PRECEDIUM *drafting assistance*

TESTING PRECEDENT

Testing precedent: 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

331	302	8	11
summaries read	on the AI list	kinds of testing	standards named

ABOUT THIS DOCUMENT

- REAL EXAMPLE of the Testing precedent, $299. Get yours at precedium.com/services/testing-precedent/
- 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 advice and not a test plan. This record states what cleared summaries in the product code report about their own testing (a test statement, or the standard as listed); each share is a floor, since a summary can leave out testing that was done. Which tests a device needs is for the manufacturer to decide and the FDA to judge.

Prepared 2026-11-17. The person exporting it is responsible for its contents; the FDA decides.

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01 At a glance

331 public 510(k) summaries in product code QIH, decided 2019-11-13 to 2026-10-19, were read for what each reports about its own testing.[1]

The kinds of testing reported most often: software (196), bench / non-clinical performance (94), usability / human factors (77).

302 of these devices are on the FDA's AI-enabled device list. Of those, the performance evidence reported most often: performance comparator (223 of 302), validation sample size (213 of 302), reference standard (211 of 302).

The standard named most often: IEC 62304 (63 summaries).

Every count is a floor: a summary can leave out testing that was done, so a share means 'at least this many report it'.

02 AI performance evidence reported

What the 302 AI-list summaries in QIH report about how the device's performance was shown, element by element.[1]

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

HOW SUMMARIES WORD IT

Performance comparator. K261405 (ANDI 2.2): "Use artificial intelligence for skull stripping as a pre-processing function The subject device differs from the predicate device by expanding the normative reference dataset to include additional subjects, extending the lower bound of the dataset to include subjects aged 16-17 years."[2]

Validation sample size. K253628 (Auto-Seg (SO-0012), Spine Auto-Seg (SO-0012)): "CTSpine1K - HNSCC-3DCT-RT - 19 cases Pelvis Segmentation Algorithm: The Pelvis Segmentation algorithm segments the entire CT image into different parts of the pelvis: right and left iliac, sacrum and the entire spine as a single unit."[3]

Reference standard. K253969 (ADAS 3D): "US: Toshiba (31,3%), SIEMENS (64,1%) and GE (4,7%) OUS: SIEMENS (23,5%), Philips (2,9%), GE (29,4%), Toshiba (29,4%) and Canon (14,7%) Ground truth annotations were generated using the manual tools of the FDA-cleared ADAS 3D software by two clinical experts independent of the clinical experts who established the ground truth of the training dataset."[4]

Study design. K260300 (WatchMate Software): "The verification datasets were used for internal model tuning and selection and are distinct from the independent external clinical validation study (NCT07126600) described in the Clinical Testing Summary. INDICATIONS FOR USE [807.92(A)(5)] WatchMate Software enables visualization and measurement of structures of the heart and vessels for pre-procedural planning and sizing for the left atrial appendage closure (LAAC) procedure."[5]

Age distribution. K253172 (MediAI-OA): "Training & Validation Set Independent Test Set Gender Female 2,156 (59.5%) 648 (55.2%) Male 1,467 (40.5%) 525 (44.8%) Age (Years) Age >= 60 1,904 (52.6%) 681 (58.0%) Age < 60 1,719 (47.4%) 492 (42.0%) Race Other Non-white 70 (2.0%) 12 (1.0%)"[6]

Sex breakdown. K260316 (CMN Capillary Function with Oncology Virtual Expert): "NS-HGlio is intended for the semi- automatic labeling, visualization, and volumetric quantification of high- grade brain glioma (WHO grade 3 astrocytoma, WHO grade 4 astrocytoma and WHO grade 4 glioblastoma) from a set of standard MRI images of male or female patients 18 years of age or older who are known to have pathologically proven high-grade glioma. Volumetric measurements may be compared to past measurements if available."[7]

Multiple collection sites. K252563 (Neurophet SCALE PET): "Clinical subgroups and potential confounders including scanner vendor, magnetic field strength, and diagnosis (clinically normal, mild cognitive impairment, and Alzheimer's disease) were evaluated through subgroup analysis. MR images were acquired across multiple sites using scanners from GE, Siemens, and Philips with both 1.5T and 3.0T field strengths. Segmentation accuracy was assessed using Dice Similarity Coefficient (DSC) on an independent test dataset of 64 subjects (one MR image per subject) for both cortical and subcortical brain structures."[8]

Race or ethnicity breakdown. K260077 (OrthoGrid Hip AI® 4.0): "Performance results along with other factors were also collected and reported, including: • BMI: Concentrated under 25 (61%), with limited representation over 35 (4.5%). • Ethnicity: Predominantly White (90.5%), with limited representation of Asian (2.4%) and Hispanic (7.1%) participants. • Bone disease: Most common condition is arthritis (29.8%), with smaller representation of osteoporosis (14.3%)."[9]

03 How the 12 most recent AI devices showed performance

Each device's own sentences on its validation study, quoted from its 510(k) summary with the page: what was tested, on how many cases, at how many sites, and what performance was reported. Read the figures in context; they are the companies' words, not ours.

K253628 · AUTO-SEG (SO-0012), SPINE AUTO-SEG (SO-0012) · AGADA MEDICAL, LTD. · 2026-06-29

Study: "Application Useability / Human Factors engineering principles and usability testing; Cybersecurity Testing; Stand-Alone Performance Assessment / Performance Validation;"[10]

Sample: "The Pelvis Segmentation algorithm segments the entire CT image into different parts of the pelvis: right and left iliac, sacrum and the entire spine as a single unit."[11]

Sites: "Confirmatory Non-Inferiority Performance Validation To supplement the original SAPA, an additional performance validation study was completed using 54 subjects from four additional clinical sites..."[12]

Performance: "Page 12 of 13 Characteristic / Study Endpoint Test / Evaluation Sample Size Acceptance Criteria Result (Primary / Sensitivity Analysis) is less than 0.10 (10%) per object."[13]

K260300 · WATCHMATE SOFTWARE · ANUMANA, INC. · 2026-06-15

Study: "The verification datasets were used for internal model tuning and selection and are distinct from the independent external clinical validation study (NCT07126600) described in the Clinical Testing..."[14]

Sample: "Anatomy Segmentation 36,541 annotated TEE frames 7,385 annotated TEE frames 3D Point Cloud Generation 61,284 cardiac CT scans 3,270..."[15]

Sites: "No clinical testing was necessary, however a prospective multicenter data collection study (NCT07126600) was elected to be performed. All imaging was collected as part of..."[16]

K253172 · MEDIAI-OA · CRESCOM CO., LTD. · 2026-06-15

Sites: "Site-based Data Partitioning To prevent data leakage and ensure the clinical validity of the algorithm, the study datasets were strictly partitioned by Clinical Site IDs rather than by individual..."[17]

Performance: "In particular, for the detection of KL grade >= 2, the sensitivity was 0.876 (95% CI: 0.866-0.885) and the specificity was 0.865 (95% CI: 0.856-0.873)."[18]

K260497 · DEEPVESSEL PLAQUE · KEYA MEDICAL TECHNOLOGY CO., LTD. · 2026-06-04

Study: "A retrospective, multi-center clinical validation study was conducted to evaluate the performance of the DEEPVESSEL Plaque software for the detection, quantification, and characterization of coronary..."[19]

Sample: "The R&R cases included a total of 23 subjects with a mean age of 62.2 years. Cases came from the same three U.S."[20]

Sites: "The R&R cases included a total of 23 subjects with a mean age of 62.2 years. Cases came from the same three U.S."[21]

K260077 · ORTHOGRID HIP AI® 4.0 · ORTHOGRID SYSTEMS, INC. · 2026-05-29

Study: "Specificity: Reflects the ability of the AI to correctly ignore areas where landmarks or anatomy or implant is absent.;"[22]

Sample: "The tuning and evaluation datasets included: Landmark and Implant Models: 84 THA surgical cases, 342 images; Anatomy Model: 51 THA surgical cases, 182 images. All measures met the..."[23]

Sites: "The OrthoGrid Hip AI® 4.0 system incorporates Machine Learning (ML) models trained, and tested using real-world, de-identified fluoroscopic images collected from five geographically distinct clinical..."[24]

Performance: "Table 2 : Reference VS AI Predictions - ML Models: Accuracy, Sensitivity, and Specificity ML Model Accuracy +/- STD Sensitivity Specificity Sample size N (Patients, Images) Left & Right Teardrop..."[25]

K260234 · MSK GO · SMART ALFA TEKNOLOJI SAN. VE TIC. A.S. · 2026-05-21

Study: "Performance was evaluated against a three-reader expert-defined reference standard across four endpoints: anatomical structure detection, anatomical structure highlighting via Dice similarity..."[26]

Sample: "The validation dataset was independent from the development dataset in all aspects. A total of 15,600 images from 3,017 ultrasound scans of 79 subjects were included in the analysis."[27]

Sites: "Images were captured by licensed healthcare professionals at three U.S. clinical sites. The validation dataset was independent from the development dataset in all aspects."[28]

K254131 · BAC · DEEPHEALTH, INC. · 2026-05-21

Study: "The specific organization and functioning of each component are also substantially equivalent between the two devices, and both consist of substantially equivalent components performing comparable..."[29]

Sample: "Descriptive statistics of cases included in BAC pivotal standalone performance study (n=850 for FFDM and n=925 for DBT), Numbers in parentheses for Breast Density, Patient Race, and Patient Ethnicity..."[30]

Sites: "The BAC algorithm was trained on a robust and diverse dataset of mammography exams acquired from multiple clinical sites with diverse practices."[31]

Performance: "Sensitivity and specificity for each modality met all pre-specified performance criteria: Sensitivity was 0.960 for FFDM and 0.905 for DBT, while specificity was 0.884 for FFDM and 0.906 for DBT."[32]

K252563 · NEUROPHET SCALE PET · NEUROPHET., INC. · 2026-05-15

Study: "Standalone performance tests were conducted for all modules using datasets that were completely independent from those used for development and training."[33]

Sample: "Segmentation accuracy was assessed using Dice Similarity Coefficient (DSC) on an independent test dataset of 64 subjects (one MR image per subject) for both cortical and subcortical brain structures."[34]

Sites: "MR images were acquired across multiple sites using scanners from GE, Siemens, and Philips with both 1.5T and 3.0T field strengths."[35]

K260032 · MORPH · BEAUBRAIN HEALTHCARE, INC. · 2026-05-13

Study: "The resulting output is provided in a standard DICOM format as additional MR series with segmented color overlays and morphometric reports that can be displayed on third-party DICOM workstations and..."[36]

Sample: "The validation dataset consisted of 64 MRI scans from unique subjects obtained from the ADNI,

a U.S.-based dataset."[37]

Sites: "In terms of clinical subgroup distribution, the cohort included cognitively normal subjects (CN) (29.7%), subjects with mild cognitive impairment (MCI) (37.5%), and patients diagnosed with..."[38]

