

THE LANCET

Digital Health

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. *Lancet Digit Health* 2021; published online Jan 18. [https://doi.org/10.1016/S2589-7500\(20\)30292-2](https://doi.org/10.1016/S2589-7500(20)30292-2).

Consulted data sources

Name	Region	Link
De novo premarket review database	US	https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
Premarket approval database	US	https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases
FDA Product Code Classification	US	https://www.fda.gov/medical-devices/classify-your-medical-device/download-product-code-classification-files
openFDA Device 510(k) [/device/510(k)] database	US	https://open.fda.gov/downloads/
Medizinprodukte-Anzeigen (DIMDI)	Europe (Germany)	https://www.dimdi.de/dynamic/de/medizinprodukte/datenbankrecherche/
Public Access Database for Medical Device Registration (MHRA)	Europe (United Kingdom)	http://aic.mhra.gov.uk/era/pdr.nsf/name?openpage&start=2001&count=1000
Liste des communications de dispositifs des classes IIa, IIb, et III (ANSM)	Europe (France)	https://www.ansm.sante.fr/Activites/Mise-sur-le-marche-des-dispositifs-medicaux-et-dispositifs-medicaux-de-diagnostic-in-vitro-DM-DMIA-DMDIV/DM-classes-IIa-IIb-III-et-DMIA-Communication-et-liste/(offset)/6
Elenco dei dispositivi medici (Ministero della Salute)	Europe (Italy)	http://www.salute.gov.it/interrogazioneDispositivi
Austrian Life Sciences Directory (LISAVienna)	Europe (Austria)	http://www.lifesciencesdirectory.at/
Medical Device Notifications (FAMHP)	Europe (Belgium)	https://www.vas.ehealth.fgov.be/registers/sadm/web/distribution/search

Factiva regex search

We employed regex search strategy of Factiva (Dow Jones, New York, USA) for the languages English, German, French, Italian for all publications between 31 August 2014 to 31 August 2020 to identify potential AI/ML-based medical devices for inclusion.

For the US:

((food and drug administration or FDA or US or U.S.) and (approv* or clear* or revie* or launch*) and ((approv* or clear* or revie* or launch*) same ((algorithm or medical w/3 device* or medical w/3 product* or medical w/3 software*) and (artificial intelligence or AI or machine learning or deep learning or neural network*))))

For Europe:

((CE mark* or CE appro* or conformité européenne or marc* CE or etichetta CE or marq* CE or symbole CE or Europe* w/3 launch or EU w/3 launch or E.U. w/3 launch or clear* or zugelass* or zulass* or autoriz* w/5 CE or approv* or approuv* or autoris* or konformität* or conformit* or zertif* or certificat*) and ((CE mark* or CE appro* or conformité européenne or marc* CE or etichetta CE or marq* CE or symbole CE or Europe* w/3 launch or EU w/3 launch or E.U. w/3 launch or clear* or zugelass* or zulass* or autoriz* w/5 CE or approv* or approuv* or autoris* or konformität* or conformit* or zertif* or certificat*) same ((algorithm or medical w/3 device* or medical w/3 product* or medical w/3 software* or algorithmus or algoritmo or algorithme or medizin w/3 produkt* or dispositivo medico or prodotto medico or dispositif médical or produit médical or medizin w/3 software or medizinprodukt* or medizinsoftware* or software w/3 medico or logiciel médic) and (artificial intelligence or AI or machine learning or intelligen* or deep learning or neural network or künstliche intelligenz or KI or intelligenz* artificial* or intelligence artificielle or IA or apprendimento automatico or apprentissage automatique or maschin* lernen or apprendimento delle macchine or apprentissage machine))))

Characteristics of FDA approved devices

<i>Device</i>	<i>Manufacturer</i>	<i>Approval Pathway</i>	<i>Approval Date</i>	<i>Summary*</i>	<i>Medical Specialty</i>	<i>Origin Country</i>	<i>Company Size</i>
Cognition EEG/EP System	Neuronetrix Solutions	510(k)	February 2015	Acquisition, display analysis, storage, reporting and management of EEG and AEP	Neurology	United States	Small
IRIS Intelligent Retinal Imaging Systems LLC.	Intelligent Retinal Imaging Systems LLC.	510(k)	February 2015	Storing, managing, and displaying patient data, diagnostic data and images from computerized diagnostic systems	Radiology	United States	Small
EndoTool SubQ	Monarch Medical Technologies LLC.	510(k)	April 2015	Calculation and recommendation of insulin dose	Anesthesiology	United States	Small
SnoreSounds	Appian Medical Inc.	510(k)	May 2015	Diagnostic aid for snoring evaluation in patients	Anesthesiology	United States	Small
Ahead 200	BrainScope Company Inc.	510(k)	May 2015	Aid in analysis of brain electrical activity	Neurology	United States	Small
Cognivue	Cerebral Assessment Systems Inc.	de novo	June 2015	Neurological assessment tool for dementia detection	Neurology	United States	Small
Personalized Physiology Analytics Engine	VGBio Inc.	510(k)	June 2015	Detection of change in the patient's vital signs	Cardiovascular	United States	Small
AIX1000	Gold Standard Diagnostics Inc.	510(k)	November 2015	Aid in the diagnosis of syphilis	Microbiology	United States	Small
Dario Blood Glucose Monitoring System	LabStyle Innovations Ltd.	510(k)	December 2015	Quantitative measurement of glucose in blood samples	Clinical Chemistry	United States	Small
QbCheck	QBTECH AB	510(k)	March 2016	Aid in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD	Neurology	Sweden	Small
Cydar EV	Cydar Ltd.	510(k)	July 2016	Image guidance by overlaying preoperative 3D vessel anatomy from a previously acquired CT scan	Radiology	England	Small
Steth IO	Stratoscientific Inc.	510(k)	July 2016	Detection and amplification of sounds from the heart and lungs	Cardiovascular	United States	Small
Lvivo Toolbox	DiA Imaging Analysis Ltd.	510(k)	July 2016	Decision support tool for endocardial tracking resulting from ultrasound images	Radiology	Israel	Small

Icobrain	Icometrix NV	510(k)	August 2016	Automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images	Radiology	Belgium	Small
ClearRead CT	Riverrain Technologies Inc.	510(k)	September 2016	Assistance in review of multi-slice computed tomography exams of the chest and detection of potential nodules that radiologist should review	Radiology	United States	Small
PixelShine	AlgoMedica Inc.	510(k)	September 2016	Networking, communication, processing and enhancement of CT images in DICOM format	Radiology	United States	Small
Ahead 300	BrainScope Company Inc.	510(k)	September 2016	Traumatic brain injury assessment tool	Neurology	United States	Small
Guardian Connect System	Medtronic Minimed Inc. (parent company: Medtronic plc.)	PMA	September 2016	Continuous glucose monitoring	Clinical Chemistry	United States	Large
Tyto Stethoscope	Tyto Care Ltd.	510(k)	October 2016	Electronic stethoscope that enables transmission of auscultation sound data	Cardiovascular	United States	Small
One Drop	AgaMatrix Inc.	510(k)	November 2016	Quantitative measurement of blood glucose in blood samples	Clinical Chemistry	United States	Small
CT CoPilot	ZepMed LLC.	510(k)	December 2016	Automatic labeling, visualization and volumetric quantification of brain images from CT scans	Radiology	United States	Small
CipherOx CRI Tablet	Flashback Technologies Inc.	de novo	December 2016	Noninvasive monitoring and analytics of acute blood loss	Cardiovascular	United States	Small
Cantab Mobile	Cambridge Cognition Ltd.	510(k)	January 2017	Adjunctive tool to assess memory by testing visuospatial associative learning	Neurology	England	Small
Arterys Cardio DL	Arterys Inc.	510(k)	January 2017	Analysis of cardiovascular images acquired from MR scanners	Radiology	United States	Small
Philips IntelliVue GuardianSoftware	Philips Medizin Systeme Boeblingen GmbH (parent company: Philips NV)	510(k)	January 2017	Collection, storage and management of data from Philips specified measurements and Philips Patient Monitors connected through networks	Cardiovascular	Germany	Large
SIS Software	Surgical Information Sciences Inc.	510(k)	February 2017	Viewing, presentation and documentation of medical imaging	Radiology	United States	Small
TruRhythm Detection	Medtronic Inc. (parent company: Medtronic plc.)	510(k)	February 2017	Insertable automatically-activated and patient-activated monitoring system that records subcutaneous ECG	Cardiovascular	United States	Large

SeptiCyte LAB	Immunexpress Inc.	510(k)	February 2017	Aid to differentiate sepsis from infection-negative systemic inflammation	Microbiology	United States	Small
PowerLook Tomo Detection (SecondLook)	iCAD Inc.	PMA	March 2017	Detection of soft tissue densities and calcifications in the 3D digital breast tomosynthesis slice	Radiology	United States	Small
EnsoSleep	EnsoData Inc.	510(k)	March 2017	Assessment of sleep quality and aid for diagnosis of sleep and respiratory related sleep disorders	Neurology	United States	Small
MUTYH-Associated Polyposis (MAP)	23andMe Inc.	de novo	April 2017	Genetic testing for cancer predisposition assessment	Molecular Genetics	United States	Small
Triton System	Gauss Surgical Inc.	510(k)	April 2017	Image processing device for estimation of external blood loss	General Hospital	United States	Small
AmCAD-UV	AmCad BioMed Corporation	510(k)	April 2017	Medical image processing tool for vascular pulsatility analysis	Radiology	Taiwan	Small
MATRx plus	Zephyr Sleep Technologies Inc.	510(k)	May 2017	Aid in the diagnosis and assessment of sleep disordered breathing	Anesthesiology	Canada	Small
AmCAD-US	AmCad BioMed Corporation	510(k)	May 2017	Visualization and analysis of statistical distributions of backscattered signals echoed by tissue compositions in the body	Radiology	Taiwan	Small
SmartTarget	SmartTarget Ltd.	510(k)	June 2017	Image-guided interventional and diagnostic procedures involving the prostate gland	Radiology	England	Small
syngo Application Software	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	June 2017	Diagnostic image viewing and post processing, and for viewing and post processing during interventional procedures	Radiology	United States	Large
Cardiologs	Cardiologs Technologies SAS	510(k)	June 2017	Assessment of arrhythmias using ECG data	Cardiovascular	France	Small
Arterys Viewer	Arterys Inc.	510(k)	July 2017	Digital imaging and communications in Medicine (DICOM) and non-DICOM information and data management system	Radiology	United States	Small
QuantX	Quantitative Insights Inc.	de novo	July 2017	Assistance of radiologists in assessment and characterization of breast abnormalities in digital images	Radiology	United States	Small
Advanced RBC Application	Cella Vision AB	510(k)	August 2017	Automated blood cell and peripheral blood smear locating device	Hematology	Sweden	Small

