	Traditional	127	AI
K223396	Rapid RV/LV	Ischemaview, Inc.	2023-02-01	Traditional	85	AI
K222406	Clarius AI	Clarius Mobile Health Corp.	2023-01-23	Traditional	167	AI
K214036	AVIEW	Coreline Soft Co., Ltd.	2022-12-23	Traditional	365	AI
K223268	BrainInsight	Hyperfine, Inc.	2022-12-16	Traditional	53	AI
K222275	Saige-Density	DeepHealth, Inc.	2022-12-16	Traditional	140	AI
K223032	SIS System (Version 5.6.0)	Surgical Information Sciences, Inc.	2022-11-21	Traditional	53	AI
K221762	BoneMRI v1.4	Mrlguidance B.V.	2022-11-16	Traditional	152	AI
K222428	Syngo Dynamics (Version VA40F)	Siemens Medical Solutions USA, Inc.	2022-11-14	Traditional	95	AI
K221632	Spine CAMP™	Medical Metrics, Inc.	2022-10-18	Traditional	134	AI
K211611	QIR Suite	Casis Cardiac Simulation & Imaging Software	2022-09-30	Traditional	493	AI
K221738	NS-HGlio	Neosoma, Inc.	2022-09-27	Traditional	104	AI
K221100	Viz RV/LV	Viz. Ai, Inc.	2022-08-29	Traditional	137	AI
K222172	MI View&GO	Siemens Medical Solutions USA, Inc.	2022-08-19	Special	29	AI
K213645	ClearPoint Maestro Brain Model	ClearPoint Neuro, Inc.	2022-08-08	Traditional	263	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K221432	Customize	3D-Side S.A.	2022-08-03	Traditional	78	AI
K213998	cvi42 Auto Imaging Software Application	Circle Cardiovascular Imaging, Inc.	2022-07-28	Traditional	219	AI
K220940	EchoPAC Software Only, EchoPAC Plug-in	GE Medical Systems Ultrasound and Primary Care...	2022-07-22	Traditional	113	AI
K220956	Libby Echo:Prio	Dyad Medical, Inc.	2022-07-20	Traditional	110	AI
K220815	BrainInsight	Hyperfine, Inc.	2022-07-19	Traditional	120	AI
K220497	CoLumbo	Smart Soft Healthcare AD	2022-06-23	Traditional	121	AI
K213706	AI-Rad Companion Brain MR	Siemens Healthcare GmbH	2022-04-15	Traditional	142	AI
K212624	EFAI Intelligent Cardiothoracic Ratio (iCTR) A...	Ever Fortune.Ai, Co., Ltd.	2022-04-04	Traditional	229	AI
K213779	Customize	3D-Side S.A.	2022-03-16	Traditional	103	AI
K203744	Arterys MICA	Arterys, Inc.	2022-03-14	Traditional	447	AI
K210747	Caption Interpretation Automated Ejection Frac...	Caption Health	2022-01-19	Traditional	313	AI
K212012	Follicle Clarity	Cycle Clarity	2022-01-19	Traditional	205	AI
K213544	TOMTEC-ARENA	Tomtec Imaging Systems GmbH	2022-01-06	Traditional	59	AI
K202404	BoneMRI	Mriguidance B.V.	2021-12-22	Traditional	488	AI
K212690	qXR-BT	Qure.Ai Technologies	2021-12-21	Traditional	118	AI
K213275	EchoGo Core (2.0)	Ultromics Limited	2021-12-20	Traditional	81	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K212466	LVivo Seamless	Dia Imaging Analysis, Ltd.	2021-12-09	Traditional	125	AI
K210831	OnQ Neuro	Cortechs Labs, Inc.	2021-11-19	Traditional	245	AI
K211161	Critical Care Suite with Endotracheal Tube Pos...	Ge Medical Systems, LLC	2021-10-29	Traditional	193	AI
K203785	ClariSIGMAM	Claripi, Inc.	2021-09-10	Traditional	256	AI
K203555	AmCAD-UT	Amcad Biomed Corporation	2021-09-08	Traditional	275	AI
K211431	breastscape v1.0	Olea Medical	2021-08-02	Traditional	87	AI
K211222	qER-Quant	Qure.Ai Technologies	2021-07-30	Traditional	98	AI
K210791	Us2.v1	Eko.Ai Pte Ltd. D/B/A Us2.Ai	2021-07-27	Traditional	133	AI
K210719	Change Healthcare Anatomical AI	Change Healthcare Canada Company	2021-07-20	Traditional	132	AI
K211506	PowerLook Density Assessment V4.0	Icad, Inc.	2021-07-12	Traditional	59	AI
K211459	syngo.via MI WorkFlows, Scenium, syngo MBF	Siemens Medical Solutions USA, Inc.	2021-06-10	Special	30	AI
K203502	MEDO-Thyroid	Medo DX Pte. , Ltd.	2021-04-23	Traditional	144	AI
K210556	Preview Shoulder	Genesis Software Innovations	2021-04-21	Traditional	55	AI
K203256	Imbio RV/LV Software	Imbio, LLC	2021-03-09	Traditional	125	AI
K210053	LVivo Software Application	Dia Imaging Analysis, Ltd.	2021-02-05	Special	28	AI
K201411	Visage Breast Density	Visage Imaging GmbH	2021-01-29	Traditional	246	AI