K260785 · DS CORE CBCT ANATOMY · DENTSPLY SIRONA · 2026-04-23

Study: "These models support anatomical segmentation, keypoint detection (tooth and root tip detection), and automatic scan orientation (ASO) with their performance assessed against expert ground truth..."[39]

Sample: "Sirona systems, which represented the largest sample size, showed a strong overall pass rate of 92%. 1maging Sciences International devices demonstrated an 86% pass rate, while Carestream Dental and..."[40]

Performance: "The Anatomy Segmentation model met all primary endpoints: mean Dice for dentition was 93%, for jaw 94%, and for mandibular canal 78%, with all lower bounds of the 95% confidence intervals meeting or..."[41]

K252332 · FOLLISCAN · MIM FERTILITY · 2026-04-20

Study: "Because the Folliscan is a software-only device that retrospectively analyzes existing transvaginal ultrasound cine-loops and 3D scans without patient contact, energy application, or alteration to..."[42]

Sample: "These data were split into 5,972 training scans and 294 validation scans, while the held-out test set comprised 138 scans from 64 patients obtained from five clinics, including 45 scans from Advanced..."[43]

Sites: "Taken together, these results demonstrate that the Folliscan device provides clinically accurate and reliable automated follicle detection, counting, and measurement across a diverse, multi-site,..."[44]

K253502 · CRITICAL CARE SUITE WITH ENTERIC TUBE POSITIONING AI ALGORITHM · GE MEDICAL SYSTEMS, LLC · 2026-04-14

Study: "The test plans and results have been executed with acceptable results. Summary of Clinical Tests: The performance of the Enteric Tube Positioning AI Algorithm was tested against a ground truth..."[45]

Sample: "The performance of the Enteric Tube Positioning AI Algorithm was tested against a ground truth dataset. The ground truth dataset contained 954 images that were not used in the development of the..."[46]

Sites: "The performance of the Enteric Tube Positioning AI Algorithm was tested against a ground truth dataset. The ground truth dataset contained 954 images that were not used in the development of the..."[47]

Performance: "The Enteric Tube Positioning AI Algorithm achieved a sensitivity of 0.992 (0.982, 0.997) and a specificity of 0.975 (0.947, 0.991)."[48]

04 Testing reported, by kind

Kind of testing	Summaries reporting it	Share
Software	at least 196 of 331	59%
Bench / non-clinical performance	at least 94 of 331	28%

Kind of testing	Summaries reporting it	Share
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%

HOW SUMMARIES WORD IT

Software. K262134 (NeuroDR): "Performance Data 9.1. Software Verification and Validation Testing..."[49]

Bench / non-clinical performance. K262390 (BoneXpert): "Clinical and bench testing support that BoneXpert performs as intended and that these differences do not raise different questions of safety or..."[50]

Usability / human factors. K260055 (syngo.CT Brain Quantification): "Including Amendment 1 (2016)] 13-79 NEMA PS 3.1 - 3.20 2023e 2023 Digital Imaging and Communications in Medicine (DICOM) Set 12-352 ISO 14971 Third Edition 2019-12 Application of Risk Management to Medical Devices 5-125 IEC..."[51]

Cybersecurity. K260055 (syngo.CT Brain Quantification): "Non-Clinical Testing Summary Non-clinical testing submitted in support of substantial equivalence included software verification and validation testing, algorithm performance testing, cybersecurity testing, system integration..."[52]

Clinical data. K260055 (syngo.CT Brain Quantification): "Clinical Testing Summary Clinical performance of the device was evaluated in a retrospective, stand-alone study using anonymized non- contrast head CT datasets collected from multiple clinical institutions in the..."[53]

Electrical safety. K250484 (PIUR tUS inside): "Software performance, verification and validation testing demonstrated that the PIUR tUS inside System met all design requirements and specifications. Electrical safety and EMC testing were conducted on the PIUR tUS..."[54]

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'.

05 Standards named

Standard	Summaries naming it	Share
IEC 62304	63 of 331	19%

Standard	Summaries naming it	Share
IEC 62366-1	37 of 331	11%
IEC 62366	10 of 331	3%
IEC 82304-1	6 of 331	2%
IEC 81001-5-1	4 of 331	1%
AAMI 57	2 of 331	1%
IEC 60601-1	2 of 331	1%
IEC 60601-1-2	2 of 331	1%
IEC 62366-2	1 of 331	<1%
ISO 10993-1	1 of 331	<1%
ISO 62304	1 of 331	<1%

06 How it has changed over time

The same shares, by when the device was decided: whether reporting is becoming more common. Summaries held: 2016-2020 13, 2021-2023 88, 2024 on 230; of them on the AI list: 2016-2020 13, 2021-2023 88, 2024 on 201.[1]

AI evidence element	2016-2020	2021-2023	2024 on
Performance comparator	31%	68%	79%
Validation sample size	31%	65%	76%
Reference standard	31%	60%	77%
Study design	31%	65%	64%
Age distribution	0%	43%	47%
Sex breakdown	0%	32%	43%
Multiple collection sites	0%	28%	37%
Race or ethnicity breakdown	0%	13%	21%
Sensitivity	15%	15%	10%
Specificity	8%	11%	8%

AI evidence element	2016-2020	2021-2023	2024 on
Prospective collection	0%	3%	3%
AUC	0%	1%	1%
Patient outcomes	0%	0%	0%

Kind of testing	2016-2020	2021-2023	2024 on
Software	85%	61%	57%
Bench / non-clinical performance	23%	23%	31%
Usability / human factors	15%	17%	26%
Cybersecurity	0%	1%	10%
Clinical data	0%	9%	6%
Electrical safety	0%	2%	2%
Electromagnetic compatibility	0%	1%	1%
Biocompatibility	0%	0%	0%

A share is the part of that period's summaries that report it; a dash means no summary in the period. Periods with few summaries move a lot on one device.

Appendix: the evidence each AI device's summary states

All 302 AI-list devices in QIH with a summary held, newest first: whether the summary states each kind of evidence, with the page to read.[1]

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K253969 ADAS 3D	2026-06-29	-	-	-	p. 17	-	-	-
K253628 Auto-Seg (SO-0012), Spine Auto-Seg (SO...	2026-06-29	p. 11	p. 15	-	p. 13	p. 12	p. 16	p. 13
K253786 syngo.CT Coronary Cockpit	2026-06-25	p. 9	-	-	p. 10	-	p. 10	p. 10
K260316 CMN Capillary Function with Oncology V...	2026-06-22	p. 9	-	-	p. 9	-	-	p. 11
K261713 Synapse PACS (7.6.0)	2026-06-18	-	-	-	-	-	-	-
K260300 WatchMate Software	2026-06-15	p. 6	p. 14	p. 14	p. 14	p. 7	-	-
K253172 MediAI-OA	2026-06-15	-	p. 8	-	p. 9	-	p. 10	p. 8
K253690 LungMaps	2026-06-15	p. 8	-	-	-	-	-	p. 8
K260406 Brainomix 360 Hyperdensity	2026-06-12	-	-	-	p. 7	p. 7	-	-
K260322 Acorn 3D Software (AC-SEG-4009); Acorn...	2026-06-11	-	-	-	-	p. 7	-	-
K260497 DEEPVESSEL Plaque	2026-06-04	p. 12	p. 12	-	p. 7	p. 13	-	p. 12
K260077 OrthoGrid Hip AI® 4.0	2026-05-29	p. 11	p. 10	-	p. 11	p. 11	p. 11	p. 12
K261405 ANDI 2.2	2026-05-28	-	-	-	-	-	-	p. 6

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K260324 Vitrea CT Transcatheter Aortic Valve R...	2026-05-22	p. 6	-	-	p. 7	p. 6	-	p. 16
K260234 MSK Go	2026-05-21	p. 10	p. 10	p. 10	p. 10	p. 10	-	p. 11
K254131 BAC	2026-05-21	p. 8	p. 7	-	-	p. 7	p. 8	p. 8
K261273 Neurophet AQUA	2026-05-15	-	-	-	-	-	-	-
K254120 SubtleHD-CT (1.x)	2026-05-15	p. 11	-	-	-	p. 8	-	p. 9
K261289 UNiD™ Spine Analyzer (SW3002)	2026-05-15	-	-	-	-	-	-	-
K252563 Neurophet SCALE PET	2026-05-15	p. 14	p. 14	-	p. 14	p. 13	-	p. 13
K260032 Morph	2026-05-13	p. 12	p. 12	-	p. 12	p. 8	-	p. 11
K254189 Synapse 3D Base Tools (V7.2)	2026-04-30	-	-	-	-	-	-	-
K254184 syngo Application Software	2026-04-29	p. 12	-	-	p. 12	p. 12	-	p. 12
K260785 DS Core CBCT Anatomy	2026-04-23	p. 7	-	-	p. 6	p. 6	p. 6	p. 7
K253077 uOmnispace.MR	2026-04-22	-	-	-	p. 22	-	-	-
K252332 Folliscan	2026-04-20	p. 12	p. 11	-	p. 11	p. 9	-	-
K253502 Critical Care Suite with Enteric Tube ...	2026-04-14	p. 8	p. 8	-	p. 8	p. 8	p. 9	p. 8
K253930 Overjet Iris Intelligent Imaging System	2026-04-10	p. 9	-	-	p. 9	p. 9	p. 9	p. 9

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K253689 syngo Dynamics (VA41F)	2026-04-10	p. 13	p. 13	-	p. 13	p. 12	-	p. 13
K254015 CoLumbo C-Spine	2026-04-01	p. 9	-	-	p. 9	p. 9	-	-
K254207 AiORTA - Plan v2.0	2026-03-30	-	-	-	-	-	-	-
K253775 SwiftMR	2026-03-26	-	-	-	-	p. 8	-	p. 9
K253614 EchoNavigator R5.0	2026-03-17	p. 11	-	-	p. 11	-	-	-
K253944 Data Analysis Facilitation Suite (DAFS)	2026-03-16	p. 6	p. 6	-	p. 6	p. 6	-	p. 6
K252261 InferCare RECIST	2026-03-13	p. 9	-	-	p. 9	p. 8	-	-
K253551 VELYS™ Hip Navigation	2026-03-06	-	-	-	p. 10	p. 11	-	-
K252538 CEPHX3D	2026-03-05	p. 13	-	-	p. 13	p. 14	-	-
K253593 Clarius Ejection Fraction AI	2026-03-02	p. 13	p. 12	-	p. 12	p. 12	-	-
K260217 AI Platform 2.2 (AIP002)	2026-02-24	p. 9	p. 9	-	p. 10	p. 8	-	-
K252084 AI4CMR v2.0	2026-02-11	p. 11	p. 11	-	p. 10	p. 10	-	p. 10
K254016 MI View&GO	2026-02-10	p. 8	-	-	p. 9	p. 7	-	p. 8
K252496 Neurophet AQUA AD Plus	2026-01-29	p. 14	p. 13	-	p. 16	p. 13	-	p. 13
K252091 Surgical Reality Viewer	2026-01-29	p. 9	-	-	p. 10	p. 9	-	p. 10