SOZO	ImpediMed Ltd.	510(k)	August 2017	Aid to clinical assessment of unilateral lymphedema	Cardiovascular	Australia	Large
DeepView Wound Imaging System	SpectralMD Inc.	510(k)	August 2017	Intended for studies of blood flow in the microcirculation	Cardiovascular	United States	Small
Poseidon Ultrasound System	Butterfly Network Inc.	510(k)	September 2017	Diagnostic ultrasound imaging and measurement of anatomical structures and fluids	Radiology	United States	Small
NeuroQuant	CorTechs Labs Inc.	510(k)	September 2017	Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from MR images	Radiology	United States	Small
BladderScan PRIME PLUS	Verathon Inc.	510(k)	September 2017	Ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively	Radiology	United States	Large
Peerbridge Cor System	Peerbridge Health Inc.	510(k)	September 2017	Capture and transmission of symptomatic events and continuous external ECG information for 24 hours and up to 7 days	Cardiovascular	United States	Small
Quantra	Hologic Inc.	510(k)	October 2017	Segregation of breast density into categories	Radiology	United States	Large
INFINITT PACS 7.0	Infinitt Healthcare Co. Ltd.	510(k)	October 2017	Image analysis and operational workflow improvement tool	Radiology	South Korea	Large
Stethee Pro	M3dicine Pty. Ltd.	510(k)	October 2017	Electronic stethoscope for detection and amplification of sounds from heart, lungs, arteries, veins and other internal organs	Cardiovascular	Australia	Small
Rooti Rx	Rooti Labs Ltd.	510(k)	November 2017	Heart monitoring and recommendation tool from ECG data	Cardiovascular	Taiwan	Small
QVCAD	Qview Medical Inc.	PMA	December 2017	Aid to detect mammography-occult lesions in regions not known to have suspicious findings	Radiology	United States	Small
Neuronaute	Bioserenity SAS	510(k)	December 2017	Acquisition, record, storage, transmission and display of EEG	Neurology	France	Small
Radiomics App	Microsoft Corp.	510(k)	December 2017	Organ and tumor contouring assistance for radiation planning from MRI and CT scans	Radiology	United States	Large
cNeuro cMRI	Combinostics Oy	510(k)	January 2018	Quantitative assessment of brain images for neurodegenerative diseases by evaluating MRI images	Radiology	Finland	Small

CEREC Ortho Software	Dentsply Sirona Inc.	510(k)	January 2018	Data acquisition and modeling analysis for orthodontic patients and conditions	Dental	United States	Large
Illumeo System	Philips Medical Systems Technologies Ltd. (parent company: Koninklijke Philips NV)	510(k)	January 2018	Image management system to acquire, store, distribute, process and display images and associated data throughout clinical environment	Radiology	United States	Large
Arterys Oncology DL	Arterys Inc.	510(k)	January 2018	Support of oncological workflow by helping user confirm absence or presence of lesions; application supports anatomical datasets, such as CT or MR	Radiology	United States	Small
Empatica Care	Empatica S.R.L.	510(k)	January 2018	Epileptic seizures detection through wearable technology	Neurology	Italy	Small
Glooko Mobile Insulin Dosing System	Glooko Inc.	510(k)	February 2018	Patient insulin dosing decision support and remote monitoring	Anesthesiology	United States	Small
UNiD Spine Analyzer	Medicrea International SA	510(k)	February 2018	Viewing and measuring images and planning of orthopedic surgeries	Radiology	France	Small
ContaCT	Viz.ai Inc.	de novo	February 2018	Image analysis for findings suggestive of a pre-specified clinical condition	Radiology	United States	Small
NeuroEEG	Memory MD Inc.	510(k)	February 2018	Acquisition, record, transmission, and display of electrical brain activity	Neurology	United States	Small
DM-Density	Densitas Inc.	510(k)	February 2018	Breast density calculation to aid physicians in the assessment of breast tissue composition	Radiology	United States	Small
iQMR	Medic Vision - Imaging Solutions Ltd.	510(k)	March 2018	Networking, communication, processing and enhancement of MRI images in DICOM format	Radiology	United States	Small
Quantib Brain	Quantib BV	510(k)	March 2018	Non-invasive medical imaging processing application intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures from a set of MR images	Radiology	Netherlands	Small
Tissue of Origin Test Kit-FFPE	Cancer Genetics Inc.	510(k)	March 2018	In vitro diagnostic intended to measure degree of similarity between RNA expression patterns in a patient's formalin-fixed, paraffin-embedded (FFPE) tumor and RNA expression patterns	Clinical Toxicology	United States	Large

Imbio CT Lung Density Analysis Software	Imbio LLC.	510(k)	March 2018	Tool to modify the contours of segmentation masks produced by Imbio algorithms or to manually create segmentation mask contours	Radiology	United States	Small
Acumen Hypotension Prediction Index Ev1000 Clinical Platform	Edwards Lifesciences LLC.	de novo	March 2018	Detection support for future hypotensive events	Cardiovascular	United States	Small
WAVE Clinical Platform - Visensia Software	Excel Medical Electronics LLC.	510(k)	April 2018	Remote monitoring platform to route, store and display data, alarms, results and diagnostic information from medical devices, electronic medical records and clinical information systems	Cardiovascular	United States	Small
PowerLook Density Assessment (SecondLook)	iCAD Inc.	510(k)	April 2018	Breast density evaluation to aid in the assessment of breast tissue composition	Radiology	United States	Small
MUSICA	Agfa HealthCare NV	510(k)	April 2018	Performance of dynamic imaging examinations (fluoroscopy and/or rapid sequence)	Radiology	Belgium	Large
IDx-DR	IDx LLC.	de novo	April 2018	Incorporates adaptive algorithm to evaluate ophthalmic images for diagnostic screening to identify retinal diseases or conditions	Ophthalmic	United States	Large
RAPID Platform	iSchemaView Inc.	510(k)	April 2018	Viewing, processing and analysis of functional and dynamic imaging datasets acquired with CT Perfusion, CT Angiography and MRI including a Diffusion Weighted MRI	Radiology	Sweden	Small
syngo.MR Applications	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	April 2018	Post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-Pet images and MR spectra	Radiology	United States	Large
Viz-CTP	Viz.ai Inc.	510(k)	April 2018	Performance of image processing, analysis and communication of CT perfusion scans of the brain	Radiology	United States	Small
NeuroCap	Memory MD Inc.	510(k)	April 2018	EEG electrode array intended for use in ER, ICU and OR for recording of STAT EEGs	Neurology	United States	Small
Venue Ultrasound	GE Medical Systems Ultrasound and Primary Care Diagnostics Inc. (parent company: General Electric Company)	510(k)	May 2018	Ultrasound imaging, measurement and analysis of the human body and fluid for clinical applications	Radiology	United States	Large

Sense System With IBT Electrodes	Infinite Biomedical Technologies LLC.	510(k)	May 2018	External prosthetic fittings of upper limbs	Neurology	United States	Small
VentriPoint Medical System Plus (VMS+)	Ventripoint Diagnostics Ltd.	510(k)	May 2018	Intended to record, analyze, store and retrieve digital ultrasound images for computerized 3D image processing	Radiology	Canada	Large
MindMotion GO	MindMaze SA	510(k)	May 2018	Support of physical rehabilitation (including, for example, rehabilitation exercises for the upper extremity)	Neurology	Switzerland	Small
Eclipse Treatment Planning System V15.6	Varian Medical Systems Inc.	510(k)	May 2018	Radiotherapy treatment planning for patients with malignant or benign diseases	Radiology	United States	Large
OsteoDetect	Imagen Technologies Inc.	de novo	May 2018	Analysis of radiographs to identify and highlight distal radius fractures	Radiology	United States	Small
Senhance Surgical System	TransEnterix Inc.	510(k)	May 2018	Assistance in laparoscopic surgery	Gastroenterology and Urology	United States	Small
LungQ	Thirona Corp.	510(k)	June 2018	Support in diagnosis and documentation of pulmonary tissues images (eg, abnormalities) from CT thoracic datasets	Radiology	Netherlands	Small
DreaMed Advisor Pro	DreaMed Diabetes Ltd.	de novo	June 2018	Insulin dosing decision support for diabetes management	Clinical Chemistry	Israel	Small
HealthCCS	Zebra Medical Vision Ltd.	510(k)	June 2018	Non-invasive post-processing software used to evaluate calcified plaques in coronary arteries	Radiology	Israel	Small
EchoMD AutoEF Software	Bay Labs Inc.	510(k)	June 2018	Provides automated estimation of left ventricular ejection fraction based on acquired transthoracic cardiac ultrasound images	Radiology	United States	Small
NuVasive Pulse System	NuVasive Inc.	510(k)	June 2018	Intraoperative neurophysiologic monitoring during spinal surgery, neck dissection, thoracic surgeries, and upper and lower extremities	Neurology	United States	Large
Uscan	EchoNous Inc.	510(k)	July 2018	Non-invasive imaging of human body with ultrasound	Radiology	United States	Small
Workflow Box	Mirada Medical Ltd.	510(k)	July 2018	Route DICOM-compliant data to and from processing components	Radiology	England	Small
Dip.io	Healthy.io Ltd.	510(k)	July 2018	Semi-quantitative detection of analytes in urine	Clinical Chemistry	Israel	Small

Quantitative Total Extensible Imaging (QTXI)	AIQ Solutions Inc.	510(k)	July 2018	Aid in evaluation and information management of digital medical images	Radiology	United States	Small
Natural Cycles	Natural Cycles Nordic AB	de novo	August 2018	Fertility monitoring: pregnancy prevention (contraception) or pregnancy planning (conception)	Obstetrics/Gynecology	Sweden	Small
AmCAD-UT	AmCad BioMed Corp.	510(k)	August 2018	Assistance in analysis of thyroid ultrasound images	Radiology	Taiwan	Large
ECG App	Apple Inc.	de novo	September 2018	To create, record, store, transfer, and display ECG; determines presence of atrial fibrillation or sinus rhythm on classifiable waveform	Cardiovascular	United States	Large
Irregular Rhythm Notification Feature	Apple Inc.	de novo	September 2018	Analysis of pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation	Cardiovascular	United States	Large
VolparaDensity	Volpara Health Technologies Ltd.	510(k)	September 2018	Based on digital breast x-ray systems, calculation and quantification of a density map and from that determination of volumetric breast density	Radiology	New Zealand	Small
RightEye Vision System	RightEye LLC.	510(k)	September 2018	Eye-movement recording, viewing, and analyzing in support for identification of visual tracking impairment	Neurology	United States	Small
FibriCheck	Qompium NV	510(k)	September 2018	Monitoring and recording of heart rhythms for patients diagnosed with or susceptible to developing atrial fibrillation	Cardiovascular	Belgium	Small
Ziostation2	Ziosoft Inc.	510(k)	October 2018	Image visualization enhancement for diagnostic support from different imaging tools	Radiology	United States	Small
NvisionVLE Imaging System	NinePoint Medical Inc.	510(k)	October 2018	Imaging platform for evaluation of human tissue microstructure	Radiology	United States	Small
Arterys MICA	Arterys Inc.	510(k)	October 2018	Diagnostic application that displays, processes, stores and transfers DICOM and non-DICOM medical data, with exception of mammography	Radiology	United States	Small
Automatic View Recognition	GE Medical Systems Ultrasound and Primary Care Diagnostics (parent company: General Electric Company)	510(k)	October 2018	Automated workflow improvement tool for Vivid E95 / Vivid E90 general-purpose ultrasound systems, specialized for use in cardiac imaging	Radiology	United States	Large

Accipio Ix	MaxQ-AI Ltd.	510(k)	October 2018	Aid in prioritizing clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage in acute care environment	Radiology	Israel	Small
HemoScreen	PixCell Medical Technologies Ltd.	510(k)	October 2018	Point-of-care hematology analyzer for complete blood count analysis	Hematology	Israel	Small
NvisionVLE Imaging System, NvisionVLE Optical Probe, NvisionVLE Inflation System	NinePoint Medical Inc.	510(k)	November 2018	Imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue	Radiology	United States	Small
Athelas One	Athelas Inc.	510(k)	November 2018	Quantitative determination of white blood cells and neutrophil percentages in capillary or K2EDTA venous whole blood	Hematology	United States	Small
LensHooke X1 Pro Semen Quality Analyzer	Bonraybio Co. Ltd.	510(k)	November 2018	Optical device for human semen analysis	Hematology	Taiwan	Small
AI-ECG Platform	Shenzhen Carewell Electronics Ltd.	510(k)	November 2018	Assistance in measuring and interpreting 12-lead resting ECG	Cardiovascular	China	Small
Transpara	ScreenPoint Medical BV	510(k)	November 2018	Reading aid for physicians interpreting screening mammograms to identify regions suspicious for breast cancer and assess their likelihood of malignancy	Radiology	Netherlands	Small
Persyst Spike Detection	Persyst Development Corp.	510(k)	November 2018	Review, monitoring and analysis of EEG recordings made by EEG devices	Neurology	United States	Small
SubtlePET	Subtle Medical Inc.	510(k)	November 2018	Image processing software for transfer, storage, and noise reduction of FDG and amyloid PET images	Radiology	United States	Small
FerriSmart Analysis System	Resonance Health Analysis Services Pty. Ltd.	510(k)	November 2018	Measurement and monitoring of liver iron concentration and burden; aid in identification and monitoring of thalassemia	Radiology	Australia	Small
AMRA Profiler	AMRA Medical AB	510(k)	December 2018	Magnetic resonance diagnostic device software application for non-invasive fat and muscle evaluation	Radiology	Sweden	Small