Number	Device	Applicant	Decided	Type	Days	Flags
K201195	syngo.via MI Workflows, syngo MBF	Siemens Medical Solutions USA, Inc.	2020-11-18	Traditional	198	AI
K202013	WRDensity by Whiterabbit.ai	Whiterabbit.Ai , Inc.	2020-10-30	Traditional	101	AI
K202546	LVivo Seamless	Dia Imaging Analysis, Ltd.	2020-09-29	Special	27	AI
K193283	AI-Rad Companion Prostate MR	Siemens Medical Solutions USA, Inc.	2020-07-30	Traditional	246	AI
K200621	Caption Interpretation Automated Ejection Frac...	Caption Health	2020-07-22	Traditional	135	AI R
K192969	Ezra Plexo Software	Ezra Ai, Inc.	2020-07-10	Traditional	261	AI
K200232	LVivo Software Application	Dia Imaging Analysis, Ltd.	2020-06-23	Traditional	145	AI
K200356	MEDO ARIA	Medo.Ai	2020-06-11	Traditional	119	AI
K200974	QLAB Advanced Quantification Software	Philips Health Care	2020-06-03	Traditional	51	AI
K192601	uWS-MR	Shanghai United Imaging Healthcare Co., Ltd.	2020-06-01	Traditional	255	AI
K192437	Arterys MICA	Arterys, Inc.	2020-03-25	Traditional	201	AI
K191647	QLAB Advanced Quantification Software	Philips Health Care	2019-12-20	Traditional	183	AI
K191171	EchoGo Core	Ultromics, Ltd.	2019-11-13	Traditional	196	AI

15 Questions the record raises

Drawn from the figures above, for a Pre-Submission meeting or your own team. Questions only: the record describes past filings, not yours, and the FDA decides.

1. Only 9 of the 302 AI-device summaries in QIH state prospective collection. What does the FDA expect a submission for your device to show on this?

2. Only 53 of the 302 AI-device summaries in QIH state race or ethnicity breakdown. What does the FDA expect a submission for your device to show on this?

3. Only 100 of the 302 AI-device summaries in QIH state multiple collection sites. What does the FDA expect a submission for your device to show on this?

4. 123 of 262 predicate links in QIH point to devices in LLZ. Would a predicate from LLZ be appropriate for your device, given its indications?

5. 41 Special 510(k)s in QIH took a median of 29 days. For later changes to your device, which kinds of modification would fit a Special 510(k)?

6. 2 recall events are listed in QIH (see Recalls). Which of those failure modes should your own risk analysis and labelling address?

16 Sources and method

Register: openFDA 510(k) and PMA data and the FDA's De Novo pages, as published by Device Evidence.

Predicate links: 510(k) summaries decided 2016 onwards, read and checked against the FDA register (existence, decision order, device name); only links that passed every check are used (Device Evidence D-071).

Indications: the summary's FDA Form 3881 box, or its Indications for Use heading, quoted verbatim.

Testing: lines read from the summary by rules and confirmed against their own sentence by an independent check; no wrong line on 760 hand-read summaries (2026-11-14). About half of the testing a summary reports passes both, so a test not listed may still have been done.

Recalls: openFDA device recall and enforcement data, joined on the submission number.

17 Get this landscape brief for your device

This is a real landscape brief, made from the FDA's record exactly as a buyer receives it.

For your own product code: the same report, built from the FDA's record for it. $249, within one working day of your enquiry.

HOW TO START

Go to precedium.com/services/landscape-brief/ and send an enquiry, or email hello@precedium.com. A person replies within one working day.

Not sure which service fits? Send one document for a free first read (precedium.com/first-read/): a one-page reply in two working days, with a fixed quote.

Consultants: any service at 20% off, delivered under your firm's name. Precedium prepares content; the FDA decides.

Appendix: sources

Every footnote number in this document resolves to one line below.

1 Device Evidence, the verified FDA record (register, confirmed predicate links, indications, testing as each summary reports it, openFDA recalls) (read 2026-11-17).

2 K211611, 510(k) summary (FDA) (page 3).

3 K241038, 510(k) summary (FDA) (page 3).

4 K240791, 510(k) summary (FDA) (page 4).

5 K253969, 510(k) summary (FDA) (page 4).

6 K200621, 510(k) summary (FDA) (page 3).

7 FDA, Predetermined Change Control Plans: List of Authorized Devices with PCCPs, content current as of 2026-10-20, captured 2026-10-26.

8 openFDA device recall and enforcement data (joined on the submission number).