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K253735 AV Vascular	2026-01-22	p. 6	p. 7	-	p. 6	p. 7	-	p. 6
K253057 AI-Rad Companion Brain MR	2026-01-22	p. 14	-	-	p. 14	p. 13	-	p. 15
K252634 Imagine® Enterprise Suite	2026-01-16	p. 17	p. 17	-	p. 17	p. 17	-	-
K253532 TruSPECT Processing Station	2025-12-30	p. 9	p. 9	-	p. 9	p. 9	-	p. 9
K252856 PeekMed web	2025-12-22	p. 15	p. 15	-	p. 16	-	-	-
K252029 AI-CVD	2025-12-19	-	p. 13	-	p. 13	p. 12	-	-
K252670 Alzevita	2025-12-19	p. 8	-	-	p. 8	p. 8	-	p. 6
K252235 PVAD IQ Software	2025-12-18	p. 8	-	-	p. 8	-	p. 8	-
K250914 MediAI-BA	2025-12-18	p. 8	p. 8	-	p. 8	-	-	p. 6
K252922 Neosoma Brain Mets	2025-12-17	p. 12	p. 12	-	p. 12	p. 12	p. 12	p. 12
K251763 IRISeg	2025-12-16	-	-	-	-	-	-	-
K251514 Overjet CBCT Assist	2025-12-05	p. 11	-	-	p. 11	p. 11	p. 11	-
K252103 Acorn 3D Software (AC-SEG-4009); Acorn...	2025-12-02	p. 13	-	-	p. 7	p. 7	-	p. 13
K251078 AutoDensity	2025-11-14	p. 12	-	-	p. 12	p. 12	-	p. 14
K252452 PeekMed web	2025-11-12	p. 15	p. 15	-	p. 16	-	-	-
K250330 3mensio Workstation	2025-11-03	p. 9	-	-	p. 9	-	-	p. 9

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K250337 AiORTA - Plan	2025-10-30	p. 11	-	-	p. 10	p. 10	-	-
K251027 cvi42 Coronary Plaque Software Applica...	2025-10-27	-	p. 12	-	p. 13	p. 12	-	-
K251059 Syngo Carbon Clinicals (VA41)	2025-10-24	p. 12	-	-	p. 12	p. 12	-	p. 12
K250288 TeraRecon Cardiovascular.Calcification...	2025-10-23	p. 6	p. 6	-	p. 6	p. 6	-	-
K252298 ANDI 2.0	2025-10-22	p. 7	p. 7	-	p. 7	p. 7	-	p. 7
K252665 brAIn™ Shoulder Positioning	2025-10-20	p. 11	-	-	p. 11	-	-	p. 11
K252214 AIAS Cephalon	2025-10-07	p. 7	-	-	p. 7	-	-	p. 7
K252007 BlineSlide	2025-10-06	p. 12	-	-	p. 12	p. 5	p. 12	-
K250023 SMART PCFD	2025-09-29	p. 6	-	-	p. 7	p. 7	p. 6	p. 6
K252105 Ligence Heart	2025-09-26	p. 8	-	-	-	p. 8	-	p. 8
K251527 Brain WMH	2025-09-25	p. 8	p. 8	-	p. 8	p. 8	-	p. 8
K251483 SwiftSight-Brain	2025-09-23	p. 8	p. 8	-	p. 8	-	-	-
K251987 Rapid Aortic Measurements	2025-09-23	p. 9	-	-	p. 10	-	-	p. 9
K250369 Axial3D Insight	2025-09-18	p. 10	p. 14	-	p. 13	-	-	-
K250237 InferOperate Suite	2025-09-15	p. 10	-	-	p. 10	-	-	p. 6

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K244002 AngioWaveNet	2025-09-10	p. 7	-	-	-	p. 6	-	p. 8
K251072 Segmentron Viewer	2025-09-09	p. 7	-	-	p. 6	p. 6	-	-
K251656 Careverse CoronaryDoc (Careverse Coron...	2025-09-04	-	-	-	p. 9	-	-	-
K252539 Tempus Pixel	2025-09-03	p. 9	-	-	-	-	-	-
K243859 PRAEVAorta®2	2025-08-29	p. 13	-	-	p. 13	p. 10	-	p. 8
K243685 MammoScreen BD	2025-08-22	p. 11	p. 9	-	p. 9	p. 9	-	p. 10
K252362 GBrain MRI	2025-08-22	p. 12	-	-	p. 12	-	-	p. 13
K251837 Salix Coronary Plaque (V1.0.0)	2025-08-20	p. 13	p. 13	-	p. 12	p. 13	-	p. 13
K251747 VEA Align; spineEOS	2025-08-15	p. 15	-	-	p. 15	p. 15	-	p. 12
K250755 DS Core Diagnosis	2025-08-12	p. 6	-	-	-	p. 6	-	-
K251629 UNiD™ Spine Analyzer	2025-08-07	p. 8	-	-	p. 8	-	-	p. 8
K243919 Voxel Dosimetry (00859873006226)	2025-07-30	-	-	-	-	-	-	-
K251342 EchoPAC Software Only / EchoPAC Plug-in	2025-07-16	p. 10	p. 11	-	p. 11	-	-	p. 10
K251096 PeekMedweb	2025-07-14	p. 13	p. 13	-	p. 14	-	-	-
K251766 TumorSight Viz	2025-07-08	p. 7	p. 7	-	p. 8	p. 12	-	p. 7
K251528 syngo.via MI Workflows;	2025-07-03	p. 9	-	-	p. 11	p. 9	-	p. 9

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
Scenium; syngo...								
K243779 Bunkerhill Abdominal Aortic Quantifica...	2025-07-01	p. 10	-	-	p. 10	p. 10	-	p. 9
K250670 EchoConfidence (USA)	2025-06-30	p. 6	-	-	p. 7	p. 6	-	p. 6
K243647 Synapse PACS (7.5)	2025-06-30	p. 7	-	-	p. 7	p. 6	-	p. 7
K250484 PIUR tUS inside	2025-06-30	-	-	-	p. 10	p. 11	-	-
K243633 Brainlab Elements (7.0); Brainlab Elem...	2025-06-13	p. 22	p. 22	-	p. 22	p. 21	-	p. 22
K250354 Viz Subdural+, Viz SUBDURAL PLUS	2025-06-10	p. 10	p. 10	-	p. 10	p. 10	-	-
K251009 Cirrus Resting State fMRI Software	2025-06-06	p. 7	p. 8	-	-	p. 8	p. 8	p. 8
K251456 BrightHeart View Classifier	2025-06-05	p. 7	p. 7	-	p. 8	p. 7	p. 8	p. 8
K243810 TraumaCad Neo (1.1)	2025-06-04	p. 10	p. 10	-	p. 11	-	-	p. 11
K243005 AudaxCeph Cephalogram Analysis Software	2025-05-30	-	-	-	-	-	-	-
K243863 Opulus™ Lymphoma Precision	2025-05-30	p. 7	p. 7	-	p. 7	-	-	p. 8
K250367 CoLumboX	2025-05-28	p. 9	-	-	p. 9	p. 9	-	p. 8
K243378 Rapid MLS	2025-05-28	p. 7	p. 7	-	p. 7	p. 7	-	p. 7

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K250005 Clever One	2025-05-23	-	-	-	-	-	-	-
K243989 Second Opinion® 3D	2025-05-23	p. 10	-	-	-	p. 7	-	-
K243762 Synapse 3D Base Tools (V7.0)	2025-05-21	p. 14	-	-	-	-	-	p. 14
K242624 Medical Image Post-processing Software...	2025-05-14	p. 23	-	-	p. 23	-	-	p. 23
K243230 Second Opinion® BLE	2025-05-09	p. 10	-	-	p. 11	p. 7	-	p. 10
K250226 Clarius Median Nerve AI	2025-05-08	p. 13	p. 12	-	p. 12	p. 12	-	-
K243684 BrightHeart View Classifier	2025-05-07	p. 8	p. 8	-	p. 8	p. 8	p. 9	p. 8
K250328 UltraExtend NX CUW-U001S V2.0 Ultrasou...	2025-04-30	-	-	-	p. 8	-	-	-
K242500 LARALAB	2025-04-16	p. 10	-	-	p. 10	-	-	p. 10
K243853 Clarius Prostate AI	2025-04-16	p. 13	p. 13	-	-	p. 13	-	-
K250416 GBrain MRI	2025-04-11	-	-	-	p. 12	-	-	-
K241982 DeepFoqus (DeepFoqus-Accelerate)	2025-04-04	-	-	-	p. 8	p. 7	-	-
K242551 syngo Dynamics (Version VA41D)	2025-04-03	p. 13	p. 13	-	p. 13	-	-	p. 13
K241984 Hi-D Imaging 4TAVR	2025-04-02	p. 9	p. 9	-	p. 10	-	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K242166 TribusConnect	2025-03-31	p. 17	p. 17	-	p. 18	p. 16	-	p. 17
K243038 Salix Central	2025-03-27	p. 9	p. 6	-	p. 6	-	-	p. 10
K241961 Vent Creativity Knee v1.0 (Hermes)	2025-03-20	-	-	-	-	p. 7	-	-
K250042 PeekMed web	2025-03-19	p. 14	p. 14	-	p. 15	-	-	-
K243689 AVIEW	2025-03-19	-	-	-	-	-	-	-
K243862 LVivo Software Application	2025-03-17	p. 8	p. 8	-	p. 9	p. 10	p. 9	p. 8
K242338 Cleerly LABS (v2.0)	2025-03-07	-	-	-	-	-	-	-
K243331 LVivo Seamless	2025-03-06	p. 8	-	-	p. 8	-	-	p. 8
K243933 Ceevra Reveal 3+	2025-03-04	p. 8	-	-	-	p. 9	-	p. 9
K243235 LVivo Software Application	2025-03-03	p. 8	-	-	p. 8	-	-	p. 8
K241922 Myomics	2025-02-28	p. 9	-	-	-	p. 9	-	-
K241222 Ventripoint Medical System Plus (VMS+)...	2025-02-26	p. 7	-	-	p. 7	p. 6	-	-
K242607 ScanDiags Ortho L-Spine MR-Q	2025-02-21	p. 9	p. 9	-	p. 9	p. 9	-	p. 8
K243696 AVIEW CAC	2025-02-14	-	-	-	-	-	-	-
K243250 SubtleHD (1.x)	2025-02-12	p. 11	-	-	p. 10	p. 8	-	p. 10