Cardio-HART	Cardio-Phoenix Inc.	510(k)	December 2018	Acquire and record the three different types of heart bio-signals (ECG, PCG, and MCG) and combine the results as an aid to diagnostic interpretation	Cardiovascular	United States	Small
Centricity Universal Viewer	GE Healthcare Inc. (parent company: General Electric Company)	510(k)	December 2018	Display of medical images and data from various imaging sources and from other healthcare information sources	Radiology	United States	Large
vascuCAP	Elucid Bioimaging Inc.	510(k)	December 2018	Processing, review, analysis, communication and media interchange of images acquired from CT imaging devices	Radiology	United States	Small
Quantib ND	Quantib BV	510(k)	December 2018	Non-invasive medical imaging processing application intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from MR images	Radiology	Netherlands	Small
AmCAD-UO	AmCad BioMed Corp.	510(k)	December 2018	Analysis and quantification of upper airway from ultrasound system	Radiology	Taiwan	Large
EyeBOX	Oculogica Inc.	de novo	December 2018	Traumatic brain injury eye movement assessment aid	Neurology	United States	Small
MRCP+	Perspectum Diagnostics Ltd.	510(k)	January 2019	Regions of variation of duct widths detection for diagnostic support from MRCP images	Radiology	England	Small
Study Watch	Verily Life Sciences LLC. (parent company: Alphabet Inc.)	510(k)	January 2019	Record, store, transfer and display single-channel ECG rhythms	Cardiovascular	United States	Small
Artificial Intelligence Prescription (AIRx)	GE Medical Systems LLC. (parent company: General Electric Company)	510(k)	January 2019	Whole body magnetic resonance scanner designed to support high resolution, high signal-to-noise ratio with automated workflow tool for SIGNA Premier MRI brain scans	Radiology	United States	Large
AI-Rad Companion Engine	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	February 2019	Software platform that provides basic visualization and enables external post-processing extension for medical images used for diagnostic purposes	Radiology	United States	Large
d-Nav Insulin Management System	Hygieia Inc.	510(k)	February 2019	Calculation next dose of insulin to aid in optimizing insulin management	Anesthesiology	United States	Small
Coala Heart Monitor	Coala Life AB	510(k)	February 2019	Record, store and transfer ECG rhythms and heart sound	Cardiovascular	Sweden	Small

RX-1 Rhythm Express Remote Cardiac Monitoring System	VivaQuant Inc.	510(k)	February 2019	Continuous recording of ECG data and analysis of arrhythmia	Cardiovascular	United States	Small
Early Bird Bleed Monitoring System	Saranas Inc.	de novo	March 2019	Bleed detection system for peri- and post-procedural monitoring of endovascular procedures	Cardiovascular	United States	Small
RhythmAnalytics	Biofourmis Singapore Pte. Ltd.	510(k)	March 2019	Assessment of cardiac arrhythmias	Cardiovascular	Singapore	Small
cmTriage	CureMetrix Inc.	510(k)	March 2019	Notification tool to prioritize specific patients for screening mammograms	Radiology	United States	Small
KardiaAI	AliveCor Inc.	510(k)	March 2019	Ambulatory ECG rhythm assessment	Cardiovascular	United States	Small
CardioFlux with Faraday Analytical Cloud	Genetesis Inc.	510(k)	March 2019	Non-invasive measurement and display of the magnetic signals produced by the electric currents of the heart.	Cardiovascular	United States	Small
Unicel DxH 800 Cellular Analysis System With Early Sepsis Indicator Application	Beckman Coulter Inc.	510(k)	March 2019	Diagnostic and prediction algorithm for early sepsis detection	Microbiology	United States	Large
Loop System	Spry Health Inc.	510(k)	March 2019	Physiological change detection support through real-time data collection	Cardiovascular	United States	Small
Bone VCAR	GE Medical Systems SCS (parent company: General Electric Company)	510(k)	April 2019	Post processing application for use in the analysis of CT spine images	Radiology	France	Large
Deep Learning Image Reconstruction	GE Healthcare Japan Corporation (parent company: General Electric Company)	510(k)	April 2019	Image reconstruction method intended to produce cross-sectional images of the head and body	Radiology	Japan	Large
Aidoc Pulmonary Embolism	Aidoc Medical Ltd.	510(k)	April 2019	Radiological computer aided triage and notification software indicated for use in the analysis of head CTA images	Radiology	Israel	Small
eMurmur ID	CSD Labs GmbH	510(k)	April 2019	Detection and identification of heart murmurs	Cardiovascular	Austria	Small
LungVision System	Body Vision Medical Ltd.	510(k)	April 2019	Segmentation tool for 3D CT datasets to overall and register the datasets with live X-ray images of the same anatomy to support catheter/device navigation	Radiology	United States	Small

HealthPNX	Zebra Medical Vision Ltd.	510(k)	May 2019	Pneumothorax detection support and alert for urgent findings from X-ray images	Radiology	Israel	Small
SurgicalAR	MEDIVIS Inc.	510(k)	May 2019	Display of medical images and other healthcare data, including functions for image review, basic measurements and 3D visualization	Radiology	United States	Small
APAS Independence instrument	Clever Culture Systems AG	510(k)	May 2019	Automates urine culture plate imaging and interpretation to detect presence or absence of microbial growth	Microbiology	Switzerland	Small
Complete Control System Gen2	Coapt LLC.	510(k)	May 2019	External prosthetic fittings of the upper limbs	Neurology	United States	Small
Aidoc C-Spine (Briefcase)	Aidoc Medical Ltd.	510(k)	May 2019	Radiological computer aided triage and notification software indicated for use in the analysis of cervical spine CT images	Radiology	Israel	Small
Advanced intelligent Clear-IQ Engine (AiCE)	Canon Medical Systems Corporation (parent company: Canon Inc.)	510(k)	June 2019	Noise reduction algorithm that improves image quality and reduces image noise for abdomen, pelvis, chest, cardiac, extremities and head applications	Radiology	Japan	Large
HealthICH	Zebra Medical Vision Ltd.	510(k)	June 2019	Software workflow tool designed to aid clinical assessment of adult non-contrast head CT with features suggestive of intracranial hemorrhage	Radiology	Israel	Small
ClariCT.AI	ClariPI Inc.	510(k)	June 2019	Networking, communication, processing and enhancement of CT images	Radiology	South Korea	Small
RayStation	RaySearch Laboratories AB	510(k)	June 2019	Treatment planning and analysis of radiation therapy	Radiology	Sweden	Large
Intra-Operative Positioning System Platform	Centerline Biomedical Inc.	510(k)	June 2019	Evaluation of vascular anatomy as captured via 3D modeling from previously acquired CT scan data	Cardiovascular	United States	Small
CLARUS 700	Carl Zeiss Meditec Inc.	510(k)	June 2019	Capture, display, annotate and store images to aid in diagnosis and monitoring of diseases and disorders occurring in retina, ocular surfaces and visible adnexa	Ophthalmic	United States	Large
LiverMultiScan	Perspectum Diagnostics Ltd.	510(k)	June 2019	MR diagnostic device software application for non-invasive liver evaluation	Radiology	England	Small

Koios DS for Breast	Koios Medical Inc.	510(k)	July 2019	Assessment of breast ultrasound images of patients with soft tissue breast lesions	Radiology	United States	Small
RayCare 2.3	RaySearch Laboratories AB	510(k)	July 2019	Support of workflows, scheduling and clinical information management for oncology care and follow-up	Radiology	Sweden	Large
DeepCT	Deep01 Ltd.	510(k)	July 2019	Analysis of non-contrast CT images of the brain acquired in acute setting and notification of a specialist when intracranial hemorrhage suspected	Radiology	Taiwan	Small
PhysIQ Heart Rhythm and Respiratory Module	physIQ Inc.	510(k)	July 2019	Calculation of heart rate and heart rate variability, detection of atrial fibrillation and determination of respiration rate using ambulatory ECG and triaxial accelerometer data	Cardiovascular	United States	Small
Current Health Wearable Platform	Current Health Ltd.	510(k)	July 2019	Intended to provide visual and audible physiologic multi-parameter alarms	Cardiovascular	England	Small
KIDScore D3	Vitrolife A/S	510(k)	July 2019	Decision support for prediction of likelihood of embryos developing to the blastocyst stage by scoring them according to their statistical viability	Obstetrics/Gynecology	Denmark	Small
AI-Rad Companion Chest CT Software	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	July 2019	Image processing software that provides analysis from CT images to support physicians in evaluation and assessment of cardiovascular diseases	Radiology	United States	Large
ACR Lab	Healthy.io Ltd.	510(k)	July 2019	Semi-quantitative detection of albumin and creatinine in urine, as well as the presentation of their ratio; aid in the diagnosis for kidney function	Clinical Chemistry	Israel	Small
aBSI	EXINI Diagnostics AB	510(k)	August 2019	General picture archiving and communications system tools including applications for lesion marking and quantitative analysis of nuclear medicine imaging	Radiology	Sweden	Small
Critical Care Suite	GE Medical Systems LLC. (parent company: General Electric Company)	510(k)	August 2019	Triage and notification device that analyses frontal chest x-ray images for presence of pneumothorax	Radiology	United States	Large
HeartFlow FFRCT Analysis	HeartFlow Inc.	510(k)	August 2019	Analysis of CT images for clinically stable symptomatic patients with coronary artery disease	Cardiovascular	United States	Small

Biovitals Analytics Engine	Biofourmis Singapore Pte. Ltd.	510(k)	August 2019	Ambulatory physiologic monitoring for therapeutic decision support	Cardiovascular	Singapore	Small
Clarius Ultrasound Scanner	Clarius Mobile Health Corporation	510(k)	August 2019	Diagnostic ultrasound imaging and fluid flow analysis	Radiology	Canada	Small
D2P software	3D Systems Inc.	510(k)	August 2019	Software interface and image segmentation of DICOM imaging data	Radiology	United States	Large
Myo Plus	Otto Bock Healthcare Products GmbH	510(k)	September 2019	Exoprosthetic fittings of the upper limbs	Neurology	Austria	Large
AI-Rad Companion Cardiovascular	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	September 2019	Image processing software for analysis from CT images to support physicians in evaluation and assessment of cardiovascular diseases	Radiology	United States	Large
BrainScope TBI	BrainScope Company Inc.	510(k)	September 2019	Aid in the evaluation of patients who have sustained a closed head injury and have a GCS of 13-15	Neurology	United States	Small
SubtleMR	Subtle Medical Inc.	510(k)	September 2019	Image processing software for image enhancement in MRI images	Radiology	United States	Small
syngo.via RT Image Suite	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	September 2019	3D and 4D image visualization, multimodality manipulation and contouring tool that helps preparation and response assessment of treatments	Radiology	United States	Large
StoneChecker	Imaging Biometrics LLC.	510(k)	September 2019	Application which assists trained professionals in evaluating DICOM computed tomography image studies of patients diagnosed with kidney stones	Radiology	United States	Small
ProFound AI for Digital Breast Tomosynthesis	iCAD Inc.	510(k)	October 2019	Computer-assisted detection and diagnosis (CAD) software device intended to be used while reading digital breast tomosynthesis (DBT) exams	Radiology	United States	Small
Fluoroshield	Omega Medical Imaging LLC.	510(k)	October 2019	Modification device to provide an automated region of interest that reduces exposure to the patient and operator	Radiology	United States	Small
Merge PACS	Merge Healthcare Inc.	510(k)	October 2019	Real-time picture archiving and communication system	Radiology	United States	Large
RTHawk, HeartVista Cardiac Package	HeartVista Inc.	510(k)	October 2019	Acquisition, reconstruction and display of cardiovascular MR images	Radiology	United States	Small

AIXPLORER Mach 30 Ultrasound Diagnostic Systems	Supersonic Imagine SA	510(k)	October 2019	Ultrasound diagnostic systems and transducers intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, doppler fluid flow analysis	Radiology	France	Small
EarlyVue VS30	Philips Medizin Systeme Boeblingen GmbH (parent company: Philips NV)	510(k)	October 2019	Measure, display, alarm and record physiological information	Radiology	Germany	Large
Sight OLO	Sight Diagnostics Ltd.	510(k)	November 2019	Quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples	Hematology	Israel	Small
MIMOSA Imager	MIMOSA Diagnostics Inc.	510(k)	November 2019	Non-invasive estimation of spatial distribution of percent oxygen saturation in a volume of tissue	Cardiovascular	Canada	Small
WellDoc BlueStar	WellDoc Inc.	510(k)	November 2019	Digital care guidance for diabetes patients	General Hospital	United States	Small
7D Surgical System	7D Surgical Inc.	510(k)	November 2019	Stereotaxic image guidance system intended for spatial positioning and orientation of neurosurgical instruments	Neurology	Canada	Small
IB Lab Koala	IB Lab GmbH	510(k)	November 2019	Radiological fully-automated image processing software device of computed or directly digital images intended to aid medical professionals in measurement of minimum joint space width	Radiology	Austria	Small
Cleerly Labs	Cleerly Inc.	510(k)	November 2019	Interactive tool for viewing and analyzing CT data for determining presence and extent of coronary plaques and stenosis	Radiology	United States	Small
MEDIP PRO	MEDICALIP Co. Ltd.	510(k)	November 2019	Software interface and image segmentation system for transfer of DICOM imaging information from medical scanner to output file; pre-operative software for treatment planning	Radiology	South Korea	Small
EchoGo Core	Ultromics Ltd.	510(k)	November 2019	Quantification and reporting of results of cardiovascular function to support physician diagnosis	Radiology	England	Small
RSI-MRI+	MultiModal Imaging Services Corp.	510(k)	November 2019	Automatic post-acquisition image processing software for analysis of diffusion-weighted and anatomical magnetic resonance imaging data	Radiology	United States	Small

HealthCXR	Zebra Medical Vision Ltd.	510(k)	November 2019	Software workflow tool to aid clinical assessment of adult chest X-ray with features suggestive of pleural effusion	Radiology	Israel	Small
PhantomMSK Trauma	OrthoGrid Systems Inc.	510(k)	December 2019	Image-processing software to assist in positioning of orthopedic trauma components	Radiology	United States	Small
FFRangio System	CathWorks Ltd.	510(k)	December 2019	Analysis of previously acquired angiography DICOM data for patients with coronary artery disease	Cardiovascular	Israel	Small
NemoScan	Software Nemotec S.L.	510(k)	December 2019	Diagnostic and treatment support for dental implantology	Radiology	Spain	Small
QyScore software	Qynapse SAS	510(k)	December 2019	Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from MR images	Radiology	France	Small
Syngo CT CaScoring	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	December 2019	Evaluation and documentation of calcified coronary lesions using CT scanning data sets	Radiology	United States	Large
Biosticker System	BioIntelliSense Inc.	510(k)	December 2019	Remote monitoring system for continuous collection of physiological data	Cardiovascular	United States	Small
Smartho-D2 Electronic Stethoscope	Hefei Mintti Medical Technology Co. Ltd.	510(k)	December 2019	Detection and amplification of sounds from heart, lungs, and other internal organs with use of a selective frequency	Cardiovascular	China	Small
Aidoc Intracranial Hemorrhage (Briefcase)	Aidoc Medical Ltd.	510(k)	December 2019	Workflow triage by flagging and communication of suspected findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH)	Radiology	Israel	Small
Aidoc Large Vessel Occlusion (Briefcase)	Aidoc Medical Ltd.	510(k)	December 2019	Workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) pathologies	Radiology	Israel	Small
QLAB Advanced Quantification Software	Philips Medical Systems Nederland BV (parent company: Koninklijke Philips NV)	510(k)	December 2019	Viewing and quantification of image data acquired on Philips ultrasound systems	Radiology	United States	Large
Air Next	NuvoAir AB	510(k)	January 2020	Lung function and spirometry testing	Anesthesiology	Sweden	Small

EKO Analysis Software	Eko Devices Inc.	510(k)	January 2020	Support in the evaluation of patients' heart sounds and ECG's	Cardiovascular	United States	Small
Auto Positioning	GE Hangwei Medical Systems Co. Ltd. (parent company: General Electric Company)	510(k)	January 2020	Provide consistent patient positioning for optimal image quality and automatic exposure control	Radiology	China	Large
MRCAT Brain	Philips Medical Systems MR Finland (parent company: Philips NV)	510(k)	January 2020	Radiation therapy planning through automated image segmentation for brain tumor patients	Radiology	Finland	Large
Caption Guidance	Bay Labs Inc.	de novo	February 2020	Acquisition of cardiac ultrasound images	Radiology	United States	Small
Ethos Radiotherapy System	Varian Medical Systems Inc.	510(k)	February 2020	Managing and monitoring radiation therapy treatment plans and sessions	Radiology	United States	Large
ACTEON Imaging Suite	de Gotzen S.r.L.	510(k)	February 2020	Dental and maxillofacial diagnostic imaging	Radiology	Italy	Small
Affinity Viewer	Hermes Medical Solutions AB	510(k)	February 2020	Process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstations, PACS or acquisition stations	Radiology	Sweden	Small
densitasAI	Densitas Inc.	510(k)	February 2020	Breast density assessment support from mammograms	Radiology	Canada	Small
red dot algorithm	Behold.AI Technologies Ltd.	510(k)	February 2020	Aid clinical assessment of adult chest X-ray cases with features suggestive of pneumothorax	Radiology	England	Small
Icobrain-CTP	Icometrix NV	510(k)	February 2020	Analysis and communication capabilities for dynamic imaging datasets that are acquired with CT Perfusion imaging protocols	Radiology	Belgium	Small
AccuContour	Xiamen Manteia Technology Ltd.	510(k)	February 2020	Registration of multimodality images and segment CT images, to generate needed information for treatment planning, evaluation and adaptation	Radiology	China	Small
Broncholab	Fluida Inc.	510(k)	March 2020	Support in diagnosis and documentation of pulmonary tissue images (eg, abnormalities) from CT thoracic datasets	Radiology	United States	Small
NightOwl	Ectosense NV	510(k)	March 2020	Evaluation of sleep-related breathing disorders suggestive of sleep apnea	Anesthesiology	Belgium	Small

Syngo.CT Lung CAD	Siemens Medical Solutions Inc. (parent company: Siemens AG)	510(k)	March 2020	Assistance in detection of solid pulmonary nodules during review of multi-detector computed tomography examinations of the chest	Radiology	United States	Small
SonoVision Ultrasound System	Tissue Differentiation Intelligence LLC.	510(k)	March 2020	Ultrasound system for visualization and evaluation of nerves, vascular and other anatomical structures	Radiology	United States	Small
AI-Rad Companion Musculoskeletal	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	March 2020	Image processing software with the following functionality: segmentation of vertebrae, labelling of vertebrae, measurement of heights in each vertebra, measurement of mean Hounsfield value in volume of interest within vertebra	Radiology	United States	Large
Viz ICH	Viz.AI Inc.	510(k)	March 2020	Analysis of CT images of the brain acquired in acute setting and notification to specialist when intracranial hemorrhage suspected	Radiology	United States	Small
AI-ECG Tracker	Shenzhen Carewell Electronics Co. Ltd.	510(k)	March 2020	Assessment of arrhythmias using ECG data acquired from adults without pacemakers	Cardiovascular	China	Small
Hepatic VCAR	GE Medical Systems SCS (parent company: General Electric Company)	510(k)	March 2020	Image analysis software that allows analysis and visualization of liver CT data	Radiology	France	Large
MammoScreen	Therapixel SA	510(k)	March 2020	Help to identify findings on screening FFDM acquired with compatible mammography systems and assess level of suspicion	Radiology	France	Small
syngo.CT Cardiac Planning	Siemens Medical Solutions USA Inc. (parent company: Siemens AG)	510(k)	March 2020	Image analysis software package for evaluating contrast enhanced CT images; analysis of morphology and pathology of vascular and cardiac structures	Radiology	United States	Large
KOSMOS	EchoNous Inc.	510(k)	March 2020	Clinical assessment of cardiac and pulmonary systems and abdomen by acquiring ultrasound images, ECG rhythms and digital auscultation sounds and waveforms	Cardiovascular	United States	Small
Rapid ICH	iSchemaView Inc.	510(k)	March 2020	Radiological computer aided triage and notification software for use in analysis of CT images	Radiology	United States	Small

* The summary was extracted and summarized from the FDA's documentation and is not comprehensive. Please consult the FDA's website or contact the manufacturers for further information.

Characteristics of CE marked devices

<i>Device</i>	<i>Manufacturer</i>	<i>CE Marking</i>	<i>Summary†</i>	<i>Medical Specialty</i>	<i>Origin Country</i>	<i>Company Size</i>
ER APP, Breast Cancer	Visiopharm A/S	February 2015	Determination of estrogen receptor positivity and negativity in breast cancer	Pathology	Denmark	Small
PR APP, Breast Cancer	Visiopharm A/S	February 2015	Determination of progesterone receptor positivity and negativity in breast cancer	Pathology	Denmark	Small
Veolity LungCAD	MeVis Medical Solutions AG	March 2015	Workflow improvement and quality enhancement in lung CT	Radiology	Germany	Small
EyeArt	Eyenuk Inc.	March 2015	Diabetic retinopathy detection support	Ophthalmic	United States	Small
Icobrain MS	Icometrix NV	March 2015	Quantification tools for abnormalities and changes in brain structures	Neurology	Belgium	Small
e-ASPECTS	Brainomix Ltd.	March 2015	Decision support tool for assessing stroke signs from CT scans	Radiology	England	Small
DM-Density	Densitas Inc.	April 2015	Breast density calculation to aid physicians in the assessment of breast tissue composition	Radiology	Canada	Small
Kaiku Health	Kaiku Oy	August 2015	Outcome monitoring and symptom tracking for cancer patients	General Hospital	Finland	Small
PatientSource	PatientSource Ltd.	September 2015*	Diagnosis assistance and system integration for clinical setting	General Hospital	England	Small
Triton System	Gauss Surgical Inc.	November 2015	Image processing device for estimation of external blood loss	General Hospital	United States	Small
ClearRead CT	Riverain Technologies LLC.	November 2015	Assistance in review of multi-slice computed tomography exams of the chest and detection of potential nodules that radiologist should review	Radiology	United States	Small
Transpara	ScreenPoint Medical BV	December 2015	Reading aid for physicians interpreting screening mammograms to identify regions suspicious for breast cancer	Radiology	Netherlands	Small
AMRA Profiler	AMRA Medical AB	December 2015	MR diagnostic device software application for non-invasive fat and muscle evaluation	Radiology	Sweden	Small