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K241659 Ultrasound Workspace (UWS 6.0)	2025-02-10	-	-	-	p. 16	p. 19	-	-
K241593 BoneMetrics (US)	2025-02-05	p. 12	-	-	p. 12	p. 12	-	p. 8
K243158 TeraRecon Aorta.CT (1.1.0)	2025-01-23	p. 8	-	-	p. 8	p. 8	-	-
K243350 Rapid Neuro3D	2025-01-22	p. 11	-	-	p. 11	p. 11	-	p. 11
K242334 Ezra Flash	2025-01-02	-	-	-	-	-	-	p. 6
K241696 Ortho AI	2025-01-02	p. 8	-	-	p. 9	p. 9	-	p. 9
K242270 OrthoNext Platform System	2024-12-19	p. 10	-	-	p. 12	-	p. 10	-
K243705 Saige-Density (2.5.0)	2024-12-19	-	p. 7	-	-	p. 7	-	-
K240793 MSKai	2024-12-16	p. 12	p. 12	p. 18	p. 12	p. 11	-	p. 13
K242461 IRISeg	2024-12-10	p. 10	-	-	p. 10	p. 9	-	-
K241543 DrAid™ for Liver Segmentation	2024-12-06	p. 8	-	-	p. 8	p. 8	-	p. 8
K240680 CDM Insights	2024-12-06	p. 11	-	-	p. 11	p. 10	-	p. 6
K240645 Sonix Health	2024-11-27	p. 9	-	-	p. 9	-	-	-
K242203 BriefCase-Quantification	2024-11-22	p. 10	p. 10	-	p. 10	p. 10	-	p. 10
K242359 Strain AI (SAI001)	2024-11-20	-	p. 7	-	p. 7	-	-	p. 7

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K241312 TeraRecon Cardiac.Chambers.MR (1.0.0)	2024-11-05	p. 7	-	-	p. 7	p. 7	-	p. 8
K241108 RemedyLogic AI MRI Lumbar Spine Reader	2024-10-30	p. 10	p. 10	p. 14	p. 10	p. 9	-	p. 10
K242215 Neurophet AQUA (V3.1)	2024-10-25	p. 9	p. 9	-	p. 9	-	-	-
K243189 TumorSight Viz	2024-10-25	p. 7	-	-	p. 8	p. 12	-	p. 7
K242781 cvi42 Software Application	2024-10-15	p. 18	p. 7	-	p. 17	p. 17	-	-
K241430 EchoMeasure	2024-10-10	p. 10	p. 10	p. 9	p. 10	p. 9	-	p. 10
K240553 LVivo Software Application	2024-10-04	p. 8	-	-	-	p. 8	p. 8	p. 8
K241561 MammoScreen BD	2024-10-02	p. 10	p. 9	-	p. 9	p. 9	-	p. 14
K240943 LungVision	2024-10-01	p. 8	-	-	p. 8	p. 8	-	-
K240036 PIUR tUS Infinity	2024-09-20	p. 8	-	-	p. 10	p. 11	-	p. 8
K241280 Constellation (CON-001)	2024-09-12	-	-	-	p. 12	-	-	-
K240094 LumiNE US; Lumi	2024-09-10	-	-	-	p. 11	-	-	p. 12
K241681 Overjet Image Enhancement Assist	2024-09-09	-	-	-	-	p. 6	-	-
K240791 ADAS 3D	2024-09-09	-	-	-	p. 14	-	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K240411 uAI Portal	2024-09-06	p. 25	-	-	p. 25	-	-	p. 25
K241847 Imbio PHA (4.0.0)	2024-08-30	-	-	-	-	-	-	-
K242275 syngo.via MI Workflows; Scenium; syngo...	2024-08-30	p. 8	-	-	p. 8	p. 7	p. 8	p. 8
K242300 MI View&GO	2024-08-30	-	-	-	-	p. 7	-	-
K241684 Overjet Charting Assist	2024-08-27	-	-	-	-	p. 7	-	-
K241098 NeuroQuant	2024-08-22	p. 8	p. 8	-	p. 7	p. 7	-	p. 8
K240740 qCT LN Quant	2024-08-16	p. 10	-	p. 6	p. 10	p. 6	-	-
K241211 CoLumbo	2024-08-15	p. 10	-	-	p. 10	p. 10	-	-
K242054 OptimMRI (v2)	2024-08-12	-	-	-	-	-	-	-
K233822 i2Contour	2024-08-08	p. 8	p. 8	-	p. 8	-	p. 9	p. 8
K240953 AI Platform 2.0 (AIP002)	2024-08-05	p. 9	p. 9	-	p. 9	-	-	-
K234009 Acorn 3D Software (AC-SEG-4009); Acorn...	2024-07-12	-	-	-	-	p. 6	-	-
K233457 RUS	2024-07-12	p. 12	-	-	-	p. 13	-	-
K241329 SubtleSYNTH (1.x)	2024-07-11	p. 6	p. 8	-	-	p. 6	-	p. 6
K240736 SMART Bun-Yo-Matic X-Ray	2024-07-02	p. 5	-	-	p. 5	p. 6	-	p. 5
K240582 VEA Align; spineEOS	2024-06-25	p. 8	-	-	p. 19	p. 19	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K233196 Medihub Prostate	2024-06-21	p. 9	-	-	p. 9	p. 7	-	p. 9
K240642 SMART Bun-Yo-Matic CT	2024-06-20	p. 5	-	-	p. 6	p. 6	p. 5	p. 5
K241083 SIS System	2024-06-14	-	-	-	p. 6	-	-	-
K233925 Relu Creator	2024-06-13	-	-	-	-	p. 5	-	-
K234042 EFAI Bonesuite XR Bone Age Pro Assessm...	2024-06-07	p. 7	p. 8	-	p. 7	p. 7	-	p. 5
K241038 Cardiac CT Function Software Application	2024-06-07	-	p. 11	-	p. 11	-	-	-
K240769 LVivo IQS	2024-05-24	p. 6	-	-	-	-	-	-
K233209 uOmnispace.CT	2024-05-17	p. 24	-	-	p. 25	-	-	p. 25
K241112 BriefCase-Quantification	2024-05-15	p. 8	p. 8	-	p. 8	p. 8	-	p. 8
K232331 InVision Precision LVEF (LVEF)	2024-04-25	-	p. 7	-	p. 7	p. 7	-	-
K233186 uOmnispace.MR	2024-04-17	p. 19	-	-	p. 20	-	-	p. 19
K240172 Preview Shoulder	2024-04-04	-	-	-	-	-	-	-
K233676 Us2.v2	2024-04-01	p. 8	-	-	p. 8	p. 8	-	p. 8
K233211 AVIEW CAC	2024-03-29	p. 9	p. 10	-	p. 9	-	-	-
K231690 iCAS-LV	2024-03-01	p. 6	p. 6	-	p. 5	p. 5	-	p. 6

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K233030 BoneMRI	2024-03-01	p. 10	p. 6	-	-	p. 10	-	p. 10
K231683 inHEART Models	2024-02-29	p. 5	-	-	p. 8	-	-	-
K232613 CT Cardiomegaly	2024-02-28	p. 12	p. 5	-	p. 5	-	-	p. 6
K233590 Overjet Charting Assist	2024-02-23	p. 6	p. 6	-	p. 6	p. 5	p. 6	p. 6
K232363 Viz HDS, Viz Volume Plus, Viz ICH+	2024-02-05	-	-	-	p. 10	p. 10	-	-
K232698 NemoScan	2024-01-18	-	-	-	-	p. 14	-	p. 5
K233512 Rapid (6.0)	2024-01-16	-	-	-	-	p. 9	-	-
K231324 DASI Dimensions (V1.0)	2024-01-08	p. 6	-	-	p. 5	p. 5	-	-
K231917 VEA Align	2024-01-05	p. 6	-	-	-	p. 10	-	-
K231130 TumorSight Viz	2023-12-26	p. 6	p. 6	-	p. 7	p. 11	-	p. 6
K231929 iQ-solutions	2023-12-18	p. 13	-	-	p. 12	p. 7	-	-
K232231 QP-Brain®	2023-12-13	-	-	-	p. 9	-	-	p. 8
K232096 Transpara Density 1.0.0	2023-12-11	p. 10	p. 10	-	p. 11	p. 8	p. 11	p. 10
K223757 Bonelogic	2023-12-08	p. 7	-	-	p. 8	p. 7	p. 7	p. 8
K232440 Adravision Perio	2023-12-05	p. 7	-	-	p. 7	p. 7	p. 8	-
K233568 Ceevra Reveal 3+	2023-12-05	p. 6	-	-	-	p. 7	-	p. 7
K232856 Syngo Carbon Clinicals	2023-12-01	-	-	-	-	p. 21	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K232000 syngo.via MI Workflows; Scenium; syngo...	2023-11-28	p. 9	-	-	p. 8	p. 8	-	-
K232501 AI Platform (AIP001)	2023-11-17	p. 7	p. 7	-	p. 7	-	-	p. 7
K232841 Axial3D Insight	2023-11-15	p. 12	-	-	-	p. 15	-	-
K232257 Clarius Bladder AI	2023-11-13	p. 12	p. 12	p. 12	p. 13	p. 12	-	p. 12
K232083 BriefCase-Quantification	2023-11-13	p. 7	p. 7	-	p. 7	p. 7	-	p. 8
K230534 BriefCase-Quantification	2023-11-08	p. 8	p. 8	-	p. 8	p. 8	-	p. 9
K231955 aprevo® Digital Segmentation	2023-11-03	-	-	-	-	-	p. 6	-
K232305 AI-Rad Companion Brain MR	2023-10-23	p. 15	-	-	p. 15	p. 13	-	p. 10
K230209 Sonix Health	2023-10-20	p. 9	p. 9	-	p. 9	-	-	p. 9
K231398 VUNO Med-DeepBrain	2023-10-04	-	-	-	-	p. 10	-	-
K230045 HipCheck	2023-09-29	p. 10	p. 11	-	-	p. 9	-	-
K231149 qXR-CTR	2023-09-22	p. 8	-	-	p. 8	p. 8	-	p. 5
K223621 DeepXray	2023-09-08	p. 6	p. 6	-	p. 6	-	p. 8	p. 7
K230913 ANDI	2023-07-25	-	-	-	-	-	-	-
K230150 OptimMRI	2023-07-21	-	-	-	-	p. 7	-	-
K230039 uOmnispace	2023-07-20	p. 14	-	-	p. 15	p. 13	-	p. 14