Cydar EV	CYDAR Ltd.	January 2016	Image guidance by overlaying preoperative 3D vessel anatomy from a previously acquired CT scan	Radiology	England	Small
Coala Heart Monitor	Coala Life AB	January 2016	Record, store and transfer ECG rhythms and heart sound	Cardiovascular	Sweden	Small
Guardian connect	Medtronic Minimed Inc. (parent company: Medtronic plc)	March 2016	Continuous glucose monitoring	Cardiovascular	Ireland	Large
Dip.io	Healthy.io Ltd.	March 2016	Smartphone-based, at-home urinalysis test	Clinical Chemistry	Israel	Small
AmCAD-US	AmCad BioMed Corporation	April 2016	Visualization and analysis of statistical distributions of backscattered signals echoed by tissue compositions in the body	Radiology	Taiwan	Small
PREDicT Test	PIvital Products Ltd.	April 2016	Prediction for success of depression treatment	Neurology	England	Small
Neuronaute	Bioserenity SAS	May 2016	Acquisition, record, storage, transmission and display of EEG	Neurology	France	Small
AmCAD-UV	AmCad BioMed Corporation	May 2016	Medical image processing tool for vascular pulsatility analysis	Radiology	Taiwan	Small
Empatica Care	Empatica S.r.L.	May 2016	Epileptic seizures detection through wearable technology	Neurology	Italy	Small
SmartTarget	SmartTarget Ltd.	June 2016	Image-guided interventional and diagnostic procedures involving the prostate gland	Radiology	England	Small
Cardiologs	Cardiologs Technologies SAS	June 2016	Assessment of arrhythmias using ECG data	Cardiovascular	France	Small
Quantib Brain	Quantib BV	June 2016	Non-invasive medical imaging processing application intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures from a set of MR images	Radiology	Netherlands	Small
FibriCheck	Qompium NV	July 2016	Monitoring and recording of heart rhythms for patients diagnosed with or susceptible to developing atrial fibrillation	Cardiovascular	Belgium	Small
LungQ	Thirona Corp.	August 2016	Support in diagnosis and documentation of pulmonary tissues images (eg, abnormalities) from CT thoracic datasets	Radiology	Netherlands	Small

CAD4TB	Delft Imaging BV	August 2016	Tuberculosis-related abnormalities detection for diagnostic support from X-ray images	Radiology	Netherlands	Small
Philips IntelliVue GuardianSoftware	Philips Medizin Systeme Boeblingen GmbH (parent company: Philips NV)	August 2016	Collection, storage and management of data from Philips specified measurements and Philips Patient Monitors connected through networks	Cardiovascular	Germany	Large
Eclipse Treatment Planning System V15.6	Varian Medical Systems Inc.	September 2016	Radiotherapy treatment planning for patients with malignant or benign diseases	Radiology	United States	Large
cNeuro cMRI	Combinostics Oy	September 2016	Quantitative assessment of brain images for neurodegenerative diseases by evaluating MRI images	Radiology	Finland	Small
Kaia Health App	Kaia Health Software Inc.	November 2016	Digital therapeutics to manage chronic diseases	General Hospital	Germany	Small
Medios AI	Remidio Innovative Solutions Pvt. Ltd.	November 2016	Offline diabetic retinopathy detection support	Ophthalmic	India	Small
Rooti Rx	Rooti Labs Ltd.	November 2016	Heart monitoring and recommendation tool from ECG data	Cardiovascular	Taiwan	Small
Acumen Hypotension Prediction Index – Ev1000 Clinical Platform	Edwards Lifesciences LLC.	November 2016	Detection support for future hypotensive events	Cardiovascular	United States	Small
CEREC Ortho Software	Dentsply Sirona Inc.	November 2016	Data acquisition and modeling analysis for orthodontic patients and conditions	Dental	United States	Large
MindMotion GO	MindMaze SA	November 2016	Support of physical rehabilitation (including, for example, rehabilitation exercises for the upper extremity)	Neurology	Switzerland	Small
Arterys Cardio DL	Arterys Inc.	December 2016	Analysis of cardiovascular images acquired from MR scanners	Radiology	United States	Small
One Drop Mobile	AgaMatrix Inc.	December 2016	Quantitative measurement of blood glucose in blood samples	General Hospital	United States	Small
EarlySense continuous monitoring solution	EarlySense Ltd.	December 2016*	Contact-free patient monitoring	General Hospital	Israel	Small
RetCAD	Delft Imaging BV	January 2017	Age-related macular degeneration or diabetic retinopathy detection support	Ophthalmic	Netherlands	Small

Natural Cycles	Natural Cycles Nordic AB	January 2017	Fertility monitoring: pregnancy prevention (contraception) or pregnancy planning (conception)	Obstetrics/Gynecology	Switzerland	Small
myAsthma	my mhealth Ltd.	January 2017	Assessment of symptoms for asthma management	General Hospital	England	Small
Mediktor	Teckel Medical SL	February 2017	Symptom analysis and diagnostic support	General Hospital	Spain	Small
Clarius Ultrasound Scanner	Clarius Mobile Health Corporation	February 2017	Diagnostic ultrasound imaging and fluid flow analysis	Radiology	Canada	Small
ColonFlag	Medial EarlySign Inc.	March 2017	High risk colorectal cancer detection support for pre-symptomatic patients	Gastroenterology/Urology	Israel	Small
Ziostation2	Ziosoft Inc.	March 2017*	Image visualization enhancement for diagnostic support	Radiology	United States	Small
syngo Application Software	Siemens Healthcare GmbH (parent company: Siemens AG)	March 2017	Diagnostic image viewing and post processing, and for viewing and post processing during interventional procedures	Radiology	Germany	Large
Current Health Wearable Platform	Current Health Ltd.	April 2017	Intended to provide visual and audible physiologic multi-parameter alarms	Cardiovascular	England	Small
Babylon	Babylon Health Ltd.	June 2017*	Symptom analysis and diagnostic support	General Hospital	England	Small
C the Signs	C the Signs Ltd.	June 2017*	Assessment of symptoms to support cancer diagnosis	General Hospital	England	Small
Imbio CT Lung Density Analysis Software	Imbio LLC.	June 2017	Tool to modify the contours of segmentation masks produced by Imbio algorithms or to manually create segmentation mask contours	Radiology	United States	Small
Sense System with IBT Electrodes	Infinite Biomedical Technologies LLC.	June 2017	External prosthetic fittings of upper limbs	Neurology	United States	Small
cNeuro cDSI	Combinostics Oy	July 2017	Dementia clinical decision support from MRI imaging biomarkers, CSF biomarkers and APOE gene	Radiology	Finland	Small
Diadem	BrainMiner Ltd.	July 2017*	Quantification of segmentable brain structures for dementia detection	Neurology	England	Small
Rapid Platform	iSchemaView Inc.	August 2017	Viewing, processing and analysis of functional and dynamic imaging datasets acquired with CT Perfusion, CT Angiography and MRI including a Diffusion Weighted MRI	Radiology	United States	Small

Quantib ND	Quantib BV	September 2017	Non-invasive medical imaging processing application intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from MR images	Radiology	Netherlands	Small
QyScore software	Qynapse SAS	September 2017	Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from MR images	Radiology	France	Small
vascuCAP	Elucid Bioimaging Inc.	October 2017	Processing, review, analysis, communication and media interchange of images acquired from CT imaging devices	Radiology	United States	Small
D2P software	3D Systems Inc.	October 2017	Software interface and image segmentation of DICOM imaging data	Radiology	Israel	Large
Dario Blood Glucose Monitoring System	LabStyle Innovations Ltd.	October 2017	Quantitative measurement of glucose in blood samples	Clinical Chemistry	United States	Small
ScanNav AI	MedaPhor Ltd.	October 2017*	Anatomical feature recognition from ultrasound images	Radiology	England	Small
Aidoc C-Spine	Aidoc Medical Ltd.	November 2017	Cervical spine fracture detection support and triaging from CT scans	Radiology	Israel	Small
Aidoc Intracranial Hemorrhage	Aidoc Medical Ltd.	November 2017	Workflow triage by flagging and communication of suspected findings of pathologies in head CT images, namely Intracranial Hemorrhage	Radiology	Israel	Small
Veye Chest	Aidence BV	December 2017	Pulmonary nodule detection support from CT scans	Radiology	Netherlands	Small
VolparaDensity	Volpara Health Technologies Ltd.	December 2017*	Based on digital breast x-ray systems, calculation and quantification of a density map and from that determination of volumetric breast density	Radiology	New Zealand	Small
GI Genius	Medtronic Inc. (parent company: Medtronic plc.)	January 2018	Colorectal cancer detection support	Gastroenterology/Urology	United States	Large
Lvivo Toolbox	DiA Imaging Analysis Ltd.	January 2018	Decision support tool for endocardial tracking resulting from ultrasound images	Radiology	Israel	Small
QVCAD	QView Medical Inc.	January 2018	Aid to detect mammography-occult lesions in regions not known to have suspicious findings	Radiology	United States	Small
Uscan	EchoNous Inc.	January 2018	Non-invasive imaging of human body with ultrasound	Radiology	United States	Small

RadiomiX Clinical	OncoRadiomics SA	January 2018	Development and validation of image-based models for precision medicine	Radiology	Belgium	Small
deprexis - broca software	GAIA AG	January 2018*	Automated digital therapy and personalised cognitive behavioural therapy interventions	Neurology	Germany	Small
Rapid CTA	iSchemaView Inc.	February 2018	Identification of large vessel occlusions by automatically processing CT scans	Radiology	United States	Small
DLCExpert	Mirada Medical Ltd.	February 2018	Contouring assistance for radiation therapy from CT scans	Radiology	England	Small
Workflow Box	Mirada Medical Ltd.	February 2018	Route DICOM-compliant data to and from processing components	Radiology	England	Small
syngo.MR Applications	Siemens Healthcare GmbH (parent company: Siemens AG)	February 2018*	Post-acquisition image processing software for viewing, manipulating, evaluating, and analyzing MR, MR-PET, CT, PET, CT-Pet images and MR spectra	Radiology	Germany	Large
DreaMed Advisor Pro	DreaMed Diabetes Ltd.	February 2018	Insulin dosing decision support for diabetes management	Clinical Chemistry	Israel	Small
PowerLook Tomo Detection (SecondLook)	iCAD Inc.	February 2018	Detection of soft tissue densities and calcifications in the 3D digital breast tomosynthesis slice	Radiology	United States	Small
Air Next	NuvoAir AB	March 2018	Lung function and spirometry testing	Anesthesiology	Sweden	Small
HealthICH	Zebra Medical Vision Inc.	March 2018	Software workflow tool designed to aid clinical assessment of adult non-contrast head CT with features suggestive of intracranial hemorrhage	Radiology	Israel	Small
HealthVCF	Zebra Medical Vision Inc.	March 2018	Vertebral compression fracture detection support from CT scans	Radiology	Israel	Small
Accipio Ix	MaxQ-AI Ltd.	March 2018	Aid in prioritizing clinical assessment of adult non-contrast head CT cases with features suggestive of acute intracranial hemorrhage in acute care environment	Radiology	Israel	Small
Early Sepsis Indicator	Beckman Coulter Inc.	April 2018	Diagnostic and prediction algorithm for early sepsis detection	Microbiology	United States	Large
e-CTA	Brainomix Ltd.	April 2018	Stroke imaging decision support from head CTA scans	Radiology	England	Small
DRISTI	Artelus Ltd.	April 2018	Diabetic retinopathy detection support	Ophthalmic	India	Small

HealthMammo	Zebra Medical Vision Inc.	May 2018	Mammograms processed and analyzed for suspected breast cancer lesions	Radiology	Israel	Small
BioMind	Hanalytics Pte. Ltd.	June 2018	Assistance in the diagnosis of neurological disorders on MR and CT scans	Radiology	Singapore	Small
PowerLook Density Assessment (SecondLook)	iCAD Inc.	June 2018	Breast density evaluation to aid in the assessment of breast tissue composition	Radiology	United States	Small
Lindera Mobilitätstest	Lindera GmbH	July 2018	Geriatric assessment to prevent falls	General Hospital	Germany	Small
ACR	Healthy.io Ltd.	July 2018	Wound analysis and management from smartphone image for direct patient use	Clinical Chemistry	Israel	Small
Arterys Oncology DL	Arterys Inc.	July 2018	Support of oncological workflow by helping user confirm absence or presence of lesions; application supports anatomical datasets, such as CT or MR	Radiology	United States	Small
FerriSmart Analysis System	Resonance Health Analysis Services Pty. Ltd.	July 2018	Measurement and monitoring of liver iron concentration and burden; aid in identification and monitoring of thalassemia	Radiology	Australia	Small
Ada - Your Health Guide	Ada Health GmbH	July 2018*	Symptom analysis and diagnostic support	General Hospital	Germany	Small
Sight OLO	Sight Diagnostics Ltd.	July 2018	Quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening capillary or venous whole blood samples	Hematology	Israel	Small
AIXPLORER Mach 30 Ultrasound Diagnostic Systems	Supersonic Imagine Inc.	July 2018	Ultrasound diagnostic systems and transducers intended for general purpose pulse echo ultrasound imaging, soft tissue elasticity imaging, doppler fluid flow analysis	Radiology	France	Small
DEEPVESSEL FFR	Keya Medical Technology Corporation Ltd.	August 2018	Assessment of the physiological functional assessment of the coronary arteries using coronary CTA scans	Cardiovascular	China	Small
Accu-Chek View	Roche Diabetes Care GmbH (parent company: Roche Holding AG)	August 2018	Diabetes monitoring and coaching tool	General Hospital	Germany	Large
Medopad	Huma Therapeutics Ltd.	August 2018	Remote patient monitoring platform through wearable and analytics platform	Cardiovascular	England	Small
Rayview	Raylytic GmbH	September 2018	Image data analysis for diagnostic support	Radiology	Germany	Small

Advanced intelligent Clear-IQ Engine (AiCE)	Canon Medical Systems Corporation (parent company: Canon Inc.)	September 2018	Noise reduction algorithm that improves image quality and reduces image noise for abdomen, pelvis, chest, cardiac, extremities and head applications	Radiology	Japan	Large
Senhance Surgical System	TransEnterix Inc.	October 2018	Assistance in laparoscopic surgery	Gastroenterology/Urology	United States	Small
NightOwl	Ectosense NV	October 2018	Evaluation of sleep-related breathing disorders suggestive of sleep apnea	Anesthesiology	Belgium	Small
Mia - Mammography Intelligent Assessment	Kheiron Medical Technologies Ltd.	October 2018	Breast cancer detection support from mammograms	Radiology	England	Small
Fluoroshield	Omega Medical Imaging LLC.	October 2018	Modification device to provide an automated region of interest that reduces exposure to the patient and operator	Radiology	United States	Small
AmCAD-UT	AmCad BioMed Corporation	October 2018	Assistance in analysis of thyroid ultrasound images	Radiology	Taiwan	Small
AmCAD-UO	AmCad BioMed Corporation	October 2018	Analysis and quantification of upper airway from ultrasound images	Radiology	Taiwan	Small
Cardisiograph	Cardisio GmbH	October 2018*	Coronary heart disease screening test for diagnostic support	Cardiovascular	Germany	Small
Symptom Assessment	Doctorlink Ltd.	October 2018*	Assistance of patients to appropriate care pathway	General Hospital	England	Small
AVATR	Inavya Ventures Ltd.	October 2018*	Health and patient data unification	General Hospital	England	Small
Tyto Stethoscope	Tyto Care Ltd.	October 2018	Electronic stethoscope that enables transmission of auscultation sound data	General Hospital	United States	Small
Invasive Tumor Detection APP	Visiopharm A/S	October 2018	Cytokeratin and p63 marker assessment for invasive and non-invasive tumor distinguishment	Pathology	Denmark	Small
Hot Spot APP	Visiopharm A/S	October 2018	Hotspot scoring method for various cancer applications	Pathology	Denmark	Small
OXSIGHT Prism	OXSIGHT Ltd.	November 2018	Smart glasses for people with a visual impairment	Ophthalmic	England	Small
AI-ECG Platform	Shenzhen Carewell Electronics Ltd.	November 2018	Assistance in measuring and interpreting 12-lead resting ECG	Cardiovascular	China	Small
DBLG1 System	diabeloop SA	November 2018	Blood sugar management tool for Type 1 diabetes patients	General Hospital	France	Small

MRCP+	Perspectum Diagnostics Ltd.	December 2018	Regions of variation of duct widths detection for diagnostic support from MRCP images	Radiology	England	Small
QUIBIM Precision image analysis platform	Quibim SL	December 2018	Imaging biomarker analysis and validation from CT scans	Radiology	Spain	Small
StoneChecker	Imaging Biometrics LLC.	December 2018	Kidney stone assessment tool based on non-contrast CT scans	Gastroenterology/Urology	England	Small
SubtlePET	Subtle Medical Inc.	December 2018	Improvement of image quality by denoising in 25% of the original scan duration	Radiology	United States	Small
Delta Clinical	ki elements UG	December 2018	Support for neuropsychological tests	Neurology	Germany	Small
Pegasus-disc	Visulytix Ltd.	December 2018*	Retinal image analysis for diagnostic support	Ophthalmic	England	Small
IB Lab Koala	IB Lab GmbH	January 2019	Radiological fully-automated image processing software device of computed or directly digital images intended to aid medical professionals in measurement of minimum joint space width	Radiology	Austria	Small
mdbrain	mediaire GmbH	January 2019	Early detection and differentiation of dementia support from MR images	Neurology	Germany	Small
Implicity	Implicity SAS	January 2019	Assisted remote monitoring for cardiovascular patients	Cardiovascular	France	Small
ChestEye Imaging Suite	Oxipit UAB	January 2019	Lung disease detection and reporting for diagnostic support from X-ray images	Radiology	Lithuania	Small
cvi42 for Cardiac MRI	Circle Cardiovascular Imaging Inc.	February 2019	Post-processing tool to assess heart function, flow and tissue attributes from MRI images	Radiology	Canada	Small
cvi42 for Cardiac CT	Circle Cardiovascular Imaging Inc.	February 2019	Post-processing tool to assess heart function, flow and tissue attributes from CT images	Radiology	Canada	Small
MUSICA	Agfa HealthCare NV	February 2019	Performance of dynamic imaging examinations (fluoroscopy and/or rapid sequence)	Radiology	Belgium	Large
DERM	Skin Analytics Ltd.	February 2019*	Skin cancer diagnosis support	General Hospital	England	Small
ART-Plan.annotate	TheraPanacea SAS	February 2019	Contouring of tumor and surrounding organs for radiotherapy	General Hospital	France	Small
R-One	Robocath SAS	February 2019	Robotic system for treatment of vascular diseases	Cardiovascular	France	Small

Aidoc Pulmonary Embolism	Aidoc Medical Ltd.	February 2019	Radiological computer aided triage and notification software indicated for use in the analysis of head CTA images	Radiology	Israel	Small
Altoida NMI	Altoida Inc.	March 2019	Mild Cognitive Impairment/Prodromal Alzheimer's Disease detection support	Neurology	United States	Small
KardiaAI	AliveCor Inc.	March 2019	Ambulatory ECG rhythm assessment	Cardiovascular	United States	Small
PixelShine	AlgoMedica Inc.	March 2019	Networking, communication, processing and enhancement of CT images in DICOM format	Radiology	United States	Small
OphtAI	Evolucare Technologies SAS	March 2019	Screening of eye pathologies for diagnostic support	Ophthalmic	France	Small
StethoMe	StethoMe sp. z o.o.	March 2019	Sound analysis for diagnostic support	General Hospital	Poland	Small
ECG App	Apple Inc.	March 2019	To create, record, store, transfer, and display ECG; determines presence of atrial fibrillation or sinus rhythm on classifiable waveform	Cardiovascular	United States	Large
Irregular Rhythm Notification Feature	Apple Inc.	March 2019	Analysis of pulse rate data to identify episodes of irregular heart rhythms suggestive of atrial fibrillation	Cardiovascular	United States	Large
Accipio ax	MaxQ-AI Ltd.	March 2019	Intercranial hemorrhage clinical assessment support from CT scans	Radiology	Israel	Small
Poseidon Ultrasound System	Butterfly Network Inc.	April 2019	Diagnostic ultrasound imaging and measurement of anatomical structures and fluids	Radiology	United States	Small
Myo Plus	Otto Bock Healthcare Products GmbH	April 2019	Exoprosthetic fittings of the upper limbs	Neurology	Austria	Large
Auto Lung Nodule Detection	Samsung Electronics Co. Ltd. (parent company: Samsung Group)	April 2019	Lung nodule detection for diagnostic support from X-ray images	Radiology	South Korea	Large
Bone Suppression	Samsung Electronics Co. Ltd. (parent company: Samsung Group)	April 2019	Bone suppression algorithm for improvement of tissue imaging from X-ray images	Radiology	South Korea	Large
Imbio CT Lung Texture Analysis (Caliper) Software	Imbio LLC.	April 2019	ILD's and other fibrotic condition identification support from CT scans	Radiology	United States	Small

BladderScan PRIME PLUS	Verathon Inc.	April 2019*	Ultrasound device intended to be used for measuring the urine volume in the bladder noninvasively	Radiology	United States	Large
syngo.Breast Care	Siemens Healthcare GmbH (parent company: Siemens AG)	May 2019	Reading and reporting for diagnostic support from mammograms	Radiology	Germany	Large
Syngo CT CaScoring	Siemens Healthcare GmbH (parent company: Siemens AG)	May 2019	Evaluation and documentation of calcified coronary lesions using CT scans	Radiology	Germany	Large
CLARUS 700	Carl Zeiss Meditec Inc.	May 2019	Capture, display, annotate and store images to aid in diagnosis and monitoring of diseases and disorders occurring in retina, ocular surfaces and visible adnexa	Ophthalmic	United States	Large
syngo.CT Cardiac Planning	Siemens Healthcare GmbH (parent company: Siemens AG)	May 2019	Image analysis software package for evaluating contrast enhanced CT images; analysis of morphology and pathology of vascular and cardiac structures	Radiology	Germany	Large
Painchek	PainChek Ltd.	May 2019	Assessment of facial movements for pain assessment	Neurology	Australia	Small
HealthPNX	Zebra Medical Vision Inc.	May 2019	Pneumothorax detection support and alert for urgent findings from X-ray images	Radiology	Israel	Small
eMurmur ID	CSD Labs GmbH	May 2019	Detection and identification of heart murmurs	Cardiovascular	Austria	Small
JPC-01K	JLK Inspection Inc.	May 2019	Prostate cancer detection for diagnostic support from MRI images	Radiology	South Korea	Small
JBS-01K	JLK Inspection Inc.	May 2019	Ischemic stroke detection for diagnostic support from MRI images	Radiology	South Korea	Small
syngo.via RT Image Suite	Siemens Healthcare GmbH (parent company: Siemens AG)	May 2019	3D and 4D image visualization, multimodality manipulation and contouring tool that helps preparation and response assessment of treatments	Radiology	Germany	Large
Smartho-D2 Electronic Stethoscope	Hefei Mintti Medical Technology Co. Ltd.	June 2019	Detection and amplification of sounds from heart, lungs, and other internal organs with use of a selective frequency	Anesthesiology	China	Small
Rayvolve	AZMed SAS	June 2019	Bone lesion detection support from X-ray images	Radiology	France	Small
Illumeo System	Philips Medical Systems Nederland BV (parent company: Koninklijke Philips NV)	June 2019*	Image management system to acquire, store, distribute, process and display images and associated data throughout clinical environment	Radiology	Netherlands	Large