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K231757 Ez3D-i /E3	2023-07-14	-	-	-	-	-	-	-
K223106 Brainlab Elements Image Fusion, Contou...	2023-07-14	-	-	-	-	p. 12	-	-
K231668 Spine CAMP™ (1.1)	2023-07-07	p. 6	-	-	-	p. 5	-	-
K222745 Axial3D Insight	2023-07-03	p. 13	-	-	-	-	-	-
K230497 Bladder AI (AIBV01)	2023-06-22	p. 7	-	-	p. 7	-	-	p. 7
K223646 IB Lab LAMA	2023-06-16	p. 11	-	-	p. 11	p. 9	p. 12	p. 5
K223556 DeepCatch	2023-06-16	p. 9	-	-	p. 10	p. 11	-	p. 10
K223855 FEops HEARTguideTM, FEops HEARTguideTM...	2023-06-06	p. 12	-	-	p. 12	p. 12	-	p. 12
K230977 SIS System	2023-05-02	-	-	-	-	-	-	-
K222676 Ceevra Reveal 3	2023-04-25	p. 7	-	-	-	-	-	p. 7
K223501 ViewFinder Software Version 1.1	2023-04-21	p. 10	p. 12	-	p. 9	-	-	p. 10
K213986 CerebralGo Plus	2023-04-13	p. 7	-	-	p. 8	p. 7	-	p. 8
K213272 Formus Hip	2023-03-31	p. 7	-	-	p. 7	-	-	p. 7
K222174 RadioLens v1.0	2023-03-28	p. 7	p. 5	-	p. 5	p. 5	p. 8	p. 5
K222036 MPXA-2000	2023-03-22	-	-	-	p. 8	p. 8	-	-
K230197 BoneMRI v1.6	2023-02-22	p. 8	p. 5	-	-	p. 8	-	p. 8

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K223296 Videa Perio Assist	2023-02-06	p. 7	-	-	p. 7	p. 7	p. 8	p. 6
K222970 LVivo IQS	2023-02-01	p. 7	-	-	-	-	-	-
K223396 Rapid RV/LV	2023-02-01	p. 7	p. 6	-	p. 7	p. 6	-	p. 7
K222406 Clarius AI	2023-01-23	p. 14	-	-	p. 14	p. 14	-	-
K214036 AVIEW	2022-12-23	p. 13	-	-	-	-	-	-
K223268 BrainInsight	2022-12-16	-	p. 6	-	p. 6	-	-	p. 7
K222275 Saige-Density	2022-12-16	p. 6	p. 6	-	p. 6	p. 6	-	-
K223032 SIS System (Version 5.6.0)	2022-11-21	-	-	-	-	-	-	-
K221762 BoneMRI v1.4	2022-11-16	p. 9	p. 5	-	p. 10	p. 9	-	p. 10
K222428 Syngo Dynamics (Version VA40F)	2022-11-14	p. 12	p. 12	-	p. 12	p. 11	-	p. 12
K221632 Spine CAMP™	2022-10-18	p. 5	-	-	p. 5	p. 5	-	-
K211611 QIR Suite	2022-09-30	-	-	-	p. 8	-	-	-
K221738 NS-HGlio	2022-09-27	p. 7	-	-	p. 7	-	-	p. 7
K221100 Viz RV/LV	2022-08-29	-	p. 8	-	p. 8	p. 8	-	-
K222172 MI View&GO	2022-08-19	-	-	-	-	-	-	-
K213645 ClearPoint Maestro Brain Model	2022-08-08	p. 5	-	-	-	p. 6	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K221432 Customize	2022-08-03	p. 6	-	-	-	p. 6	-	p. 6
K213998 cvi42 Auto Imaging Software Application	2022-07-28	p. 11	p. 5	-	-	-	-	-
K220940 EchoPAC Software Only, EchoPAC Plug-in	2022-07-22	p. 7	-	-	p. 8	-	-	p. 7
K220956 Libby Echo:Prio	2022-07-20	-	-	-	p. 7	p. 7	p. 7	-
K220815 BrainInsight	2022-07-19	-	p. 6	-	p. 6	-	-	p. 4
K220497 CoLumbo	2022-06-23	p. 10	p. 10	p. 12	p. 10	p. 9	-	p. 7
K213706 AI-Rad Companion Brain MR	2022-04-15	p. 10	-	-	p. 10	p. 9	-	p. 11
K212624 EFAI Intelligent Cardiothoracic Ratio ...	2022-04-04	p. 10	p. 10	-	p. 10	p. 10	p. 10	p. 5
K213779 Customize	2022-03-16	-	-	-	-	p. 6	-	-
K203744 Arterys MICA	2022-03-14	p. 10	-	-	p. 10	p. 10	-	-
K210747 Caption Interpretation Automated Eject...	2022-01-19	p. 6	p. 5	-	p. 6	p. 6	-	-
K212012 Follicle Clarity	2022-01-19	-	-	p. 7	-	p. 7	-	-
K213544 TOMTEC-ARENA	2022-01-06	p. 5	-	-	-	-	-	-
K202404 BoneMRI	2021-12-22	p. 8	-	-	-	p. 8	-	-
K212690 qXR-BT	2021-12-21	-	-	-	p. 7	p. 7	-	-

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K213275 EchoGo Core (2.0)	2021-12-20	p. 9	-	-	-	p. 9	-	-
K212466 LVivo Seamless	2021-12-09	p. 7	-	-	-	-	p. 7	p. 4
K210831 OnQ Neuro	2021-11-19	-	-	-	p. 8	p. 9	-	-
K211161 Critical Care Suite with Endotracheal ...	2021-10-29	-	-	-	p. 9	p. 9	p. 9	-
K203785 ClariSIGMAM	2021-09-10	p. 8	-	-	p. 7	-	-	-
K203555 AmCAD-UT	2021-09-08	-	-	-	p. 8	p. 9	-	-
K211431 breastscape v1.0	2021-08-02	-	-	-	p. 9	p. 9	-	-
K211222 qER-Quant	2021-07-30	-	-	-	p. 7	p. 8	-	-
K210791 Us2.v1	2021-07-27	p. 7	-	-	p. 8	p. 7	-	p. 7
K210719 Change Healthcare Anatomical AI	2021-07-20	-	p. 8	-	-	p. 8	-	p. 9
K211506 PowerLook Density Assessment V4.0	2021-07-12	-	-	-	-	-	-	-
K211459 syngo.via MI WorkFlows, Scenium, syngo...	2021-06-10	-	-	-	-	-	-	-
K203502 MEDO-Thyroid	2021-04-23	-	-	-	-	-	-	-
K210556 Preview Shoulder	2021-04-21	-	-	-	-	p. 14	-	-
K203256 Imbio RV/LV Software	2021-03-09	-	-	-	-	p. 7	-	-
K210053 LVivo Software Application	2021-02-05	p. 7	-	-	-	-	p. 7	p. 7

Device	Decided	Sample size	Sites	Prospective	Reference standard	Design	Performance	Demographics
K201411 Visage Breast Density	2021-01-29	p. 6	p. 6	-	p. 6	-	-	-
K201195 syngo.via MI Workflows, syngo MBF	2020-11-18	-	-	-	-	-	-	-
K202013 WRDensity by Whiterabbit.ai	2020-10-30	p. 8	-	-	p. 8	-	-	-
K202546 LVivo Seamless	2020-09-29	-	-	-	-	-	-	-
K193283 AI-Rad Companion Prostate MR	2020-07-30	-	-	-	-	p. 8	-	-
K200621 Caption Interpretation Automated Eject...	2020-07-22	-	-	-	p. 6	p. 6	p. 6	-
K192969 Ezra Plexo Software	2020-07-10	p. 7	-	-	p. 7	-	-	-
K200232 LVivo Software Application	2020-06-23	p. 10	-	-	-	p. 4	p. 12	-
K200356 MEDO ARIA	2020-06-11	-	-	-	-	-	-	-
K200974 QLAB Advanced Quantification Software	2020-06-03	-	-	-	-	-	-	-
K192601 uWS-MR	2020-06-01	-	-	-	-	-	-	-
K192437 Arterys MICA	2020-03-25	-	-	-	-	-	-	-
K191647 QLAB Advanced Quantification Software	2019-12-20	-	-	-	p. 8	-	-	-
K191171 EchoGo Core	2019-11-13	p. 7	-	-	-	p. 7	-	-

A dash means the summary does not state it in a form the reading found; that is not proof the work was not done.

07 Review time in QIH, by submission type

510(k)s decided in QIH in the last ten years, by the submission type the FDA records. All 510(k)s in the code: median 140 days, one in four over 211, one in ten over 265.[55]

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

Calendar days from receipt to decision, including time on hold. A description of past reviews, not an estimate for this one.

08 Recalls in QIH, in the FDA's words

2 recall events against devices in QIH: Class II 2. The most recent:

K250330 3mensio Workstation · Class II · 2026-05-07:"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 ... · Class II · 2021-05-19:"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."

Appendix: the testing each summary in QIH reports

All 331 summaries held for QIH, newest first: the kinds of testing and the standards each reports about the device itself, and the page the first one is on.[1]

Device	Decided	Kinds of testing	Standards	Page
K262147 CINA-Aneurysm+	2026-10-19	none confirmed	-	-
K262134 NeuroDR	2026-10-07	Software	-	5
K260055 syngo.CT Brain Quantification	2026-09-25	Clinical data, Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366-1	10
K262390 BoneXpert	2026-09-22	Bench / non-clinical performance	-	7
K261368 Rapid Platform (R6.7)	2026-09-21	Software, Usability / human factors	IEC 62304, IEC 62366	9
K261623 EchoPAC Software Only / EchoPAC ...	2026-09-16	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366-1	10
K261677 Artificial Intelligence Renal As...	2026-09-15	none confirmed	-	-
K260879 4DM	2026-09-10	Software, Usability / human factors	IEC 62304, IEC 62366-1	16
K261795 Quicktome Software Suite	2026-09-10	Bench / non-clinical performance, Software, Usability / human factors	-	7
K251417 ReVISION 2	2026-09-09	Cybersecurity, Software	IEC 62304	12
K260525 NextMR Spine	2026-09-04	Cybersecurity, Software	IEC 62304	10
K260811 Heartvue.Proton	2026-08-26	Bench / non-clinical performance, Software	-	11
K261595 Ceevra Reveal 4	2026-08-25	Software	-	8
K260584 BoneMRI	2026-08-21	none confirmed	-	-
K262127 DS Core CBCT Anatomy	2026-08-21	none confirmed	-	-
K261641 Lower Limb AI (LLAI)	2026-08-18	Bench / non-clinical performance	-	6
K253794 Prostate Core	2026-08-10	Bench / non-clinical performance, Software	IEC 62304	8