Innersight3D	InnersightLabs Ltd.	June 2019*	Modelling technology for surgery planning using models from MRI and CT scans	Radiology	England	Small
SOZO	ImpediMed Ltd.	June 2019	Aid to clinical assessment of unilateral lymphedema	Cardiovascular	Australia	Large
Epihunter	epihunter NV	June 2019	Absence seizure detection	Neurology	Belgium	Small
Complete Control System Gen2	Coapt LLC.	June 2019	External prosthetic fittings of the upper limbs	Neurology	United States	Small
RevealAI-Lung	Mindshare Medical Inc.	June 2019	Risk assessment tool for lung cancer detection support from CT scans	Radiology	United States	Small
Venue Ultrasound	GE Medical Systems Ultrasound and Primary Care Diagnostics Inc. (parent company: General Electric Company)	July 2019	Ultrasound imaging, measurement and analysis of the human body and fluid for clinical applications	Radiology	United States	Large
VentriPoint Medical System Plus (VMS+)	Ventripoint Diagnostics Ltd.	July 2019	Intended to record, analyze, store and retrieve digital ultrasound images for computerized 3D image processing	Cardiovascular	Canada	Small
ProFound AI for 2D Mammography	iCAD Inc.	July 2019	Breast cancer detection assistance and workflow solution from 2D mammograms	Radiology	United States	Small
ProFound AI for Digital Breast Tomosynthesis	iCAD Inc.	July 2019	Computer-assisted detection and diagnosis (CAD) software device intended to be used while reading digital breast tomosynthesis (DBT) exams	Radiology	United States	Small
Altris AI	Altris Inc.	July 2019	Retinal conditions detection for diagnostic support	Ophthalmic	United States	Small
Bone VCAR (BVCAR)	GE Medical Systems SCS (parent company: General Electric Company)	August 2019	Post processing application for use in the analysis of CT spine images	Radiology	France	Large
Deep Learning Image Reconstruction	GE Healthcare Japan Corporation (parent company: General Electric Company)	August 2019	Image reconstruction method intended to produce cross-sectional images of the head and body	Radiology	Japan	Large
ResAppDx-EU	ResApp Health Ltd.	August 2019	Analysis of patients' cough sounds for diagnostic support	General Hospital	Australia	Small
Ethos Radiotherapy Treatment	Varian Medical Systems Inc.	August 2019	Managing and monitoring radiation therapy treatment plans and sessions	Radiology	United States	Large

AI-Rad Companion Chest CT	Siemens Healthcare GmbH (parent company: Siemens AG)	August 2019*	Image processing software that provides analysis from CT images to support physicians in evaluation and assessment of cardiovascular diseases	Radiology	Germany	Large
AI-Rad Companion Engine	Siemens Healthcare GmbH (parent company: Siemens AG)	August 2019*	Software platform that provides basic visualization and enables external post-processing extension for medical images used for diagnostic purposes	Radiology	Germany	Large
AI-Rad Companion Cardiovascular	Siemens Healthcare GmbH (parent company: Siemens AG)	August 2019*	Image processing software for analysis from CT images to support physicians in evaluation and assessment of cardiovascular diseases	Radiology	Germany	Large
AI-Rad Companion Musculoskeletal	Siemens Healthcare GmbH (parent company: Siemens AG)	August 2019*	Thorax processing software for diagnostic support from CT scans	Radiology	Germany	Large
AVEC (Automated Visual Evaluation of the Cervix)	MobileODT Ltd.	September 2019	Cervical cancer screening support for diagnostic support	Obstetrics/Gynecology	Israel	Small
Breast-SlimView	Hera-MI SAS	September 2019	Breast cancer detection for diagnostic support from mammograms	Radiology	France	Small
JLD-01K	JLK Inspection Inc.	September 2019	Lung disease detection for diagnostic support from CT scans	Radiology	South Korea	Small
JLD-02K	JLK Inspection Inc.	September 2019	Lung disease detection for diagnostic support from X-ray images	Radiology	South Korea	Small
JBA-01K	JLK Inspection Inc.	September 2019	Cerebral aneurysm detection for diagnostic support from MR angiogram (MRA)	Radiology	South Korea	Small
JBS-04K	JLK Inspection Inc.	September 2019	Hemorrhagic stroke detection for diagnostic support from CT scans	Radiology	South Korea	Small
JAD-02K	JLK Inspection Inc.	September 2019	Cortical thickness quantification for diagnostic support from MRI images	Radiology	South Korea	Small
MRCAT Brain	Philips Medical Systems MR Finland (parent company: Philips NV)	September 2019	Radiation therapy planning through automated image segmentation for brain tumor patients	Radiology	Finland	Large
ArtiQ.PFT	ArtiQ NV	September 2019	Interpretation of pulmonary function tests (PFTs) for diagnostic support	General Hospital	Belgium	Small

QLAB Advanced Quantification Software	Philips Medical Systems Nederland BV (parent company: Koninklijke Philips NV)	September 2019	Viewing and quantification of image data acquired on Philips ultrasound systems	Radiology	United States	Large
QbCheck	QBTECH AB	September 2019	Aid in the clinical assessment of ADHD and in the evaluation of treatment interventions in patients with ADHD	Neurology	Sweden	Small
Vara	Merantix Healthcare GmbH	September 2019	Breast cancer screening support and triaging from mammograms	Radiology	Germany	Small
APAS Independence instrument	Clever Culture Systems AG	September 2019	Automates urine culture plate imaging and interpretation to detect presence or absence of microbial growth	Microbiology	Switzerland	Small
Aidoc Large Vessel Occlusion	Aidoc Medical Ltd.	September 2019	Workflow triage by flagging and communication of suspected positive findings of Large Vessel Occlusion (LVO) pathologies	Radiology	Israel	Small
Concentriq Dx	Proscia Inc.	October 2019	Computational pathology image-based workflow automation	General Hospital	United States	Small
NuVasive Pulse System	NuVasive Inc.	October 2019	Intraoperative neurophysiologic monitoring during spinal surgery, neck dissection, thoracic surgeries, and upper and lower extremities	Neurology	United States	Large
DXA Diagnostic Assistant	Dialogue Technologies Inc.	October 2019	Triage scoring based on patient history	General Hospital	Canada	Small
NvisionVLE Imaging System, NvisionVLE Optical Probe, NvisionVLE Inflation System	NinePoint Medical Inc.	October 2019*	Imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue	Radiology	United States	Small
DeepDx-Prostate Connect	Deep Bio Inc.	October 2019	Recognition of acinar adenocarcinoma of the prostate	Pathology	South Korea	Small
ClariCT.AI	ClariPI Inc.	October 2019	Networking, communication, processing and enhancement of CT images	Radiology	South Korea	Small
Auto Positioning	GE Hangwei Medical Systems Co. Ltd. (parent company: General Electric Company)	November 2019	Provide consistent patient positioning for optimal image quality and automatic exposure control	Radiology	China	Large

LiverMultiScan	Perspectum Diagnostics Ltd.	November 2019	MR diagnostic device software application for non-invasive liver evaluation	Radiology	England	Small
RBKnee	Radiobotics ApS	November 2019	Automatic detection of radiographic osteoarthritis markers from X-ray images	Radiology	Denmark	Small
Centricity Universal Viewer	GE Healthcare Inc. (parent company: General Electric Company)	November 2019	Display of medical images and data from various imaging sources and from other healthcare information sources	Radiology	United States	Large
Automatic View Recognition	GE Medical Systems Ultrasound and Primary Care Diagnostics (parent company: General Electric Company)	November 2019	Automated workflow improvement tool for Vivid E95 / Vivid E90 general-purpose ultrasound systems, specialized for use in cardiac imaging	Radiology	United States	Large
AI-ECG Tracker	Shenzhen Carewell Electronics Co. Ltd.	November 2019	Assessment of arrhythmias using ECG data acquired from adults without pacemakers	Cardiovascular	China	Small
Paige Prostate	Paige Inc.	November 2019	Cancer detection in prostate needle biopsies	Pathology	United States	Small
Paige Insight	Paige Inc.	November 2019	Digital pathology viewer for diagnostic support	Pathology	United States	Small
Lunit INSIGHT CXR 3	Lunit Inc.	November 2019	Chest abnormality detection tool from X-ray images	Radiology	South Korea	Small
DentaliQ ortho	CellmatiQ GmbH	November 2019	Pre-analysis of various jaw and tooth positions	Dental	Germany	Small
Kata	VisionHealth GmbH	November 2019	Assessment of inhalation for asthma	General Hospital	Germany	Small
KroniKare Wound Imager	KroniKare Pte. Ltd.	November 2019	Chronic wound care and management	General Hospital	Singapore	Small
Icobrain-CTP	Icometrix NV	December 2019	Analysis and communication capabilities for dynamic imaging datasets that are acquired with CT Perfusion imaging protocols	Radiology	Belgium	Small
VSI Holomedicine	apoQlar GmbH	December 2019	Surgery support through mixed reality	General Hospital	Germany	Small
VISUHEALTH - AI DR	Carl Zeiss Meditec Inc.	December 2019	Support tool for glaucoma hemifield test	Ophthalmic	Germany	Large
wheezo	RESPIRI Ltd.	December 2019	Asthma management and remote monitoring tool	General Hospital	Australia	Small
INFINITT PACS 7.0	Infinitt Healthcare Co. Ltd.	December 2019	Image analysis and operational workflow improvement tool	Radiology	South Korea	Large

Discovery AI	Pentax Medical GmbH (parent company: Pentax Corporation)	December 2019	Polyp detection support during a colorectal examination	Gastroenterology/Urology	Germany	Small
HealthCXR	Zebra Medical Vision Inc.	December 2019	Software workflow tool to aid clinical assessment of adult chest X-ray with features suggestive of pleural effusion	Radiology	Israel	Small
Integrated Cognitive Assessment (ICA)	Cognetivity Neurosciences Ltd.	December 2019	Early-stage dementia diagnostic support	Neurology	England	Small
RayStation	RaySearch Laboratories AB	December 2019	Treatment planning and analysis of radiation therapy	Radiology	Sweden	Large
RayCare 2.3	RaySearch Laboratories AB	December 2019	Support of workflows, scheduling and clinical information management for oncology care and follow-up	Radiology	Sweden	Large
StrokeViewer	Nico.lab BV	December 2019	Localization and quantification of stroke biomarkers from CT scans	Radiology	Netherlands	Small
MEDIP PRO	MEDICALIP Co. Ltd.	December 2019	Software interface and image segmentation system for transfer of DICOM imaging information from medical scanner to output file; pre-operative software for treatment planning	Radiology	South Korea	Small
JBD-01K	JLK Inspection Inc.	January 2020	Breast cancer detection for diagnostic support from mammograms	Radiology	South Korea	Small
AI-Pathway Companion Prostate Cancer	Siemens Healthcare GmbH (parent company: Siemens AG)	January 2020*	Prostate cancer detection for diagnostic support	General Hospital	Germany	Large
InferRead CT Lung	Beijing Infervision Technology Co. Ltd.	February 2020	Lung cancer screening and management tool from CT scans	Radiology	China	Small
b-box	b-rayZ GmbH	February 2020	Assessment of mammography image quality and breast density from mammograms	Radiology	Switzerland	Small
aBSI	EXINI Diagnostics AB (parent company: Progenics Pharmaceuticals Inc.)	February 2020	General picture archiving and communications system tools including applications for lesion marking and quantitative analysis of nuclear medicine imaging	Radiology	Sweden	Small
CINA ICH	Avicenna.AI SAS	February 2020	Detection and prioritization of acute intracerebral hemorrhage on non-contrast CT	Radiology	France	Small
CINA LVO	Avicenna.AI SAS	February 2020	Detection and prioritization of acute intracerebral hemorrhage on non-contrast CT	Radiology	France	Small

Medicus	Medicus AI GmbH	February 2020	Health and medical data interpretation support tool	General Hospital	Austria	Small
Metastasis Detection App	Visiopharm A/S	February 2020	Metastasis detection in lymph nodes for colorectal and breast adenocarcinoma	Pathology	Denmark	Small
BioBeats	Huma Therapeutics Ltd.	February 2020	Remote patient monitoring tool for cardiac patients	Cardiovascular	England	Small
Retinal Image Intelligent Analysis Software	Airdoc Inc.	February 2020	Diabetic retinopathy detection support	Ophthalmic	China	Small
Galen Prostate	Ibex Medical Analytics Ltd.	February 2020	Identification of suspected cancer on prostate core needle biopsies	Pathology	Israel	Small
Sens.ai	Future Processing Healthcare sp. z o.o.	March 2020	Segmentation and calculation of the volume of the brain lesions	Neurology	Poland	Small
BoneView	Gleamer.AI SAS	March 2020	Bone fracture detection from x-ray images	Radiology	France	Small
CAD EYE	FUJIFILM Europe GmbH (parent company: Fujifilm Holdings Corporation)	March 2020	Colonic polyps detection and characterization support during a colonoscopy	Gastroenterology/Urology	Germany	Large
EchoGo Pro	Ultromics Ltd.	March 2020	Cardiovascular function assessment for diagnostic support from ultrasound images	Cardiovascular	England	Small
EarlyVue VS30	Philips Medizin Systeme Boeblingen GmbH (parent company: Philips NV)	March 2020	Measure, display, alarm and record physiological information	Radiology	Germany	Large
Automated Retinal Disease Assessment	Verily Life Sciences LLC. (parent company: Alphabet Inc.)	March 2020*	Screening tool for diabetic retinopathy detection	Ophthalmic	United States	Large
KOSMOS	EchoNous Inc.	March 2020	Clinical assessment of cardiac and pulmonary systems and abdomen by acquiring ultrasound images, ECG rhythms and digital auscultation sounds and waveforms	Cardiovascular	United States	Small

† The summary was extracted from summaries of governmental websites or news outlets. The information is not comprehensive. Please consult the governments' websites or contact the manufacturers for further information.