Device	Decided	Kinds of testing	Standards	Page
K252571 mdprostate	2026-08-07	Bench / non-clinical performance, Software	ISO 62304	9
K253902 RealGUIDE	2026-08-04	Software	-	8
K253835 Affinity	2026-07-31	none confirmed	-	-
K261210 Cleerly Plaque	2026-07-29	Bench / non-clinical performance, Software	IEC 62304	8
K260192 DIANA	2026-07-24	Bench / non-clinical performance, Usability / human factors	-	6
K261349 SwiftMR	2026-07-24	none confirmed	-	-
K254096 VELMENI for DENTISTS (V4D) 3D	2026-07-23	Bench / non-clinical performance	-	8
K261535 Hi-D Imaging 4TAVR	2026-07-20	Software	-	9
K260206 SkeletonPlanner	2026-07-15	Bench / non-clinical performance, Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366	8
K260973 InferOperate Suite	2026-07-07	Software	-	9
K253969 ADAS 3D	2026-06-29	none confirmed	-	-
K253628 Auto-Seg (SO-0012), Spine Auto-S...	2026-06-29	Cybersecurity, Software, Usability / human factors	-	12
K253786 syngo.CT Coronary Cockpit	2026-06-25	Software, Usability / human factors	IEC 62304, IEC 62366-1	11
K260316 CMN Capillary Function with Onco...	2026-06-22	Software	-	9
K261713 Synapse PACS (7.6.0)	2026-06-18	Software	-	6
K260300 WatchMate Software	2026-06-15	Bench / non-clinical performance, Clinical data, Software	IEC 62304	17
K253172 MediAI-OA	2026-06-15	Software, Usability / human factors	IEC 62304, IEC 62366-1	7
K253690 LungMaps	2026-06-15	Bench / non-clinical performance	-	7

Device	Decided	Kinds of testing	Standards	Page
K260406 Brainomix 360 Hyperdensity	2026-06-12	Clinical data, Software	IEC 62304, IEC 82304-1	7
K260322 Acorn 3D Software (AC-SEG-4009);...	2026-06-11	Bench / non-clinical performance	-	7
K260497 DEEPVESSEL Plaque	2026-06-04	Software	-	12
K260077 OrthoGrid Hip AI® 4.0	2026-05-29	none confirmed	-	-
K261405 ANDI 2.2	2026-05-28	none confirmed	-	-
K260324 Vitrea CT Transcatheter Aortic V...	2026-05-22	Bench / non-clinical performance	-	6
K260234 MSK Go	2026-05-21	Software, Usability / human factors	IEC 62304, IEC 62366-1	9
K254131 BAC	2026-05-21	Bench / non-clinical performance, Software	IEC 62304	8
K261273 Neurophet AQUA	2026-05-15	none confirmed	-	-
K254120 SubtleHD-CT (1.x)	2026-05-15	Clinical data, Software	-	9
K261289 UNiD™ Spine Analyzer (SW3002)	2026-05-15	Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366, IEC 82304-1	9
K252563 Neurophet SCALE PET	2026-05-15	Bench / non-clinical performance, Software	-	13
K260032 Morph	2026-05-13	Bench / non-clinical performance	-	12
K254189 Synapse 3D Base Tools (V7.2)	2026-04-30	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304	26
K254184 syngo Application Software	2026-04-29	Bench / non-clinical performance, Usability / human factors	-	9
K260785 DS Core CBCT Anatomy	2026-04-23	Clinical data, Software	-	6
K253077 uOmnispace.MR	2026-04-22	Bench / non-clinical performance, Software	-	22
K252332 Folliscan	2026-04-20	Bench / non-clinical performance, Software	-	9

Device	Decided	Kinds of testing	Standards	Page
K253502 Critical Care Suite with Enteric...	2026-04-14	none confirmed	-	-
K253930 Overjet Iris Intelligent Imaging...	2026-04-10	none confirmed	-	-
K253689 syngo Dynamics (VA41F)	2026-04-10	Bench / non-clinical performance, Software, Usability / human factors	IEC 62366-1	12
K254015 CoLumbo C-Spine	2026-04-01	Software	-	9
K254207 AiORTA - Plan v2.0	2026-03-30	Software	-	13
K253775 SwiftMR	2026-03-26	none confirmed	-	-
K253614 EchoNavigator R5.0	2026-03-17	Bench / non-clinical performance, Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366-1, IEC 81001-5-1	9
K253944 Data Analysis Facilitation Suite...	2026-03-16	none confirmed	-	-
K252261 InferCare RECIST	2026-03-13	Cybersecurity, Software	-	9
K253551 VELYS™ Hip Navigation	2026-03-06	Bench / non-clinical performance, Software	-	11
K252538 CEPHX3D	2026-03-05	Software	-	13
K253593 Clarius Ejection Fraction AI	2026-03-02	Software, Usability / human factors	IEC 62304	11
K260217 AI Platform 2.2 (AIP002)	2026-02-24	Software	-	9
K252084 AI4CMR v2.0	2026-02-11	Software	-	13
K254016 MI View&GO	2026-02-10	none confirmed	-	-
K252496 Neurophet AQUA AD Plus	2026-01-29	Bench / non-clinical performance, Software	-	13
K252091 Surgical Reality Viewer	2026-01-29	Bench / non-clinical performance, Software	-	9
K253735 AV Vascular	2026-01-22	Bench / non-clinical performance, Software	-	6
K253057 AI-Rad Companion Brain MR	2026-01-22	Bench / non-clinical performance, Software, Usability / human factors	-	13

Device	Decided	Kinds of testing	Standards	Page
K252634 Imagine® Enterprise Suite	2026-01-16	Bench / non-clinical performance, Software	-	17
K253532 TruSPECT Processing Station	2025-12-30	Software	IEC 62304	8
K252856 PeekMed web	2025-12-22	none confirmed	-	-
K252029 AI-CVD	2025-12-19	Software	-	12
K252670 Alzevita	2025-12-19	none confirmed	-	-
K252235 PVAD IQ Software	2025-12-18	none confirmed	-	-
K250914 MediAI-BA	2025-12-18	none confirmed	-	-
K252922 Neosoma Brain Mets	2025-12-17	Software	-	12
K251763 IRISeg	2025-12-16	Cybersecurity, Usability / human factors	-	9
K251514 Overjet CBCT Assist	2025-12-05	none confirmed	-	-
K252103 Acorn 3D Software (AC-SEG-4009);...	2025-12-02	Bench / non-clinical performance	-	7
K251078 AutoDensity	2025-11-14	Bench / non-clinical performance, Clinical data	-	12
K252452 PeekMed web	2025-11-12	none confirmed	-	-
K250330 3mensio Workstation	2025-11-03	Software, Usability / human factors	IEC 62304, IEC 62366-1, IEC 82304-1	9
K250337 AiORTA - Plan	2025-10-30	Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366	12
K251027 cvi42 Coronary Plaque Software A...	2025-10-27	Bench / non-clinical performance, Software	IEC 62304	12
K251059 Syngo Carbon Clinicals (VA41)	2025-10-24	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366-1, IEC 82304-1	13
K250288 TeraRecon Cardiovascular.Calcifi...	2025-10-23	none confirmed	-	-
K252298 ANDI 2.0	2025-10-22	Bench / non-clinical performance, Software	-	7

Device	Decided	Kinds of testing	Standards	Page
K252665 brAIn™ Shoulder Positioning	2025-10-20	Software	-	10
K252214 AIAS Cephalon	2025-10-07	Software, Usability / human factors	IEC 62304	6
K252007 BlineSlide	2025-10-06	none confirmed	-	-
K250023 SMART PCFD	2025-09-29	Bench / non-clinical performance	-	9
K252105 Ligence Heart	2025-09-26	Cybersecurity, Software, Usability / human factors	-	9
K251527 Brain WMH	2025-09-25	none confirmed	-	-
K251483 SwiftSight-Brain	2025-09-23	Software	-	8
K251987 Rapid Aortic Measurements	2025-09-23	Software, Usability / human factors	IEC 62304, IEC 62366-1	9
K250369 Axial3D Insight	2025-09-18	Software, Usability / human factors	-	10
K250237 InferOperate Suite	2025-09-15	Software	-	10
K244002 AngioWaveNet	2025-09-10	Cybersecurity, Software	-	7
K251072 Segmentron Viewer	2025-09-09	none confirmed	-	-
K251656 Careverse CoronaryDoc (Careverse...	2025-09-04	Software	-	9
K252539 Tempus Pixel	2025-09-03	Cybersecurity, Software	-	8
K243859 PRAEVAorta®2	2025-08-29	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366	12
K250947 VistaSoft 4.0 and VisionX 4.0	2025-08-27	Cybersecurity	IEC 81001-5-1	6
K243685 MammoScreen BD	2025-08-22	Software, Usability / human factors	IEC 62304, IEC 62366-1	9
K252362 GBrain MRI	2025-08-22	none confirmed	-	-
K251837 Salix Coronary Plaque (V1.0.0)	2025-08-20	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304	13
K251747 VEA Align; spineEOS	2025-08-15	Usability / human factors	-	16

Device	Decided	Kinds of testing	Standards	Page
K250755 DS Core Diagnosis	2025-08-12	Usability / human factors	-	7
K251629 UNiD™ Spine Analyzer	2025-08-07	Cybersecurity, Software, Usability / human factors	IEC 62304, IEC 62366, IEC 81001-5-1, IEC 82304-1	9
K243919 Voxel Dosimetry (00859873006226)	2025-07-30	none confirmed	-	-
K251342 EchoPAC Software Only / EchoPAC ...	2025-07-16	Software, Usability / human factors	IEC 62304, IEC 62366-1	9
K251096 PeekMed web	2025-07-14	none confirmed	-	-
K251766 TumorSight Viz	2025-07-08	none confirmed	-	-
K251528 syngo.via MI Workflows; Scenium;...	2025-07-03	none confirmed	-	-
K243779 Bunkerhill Abdominal Aortic Quan...	2025-07-01	none confirmed	-	-
K250670 EchoConfidence (USA)	2025-06-30	Software, Usability / human factors	IEC 62304, IEC 62366-1, IEC 62366-2	6
K243647 Synapse PACS (7.5)	2025-06-30	Bench / non-clinical performance	-	6
K250484 PIUR tUS inside	2025-06-30	Electrical safety, Electromagnetic compatibility, Software, Usability / human factors	IEC 60601-1-2, IEC 62366-1	8
K243633 Brainlab Elements (7.0); Brainla...	2025-06-13	Software, Usability / human factors	-	21
K250354 Viz Subdural+, Viz SUBDURAL PLUS	2025-06-10	none confirmed	-	-
K251009 Cirrus Resting State fMRI Software	2025-06-06	none confirmed	-	-
K251456 BrightHeart View Classifier	2025-06-05	none confirmed	-	-
K243810 TraumaCad Neo (1.1)	2025-06-04	Bench / non-clinical performance	-	11
K243005 AudaxCeph Cephalogram Analysis S...	2025-05-30	Software, Usability / human factors	IEC 62366-1	8

Device	Decided	Kinds of testing	Standards	Page
K243863 Opulus™ Lymphoma Precision	2025-05-30	Software	-	7
K250367 CoLumboX	2025-05-28	Clinical data, Software	-	9
K243378 Rapid MLS	2025-05-28	Software, Usability / human factors	IEC 62304, IEC 62366	7
K250005 Clever One	2025-05-23	none confirmed	-	-
K243989 Second Opinion® 3D	2025-05-23	Bench / non-clinical performance	-	7
K243762 Synapse 3D Base Tools (V7.0)	2025-05-21	Bench / non-clinical performance, Usability / human factors	-	13
K242624 Medical Image Post-processing So...	2025-05-14	Software	-	22
K243230 Second Opinion® BLE	2025-05-09	Clinical data	-	10
K250226 Clarius Median Nerve AI	2025-05-08	Software, Usability / human factors	IEC 62304, IEC 62366-1	11
K243684 BrightHeart View Classifier	2025-05-07	none confirmed	-	-
K250328 UltraExtend NX CUW-U001S V2.0 UI...	2025-04-30	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366-1	7
K242500 LARALAB	2025-04-16	Cybersecurity	-	11
K243853 Clarius Prostate AI	2025-04-16	Software, Usability / human factors	IEC 62304, IEC 62366-1	12
K250416 GBrain MRI	2025-04-11	none confirmed	-	-
K241982 DeepFoqus (DeepFoqus-Accelerate)	2025-04-04	Bench / non-clinical performance, Cybersecurity, Software, Usability / human factors	AAMI 57, IEC 62304, IEC 62366-1	7
K242551 syngo Dynamics (Version VA41D)	2025-04-03	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366-1	12
K241984 Hi-D Imaging 4TAVR	2025-04-02	Software, Usability / human factors	-	9
K242166 TribusConnect	2025-03-31	Bench / non-clinical performance, Cybersecurity,	IEC 62304	16

Device	Decided	Kinds of testing	Standards	Page
		Software		
K243038 Salix Central	2025-03-27	Bench / non-clinical performance	-	9
K241961 Vent Creativity Knee v1.0 (Hermes)	2025-03-20	Software	-	7
K250042 PeekMed web	2025-03-19	none confirmed	-	-
K243689 AVIEW	2025-03-19	none confirmed	-	-
K243862 LVivo Software Application	2025-03-17	Bench / non-clinical performance, Software, Usability / human factors	IEC 62304, IEC 62366-1	10
K242338 Cleerly LABS (v2.0)	2025-03-07	Software	IEC 62304	8
K243331 LVivo Seamless	2025-03-06	Bench / non-clinical performance	-	8
K243933 Ceevra Reveal 3+	2025-03-04	Software	-	8
K243235 LVivo Software Application	2025-03-03	Bench / non-clinical performance	-	9
K241922 Myomics	2025-02-28	Software	IEC 62304	9
K241222 Ventripoint Medical System Plus ...	2025-02-26	Electrical safety, Electromagnetic compatibility	IEC 60601-1, IEC 60601-1-2	7
K242607 ScanDiags Ortho L-Spine MR-Q	2025-02-21	Software	-	9
K243696 AVIEW CAC	2025-02-14	none confirmed	-	-
K243250 SubtleHD (1.x)	2025-02-12	Clinical data, Software	-	9
K241659 Ultrasound Workspace (UWS 6.0)	2025-02-10	Software	IEC 62304	19
K241593 BoneMetrics (US)	2025-02-05	Bench / non-clinical performance	-	12
K243158 TeraRecon Aorta.CT (1.1.0)	2025-01-23	none confirmed	-	-
K243350 Rapid Neuro3D	2025-01-22	Software, Usability / human factors	IEC 62304, IEC 62366-1	11
K242334 Ezra Flash	2025-01-02	Software, Usability / human factors	-	10

Device	Decided	Kinds of testing	Standards	Page
K241696 Ortho AI	2025-01-02	Software	-	8
K242270 OrthoNext Platform System	2024-12-19	Software, Usability / human factors	IEC 62366-1	12
K243705 Saige-Density (2.5.0)	2024-12-19	none confirmed	-	-
K240793 MSKai	2024-12-16	Software, Usability / human factors	IEC 62366-1	18
K242461 IRISeg	2024-12-10	Bench / non-clinical performance, Cybersecurity, Software, Usability / human factors	IEC 62304	9
K241543 DrAid™ for Liver Segmentation	2024-12-06	Bench / non-clinical performance	-	8
K240680 CDM Insights	2024-12-06	Bench / non-clinical performance, Software	-	10
K240645 Sonix Health	2024-11-27	Software	IEC 62304	9
K242203 BriefCase-Quantification	2024-11-22	none confirmed	-	-
K242359 Strain AI (SAI001)	2024-11-20	Software	-	7
K241312 TeraRecon Cardiac.Chambers.MR (1...	2024-11-05	none confirmed	-	-
K241108 RemedyLogic AI MRI Lumbar Spine ...	2024-10-30	Software, Usability / human factors	IEC 62366-1	15
K242215 Neurophet AQUA (V3.1)	2024-10-25	none confirmed	-	-
K243189 TumorSight Viz	2024-10-25	none confirmed	-	-
K242781 cvi42 Software Application	2024-10-15	Bench / non-clinical performance	-	17
K240786 AutoChamber	2024-10-10	Software	-	9
K241430 EchoMeasure	2024-10-10	Software	-	12
K240553 LVivo Software Application	2024-10-04	Bench / non-clinical performance	-	9
K241561 MammoScreen BD	2024-10-02	Software	-	9
K240943 LungVision	2024-10-01	Bench / non-clinical performance, Electrical safety	IEC 60601-1	8

Device	Decided	Kinds of testing	Standards	Page
K240036 PIUR tUS Infinity	2024-09-20	Electrical safety, Electromagnetic compatibility, Software, Usability / human factors	-	8
K241280 Constellation (CON-001)	2024-09-12	Bench / non-clinical performance	-	12
K240094 LumiNE US; Lumi	2024-09-10	Bench / non-clinical performance, Software	-	11
K241681 Overjet Image Enhancement Assist	2024-09-09	Clinical data, Software	-	6
K240791 ADAS 3D	2024-09-09	none confirmed	-	-
K240411 uAI Portal	2024-09-06	Software	-	24
K241847 Imbio PHA (4.0.0)	2024-08-30	Bench / non-clinical performance	-	7
K242275 syngo.via MI Workflows; Scenium;...	2024-08-30	none confirmed	-	-
K242300 MI View&GO	2024-08-30	none confirmed	-	-
K241684 Overjet Charting Assist	2024-08-27	none confirmed	-	-
K241098 NeuroQuant	2024-08-22	none confirmed	-	-
K240740 qCT LN Quant	2024-08-16	Software	IEC 62304	10
K241211 CoLumbo	2024-08-15	Software, Usability / human factors	IEC 62366-1	10
K242054 OptimMRI (v2)	2024-08-12	Cybersecurity, Software	AAMI 57, IEC 62304	5
K233822 i2Contour	2024-08-08	none confirmed	-	-
K240953 AI Platform 2.0 (AIP002)	2024-08-05	Software	-	9
K234009 Acorn 3D Software (AC-SEG-4009);...	2024-07-12	Bench / non-clinical performance, Biocompatibility	ISO 10993-1	6
K233457 RUS	2024-07-12	Software	-	12
K241329 SubtleSYNTH (1.x)	2024-07-11	Bench / non-clinical performance, Software	-	6
K240736 SMART Bun-Yo-Matic X-Ray	2024-07-02	Bench / non-clinical performance	-	7

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K240582 VEA Align; spineEOS	2024-06-25	Usability / human factors	-	21
K233196 Medihub Prostate	2024-06-21	Bench / non-clinical performance, Clinical data, Software, Usability / human factors	IEC 62304, IEC 62366	7
K240642 SMART Bun-Yo-Matic CT	2024-06-20	Bench / non-clinical performance	-	7
K241083 SIS System	2024-06-14	Bench / non-clinical performance	-	6
K233925 Relu Creator	2024-06-13	none confirmed	-	-
K234042 EFAI Bonesuite XR Bone Age Pro A...	2024-06-07	Software	-	7
K241038 Cardiac CT Function Software App...	2024-06-07	Bench / non-clinical performance, Software	IEC 62304	11
K240769 LVivo IQS	2024-05-24	none confirmed	-	-
K233209 uOmnispace.CT	2024-05-17	Software	-	24
K241112 BriefCase-Quantification	2024-05-15	none confirmed	-	-
K232331 InVision Precision LVEF (LVEF)	2024-04-25	Software	-	7
K233186 uOmnispace.MR	2024-04-17	Bench / non-clinical performance, Software	-	18
K240172 Preview Shoulder	2024-04-04	none confirmed	-	-
K233676 Us2.v2	2024-04-01	Software, Usability / human factors	-	8
K233211 AVIEW CAC	2024-03-29	Software	-	9
K231690 iCAS-LV	2024-03-01	Bench / non-clinical performance, Clinical data, Software	-	7
K233030 BoneMRI	2024-03-01	Bench / non-clinical performance, Clinical data, Software	-	10
K231683 inHEART Models	2024-02-29	Cybersecurity	IEC 81001-5-1	6
K232613 CT Cardiomegaly	2024-02-28	Bench / non-clinical performance	-	13

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K233590 Overjet Charting Assist	2024-02-23	Software	-	5
K232363 Viz HDS, Viz Volume Plus, Viz ICH+	2024-02-05	Clinical data	-	10
K232698 NemoScan	2024-01-18	none confirmed	-	-
K233512 Rapid (6.0)	2024-01-16	Software, Usability / human factors	IEC 62304, IEC 62366	8
K231324 DASI Dimensions (V1.0)	2024-01-08	Cybersecurity, Software, Usability / human factors	-	7
K231917 VEA Align	2024-01-05	Usability / human factors	-	10
K231130 TumorSight Viz	2023-12-26	none confirmed	-	-
K231929 iQ-solutions	2023-12-18	Bench / non-clinical performance, Software, Usability / human factors	IEC 62366-1	15
K232231 QP-Brain®	2023-12-13	Software	-	9
K232096 Transpara Density 1.0.0	2023-12-11	Bench / non-clinical performance	-	9
K223757 Bonelogic	2023-12-08	Bench / non-clinical performance, Software	-	7
K232440 Adravision Perio	2023-12-05	Bench / non-clinical performance	-	7
K233568 Ceevra Reveal 3+	2023-12-05	Software	-	6
K232856 Syngo Carbon Clinicals	2023-12-01	Software, Usability / human factors	IEC 62304, IEC 62366-1, IEC 82304-1	21
K232000 syngo.via MI Workflows; Scenium;...	2023-11-28	none confirmed	-	-
K232501 AI Platform (AIP001)	2023-11-17	Software	-	7
K232841 Axial3D Insight	2023-11-15	Software	-	14
K232257 Clarius Bladder AI	2023-11-13	Software, Usability / human factors	IEC 62304, IEC 62366-1	11
K232083 BriefCase-Quantification	2023-11-13	none confirmed	-	-

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K230534 BriefCase-Quantification	2023-11-08	none confirmed	-	-
K231955 aprevo® Digital Segmentation	2023-11-03	none confirmed	-	-
K232305 AI-Rad Companion Brain MR	2023-10-23	Bench / non-clinical performance, Software, Usability / human factors	-	13
K230209 Sonix Health	2023-10-20	Software	IEC 62304	9
K231398 VUNO Med-DeepBrain	2023-10-04	none confirmed	-	-
K230045 HipCheck	2023-09-29	Electrical safety	-	10
K231149 qXR-CTR	2023-09-22	Clinical data	-	8
K223621 DeepXray	2023-09-08	none confirmed	-	-
K230913 ANDI	2023-07-25	Software	IEC 62304	6
K230150 OptimMRI	2023-07-21	none confirmed	-	-
K230039 uOmnispace	2023-07-20	Software	-	13
K231757 Ez3D-i /E3	2023-07-14	none confirmed	-	-
K223106 Brainlab Elements Image Fusion, ...	2023-07-14	Software	-	11
K231668 Spine CAMP™ (1.1)	2023-07-07	Bench / non-clinical performance, Software	-	5
K222745 Axial3D Insight	2023-07-03	Software, Usability / human factors	-	14
K230497 Bladder AI (AIBV01)	2023-06-22	Software	-	6
K223646 IB Lab LAMA	2023-06-16	Clinical data	-	11
K223556 DeepCatch	2023-06-16	Bench / non-clinical performance, Electrical safety, Electromagnetic compatibility, Software	-	10
K223855 FEops HEARTguideTM, FEops HEARTg...	2023-06-06	none confirmed	-	-
K230977 SIS System	2023-05-02	Software	-	5

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K222676 Ceevra Reveal 3	2023-04-25	Software	-	6
K223501 ViewFinder Software Version 1.1	2023-04-21	Bench / non-clinical performance, Software	IEC 62304	9
K213986 CerebralGo Plus	2023-04-13	none confirmed	-	-
K213272 Formus Hip	2023-03-31	Software	-	7
K222174 RadioLens v1.0	2023-03-28	Software	-	7
K222036 MPXA-2000	2023-03-22	Cybersecurity, Software	-	9
K230197 BoneMRI v1.6	2023-02-22	Clinical data, Software	-	8
K223296 Videa Perio Assist	2023-02-06	Bench / non-clinical performance, Clinical data	-	7
K222970 LVivo IQS	2023-02-01	Bench / non-clinical performance	-	8
K223396 Rapid RV/LV	2023-02-01	Software, Usability / human factors	IEC 62304, IEC 62366	6
K222406 Clarius AI	2023-01-23	Software, Usability / human factors	IEC 62304, IEC 62366-1	13
K214036 AVIEW	2022-12-23	Software	-	12
K223268 BrainInsight	2022-12-16	none confirmed	-	-
K222275 Saige-Density	2022-12-16	none confirmed	-	-
K223032 SIS System (Version 5.6.0)	2022-11-21	Software	-	5
K221762 BoneMRI v1.4	2022-11-16	Clinical data, Software	-	9
K222428 Syngo Dynamics (Version VA40F)	2022-11-14	Bench / non-clinical performance, Software, Usability / human factors	IEC 62366-1	11
K221632 Spine CAMP™	2022-10-18	Bench / non-clinical performance, Software	-	5
K211611 QIR Suite	2022-09-30	Software	-	8
K221738 NS-HGlio	2022-09-27	Software	-	6
K221100 Viz RV/LV	2022-08-29	Clinical data	-	8
K222172 MI View&GO	2022-08-19	Software	IEC 62304	8

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K213645 ClearPoint Maestro Brain Model	2022-08-08	none confirmed	-	-
K221432 Customize	2022-08-03	none confirmed	-	-
K213998 cvi42 Auto Imaging Software Appl...	2022-07-28	Bench / non-clinical performance, Software	IEC 62304	11
K220940 EchoPAC Software Only, EchoPAC P...	2022-07-22	Software, Usability / human factors	IEC 62304, IEC 62366-1	7
K220956 Libby Echo:Prio	2022-07-20	Software	-	7
K220815 BrainInsight	2022-07-19	none confirmed	-	-
K220497 CoLumbo	2022-06-23	Software, Usability / human factors	IEC 62366-1	14
K213706 AI-Rad Companion Brain MR	2022-04-15	Bench / non-clinical performance, Software, Usability / human factors	-	9
K212624 EFAI Intelligent Cardiothoracic ...	2022-04-04	Software, Usability / human factors	IEC 62366-1	10
K213779 Customize	2022-03-16	none confirmed	-	-
K203744 Arterys MICA	2022-03-14	Software	-	9
K210747 Caption Interpretation Automated...	2022-01-19	Software	-	6
K212012 Follicle Clarity	2022-01-19	Software	-	7
K213544 TOMTEC-ARENA	2022-01-06	Software	-	13
K202404 BoneMRI	2021-12-22	Clinical data, Software	-	8
K212690 qXR-BT	2021-12-21	Software	-	8
K213275 EchoGo Core (2.0)	2021-12-20	Bench / non-clinical performance, Software, Usability / human factors	IEC 62366-1	9
K212466 LVivo Seamless	2021-12-09	Bench / non-clinical performance	-	7
K210831 OnQ Neuro	2021-11-19	Bench / non-clinical performance	-	9
K211161 Critical Care Suite with Endotra...	2021-10-29	none confirmed	-	-

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K203785 ClariSIGMAM	2021-09-10	none confirmed	-	-
K203555 AmCAD-UT	2021-09-08	none confirmed	-	-
K211431 breastscape v1.0	2021-08-02	Software	-	8
K211222 qER-Quant	2021-07-30	Software	-	9
K210791 Us2.v1	2021-07-27	Software, Usability / human factors	-	7
K210719 Change Healthcare Anatomical AI	2021-07-20	Bench / non-clinical performance, Software, Usability / human factors	IEC 62366-1	10
K211506 PowerLook Density Assessment V4.0	2021-07-12	none confirmed	-	-
K211459 syngo.via MI WorkFlows, Scenium,...	2021-06-10	Software	IEC 62304	8
K203502 MEDO-Thyroid	2021-04-23	Software	-	6
K210556 Preview Shoulder	2021-04-21	none confirmed	-	-
K203256 Imbio RV/LV Software	2021-03-09	Bench / non-clinical performance, Clinical data, Software	-	7
K210053 LVivo Software Application	2021-02-05	Bench / non-clinical performance	-	7
K201411 Visage Breast Density	2021-01-29	none confirmed	-	-
K201195 syngo.via MI Workflows, syngo MBF	2020-11-18	Software	IEC 62304	8
K202013 WRDensity by Whiterabbit.ai	2020-10-30	Software	-	7
K202546 LVivo Seamless	2020-09-29	Bench / non-clinical performance	-	6
K193283 AI-Rad Companion Prostate MR	2020-07-30	Bench / non-clinical performance, Software, Usability / human factors	-	8
K200621 Caption Interpretation Automated...	2020-07-22	Software	-	5
K192969 Ezra Plexo Software	2020-07-10	Bench / non-clinical performance, Software, Usability / human factors	-	7

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K200232 LVivo Software Application	2020-06-23	none confirmed	-	-
K200356 MEDO ARIA	2020-06-11	Software	-	6
K200974 QLAB Advanced Quantification Sof...	2020-06-03	Software	-	11
K192601 uWS-MR	2020-06-01	Software	-	13
K192437 Arterys MICA	2020-03-25	Software	-	6
K191647 QLAB Advanced Quantification Sof...	2019-12-20	Software	-	8
K191171 EchoGo Core	2019-11-13	Software	-	7

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'.

09 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.

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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 K261405, 510(k) summary (FDA) (page 6).

3 K253628, 510(k) summary (FDA) (page 11).

4 K253969, 510(k) summary (FDA) (page 17).

5 K260300, 510(k) summary (FDA) (page 7).

6 K253172, 510(k) summary (FDA) (page 8).

7 K260316, 510(k) summary (FDA) (page 11).

8 K252563, 510(k) summary (FDA) (page 14).

9 K260077, 510(k) summary (FDA) (page 12).

10 K253628, 510(k) summary (FDA) (page 12).

11 K253628, 510(k) summary (FDA) (page 11).

12 K253628, 510(k) summary (FDA) (page 15).

13 K253628, 510(k) summary (FDA) (page 16).

14 K260300, 510(k) summary (FDA) (page 7).

15 K260300, 510(k) summary (FDA) (page 6).

16 K260300, 510(k) summary (FDA) (page 14).

17 K253172, 510(k) summary (FDA) (page 8).

18 K253172, 510(k) summary (FDA) (page 10).

19 K260497, 510(k) summary (FDA) (page 13).

20 K260497, 510(k) summary (FDA) (page 12).

21 K260497, 510(k) summary (FDA) (page 12).

22 K260077, 510(k) summary (FDA) (page 11).

23 K260077, 510(k) summary (FDA) (page 11).

24 K260077, 510(k) summary (FDA) (page 10).

25 K260077, 510(k) summary (FDA) (page 11).

26 K260234, 510(k) summary (FDA) (page 10).

27 K260234, 510(k) summary (FDA) (page 10).

28 K260234, 510(k) summary (FDA) (page 10).

29 K254131, 510(k) summary (FDA) (page 7).

30 K254131, 510(k) summary (FDA) (page 8).

31 K254131, 510(k) summary (FDA) (page 7).

32 K254131, 510(k) summary (FDA) (page 8).

33 K252563, 510(k) summary (FDA) (page 13).

34 K252563, 510(k) summary (FDA) (page 14).

35 K252563, 510(k) summary (FDA) (page 14).

36 K260032, 510(k) summary (FDA) (page 8).

37 K260032, 510(k) summary (FDA) (page 12).

38 K260032, 510(k) summary (FDA) (page 12).

39 K260785, 510(k) summary (FDA) (page 6).

40 K260785, 510(k) summary (FDA) (page 7).

41 K260785, 510(k) summary (FDA) (page 6).

42 K252332, 510(k) summary (FDA) (page 9).

43 K252332, 510(k) summary (FDA) (page 12).

44 K252332, 510(k) summary (FDA) (page 11).

45 K253502, 510(k) summary (FDA) (page 8).

46 K253502, 510(k) summary (FDA) (page 8).

47 K253502, 510(k) summary (FDA) (page 8).

48 K253502, 510(k) summary (FDA) (page 9).

49 K262134, 510(k) summary (FDA) (page 5).

50 K262390, 510(k) summary (FDA) (page 7).

51 K260055, 510(k) summary (FDA) (page 12).

52 K260055, 510(k) summary (FDA) (page 10).

53 K260055, 510(k) summary (FDA) (page 10).

54 K250484, 510(k) summary (FDA) (page 8).

55 Device Evidence, the verified FDA record for product code QIH (read 2026-11-17).