* AI/ML-based medical devices for which the registration date is listed since the CE marking date could not be verified.

Comparison of baseline characteristics of FDA approved device categories

Characteristic	510(k) n = 204	De novo n = 15	PMA n = 3	Chi square tests of independence
Country of Origin (n%)				$\chi^2(42) = 12.7$ $p = 1.00$ $\varphi = 0.17$ $n = 222$
Australia	3 (1.5)	0 (0)	0 (0)	
Austria	3 (1.5)	0 (0)	0 (0)	
Belgium	5 (2.5)	0 (0)	0 (0)	
Canada	6 (2.9)	0 (0)	0 (0)	
China	5 (2.5)	0 (0)	0 (0)	
Denmark	1 (0.5)	0 (0)	0 (0)	
England	9 (4.4)	0 (0)	0 (0)	
Finland	2 (1.0)	0 (0)	0 (0)	
France	8 (3.9)	0 (0)	0 (0)	
Germany	2 (1.0)	0 (0)	0 (0)	
Israel	15 (7.4)	1 (6.7)	0 (0)	
Italy	2 (1.0)	0 (0)	0 (0)	
Japan	2 (1.0)	0 (0)	0 (0)	
Netherlands	4 (2.0)	0 (0)	0 (0)	
New Zealand	1 (0.5)	0 (0)	0 (0)	
Singapore	2 (1.0)	0 (0)	0 (0)	
South Korea	3 (1.5)	0 (0)	0 (0)	
Spain	1 (0.5)	0 (0)	0 (0)	
Sweden	10 (4.9)	0 (0)	0 (0)	
Switzerland	3 (1.5)	1 (6.7)	0 (0)	
Taiwan	7 (3.4)	0 (0)	0 (0)	
United States	110 (54)	13 (87)	3 (100)	
Professional or Patient Use (n%)				$\chi^2(4) = 6.63$ $p = 0.16$ $\varphi = 0.12$ $n = 222$
Healthcare Professional	177 (87)	10 (67)	2 (67)	
Healthcare Professional and Patient	10 (4.9)	2 (13)	0 (0)	
Patient	17 (8.3)	3 (20)	1 (33)	

Medical Specialty (n%)				$\chi^2(26) = 45.1$
Anesthesiology	7 (3.4)	0 (0)	0 (0)	$p = 0.011$
Cardiovascular	35 (17)	5 (33)	0 (0)	$\varphi = 0.32$
Clinical Chemistry	4 (2.0)	1 (6.7)	1 (33)	$n = 222$
Clinical Toxicology	1 (0.5)	0 (0)	0 (0)	
Dental	1 (0.5)	0 (0)	0 (0)	
Gastroenterology/Urology	1 (0.5)	0 (0)	0 (0)	
General Hospital	2 (1.0)	0 (0)	0 (0)	
Hematology	5 (2.5)	0 (0)	0 (0)	
Microbiology	4 (2.0)	0 (0)	0 (0)	
Molecular Genetics	0 (0)	1 (6.7)	0 (0)	
Neurology	19 (9.3)	2 (13)	0 (0)	
Obstetrics/Gynecology	1 (0.5)	1 (6.7)	0 (0)	
Ophthalmic	1 (0.5)	1 (6.7)	0 (0)	
Radiology	123 (60)	4 (27)	2 (67)	
Manufacturer Size (n%)				$\chi^2(2) = 0.26$
Small	158 (77)	12 (80)	2 (67)	$p = 0.88$
Large	46 (23)	3 (20)	1 (33)	$\varphi = 0.034$
				$n = 222$

$\chi^2(N)$ = Pearson's chi-square coefficient, N = degrees of freedom. p = model significance (significant when p < 0.05). φ = effect size (Cramer's V). n = total sample size.

Post-hoc analyses of significant chi-square statistics for FDA approved devices

Characteristic	510(k) n = 204	De novo n = 15	PMA n = 3
Medical Specialty			
Anesthesiology			
<i>residuals</i>	0.80	-0.72	-0.31
<i>p-values</i>	1.00	1.00	1.00
Cardiology			
<i>residuals</i>	-1.12	1.60	-0.82
<i>p-values</i>	1.00	1.00	1.00
Clinical Chemistry			
<i>residuals</i>	-2.30	0.98	3.29
<i>p-values</i>	0.91	1.00	0.04
Clinical Toxicology			
<i>residuals</i>	0.30	-0.27	-0.12
<i>p-values</i>	1.00	1.00	1.00
Dental			
<i>residuals</i>	0.30	-0.27	-0.12
<i>p-values</i>	1.00	1.00	1.00
Gastroenterology / Urology			
<i>residuals</i>	0.30	-0.27	-0.12
<i>p-values</i>	1.00	1.00	1.00
General Hospital			
<i>residuals</i>	0.42	-0.38	-0.17
<i>p-values</i>	1.00	1.00	1.00
Hematology			
<i>residuals</i>	0.67	-0.61	-0.26
<i>p-values</i>	1.00	1.00	1.00
Microbiology			
<i>residuals</i>	0.60	-0.54	-0.24
<i>p-values</i>	1.00	1.00	1.00
Molecular Genetics			
<i>residuals</i>	-3.38	3.73	-0.12

<i>p-values</i>	0.03	0.008	1.00
Neurology			
<i>residuals</i>	-0.25	0.53	-0.56
<i>p-values</i>	1.00	1.00	1.00
Obstetrics / Gynecology			
<i>residuals</i>	-2.18	2.45	-0.17
<i>p-values</i>	1.00	0.60	1.00
Ophthalmic			
<i>residuals</i>	-2.18	2.45	-0.17
<i>p-values</i>	1.00	0.60	1.00
Radiology			
<i>residuals</i>	2.22	-2.56	0.30
<i>p-values</i>	1.00	0.44	1.00

p = model significance (significant when $p < 0.05$).

Comparison of baseline characteristics of CE marked device categories

Characteristic	Class I n = 85	Class IIa n = 95	Class IIb n = 28	Class III n = 2	Class IVD n = 11	Chi square tests of independence
Country of Origin (n%)						$\chi^2(100) = 255$ $p < 0.001$ $\varphi = 0.54$ $n = 221$
Australia	2 (2.4)	3 (3.2)	0 (0)	0 (0)	0 (0)	
Austria	3 (3.5)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Belgium	5 (5.9)	2 (2.1)	1 (3.6)	0 (0)	0 (0)	
Canada	2 (2.4)	1 (1.1)	1 (3.6)	2 (100)	0 (0)	
China	2 (2.4)	3 (3.2)	2 (7.1)	0 (0)	0 (0)	
Denmark	1 (1.2)	0 (0)	0 (0)	0 (0)	5 (45)	
England	23 (27)	5 (5.3)	0 (0)	0 (0)	0 (0)	
Finland	2 (2.4)	2 (2.1)	0 (0)	0 (0)	0 (0)	
France	3 (3.5)	8 (8.4)	3 (11)	0 (0)	0 (0)	
Germany	14 (16)	12 (13)	4 (14)	0 (0)	0 (0)	
India	1 (1.2)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Ireland	0 (0)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Israel	11 (13)	0 (0)	3 (11)	0 (0)	4 (36)	
Italy	0 (0)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Japan	0 (0)	1 (1.1)	1 (3.6)	0 (0)	0 (0)	
Lithuania	0 (0)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Netherlands	1 (1.2)	7 (7.4)	1 (3.6)	0 (0)	0 (0)	
New Zealand	1 (1.2)	0 (0)	0 (0)	0 (0)	0 (0)	
Poland	0 (0)	2 (2.1)	0 (0)	0 (0)	0 (0)	
Singapore	1 (1.2)	1 (1.1)	0 (0)	0 (0)	0 (0)	
South Korea	1 (1.2)	3 (3.2)	2 (7.1)	0 (0)	1 (9.1)	
Spain	1 (1.2)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Sweden	1 (1.2)	3 (3.2)	3 (11)	0 (0)	0 (0)	
Switzerland	2 (2.4)	2 (2.1)	0 (0)	0 (0)	0 (0)	
Taiwan	0 (0)	5 (5.3)	0 (0)	0 (0)	0 (0)	
United States	8 (9.4)	29 (31)	7 (25)	0 (0)	1 (9.1)	

Professional or Patient Use (n%)						$\chi^2(8) = 12.6$
Healthcare Professional	60 (71)	81 (85)	25 (89)	2 (100)	10 (91)	$p = 0.13$
Healthcare Professional and Patient	14 (16)	6 (6.3)	0 (0)	0 (0)	0 (0)	$\varphi = 0.17$
Patient	11 (13)	8 (8.4)	3 (11)	0 (0)	1 (9.1)	$n = 221$
Medical Specialty (n%)						$\chi^2(48) = 245$
Anesthesiology	1 (1.2)	2 (2.1)	0 (0)	0 (0)	0 (0)	$p < 0.001$
Cardiovascular	4 (4.7)	14 (15)	5 (18)	0 (0)	0 (0)	$\varphi = 0.53$
Clinical Chemistry	0 (0)	0 (0)	1 (3.6)	0 (0)	2 (18)	$n = 221$
Dental	1 (1.2)	0 (0)	0 (0)	0 (0)	0 (0)	
Gastroenterology/Urology	3 (3.5)	1 (1.1)	1 (3.6)	0 (0)	0 (0)	
General Hospital	21 (25)	5 (5.3)	3 (11)	0 (0)	0 (0)	
Hematology	0 (0)	0 (0)	0 (0)	0 (0)	1 (9.1)	
Microbiology	1 (1.2)	0 (0)	0 (0)	0 (0)	1 (9.1)	
Neurology	15 (18)	4 (4.2)	0 (0)	0 (0)	0 (0)	
Obstetrics/Gynecology	1 (1.2)	1 (1.1)	0 (0)	0 (0)	0 (0)	
Ophthalmic	5 (5.9)	6 (6.3)	0 (0)	0 (0)	0 (0)	
Pathology	0 (0)	0 (0)	0 (0)	0 (0)	7 (64)	
Radiology	33 (39)	62 (65)	18 (64)	2 (100)	0 (0)	
Manufacturer Size (n%)						$\chi^2(4) = 27.2$
Small	81 (95)	68 (72)	16 (57)	2 (100)	10 (91)	$p < 0.001$
Large	4 (4.7)	27 (28)	12 (43)	0 (0)	1 (9.1)	$\varphi = 0.35$
						$n = 221$

$\chi^2(N)$ = Pearson's chi-square coefficient, N = degrees of freedom. p = model significance (significant when $p < 0.05$). φ = effect size (Cramer's V). n = total sample size.

Post-hoc analyses of significant chi-square statistics for CE marked devices

Characteristic	Class I n = 85	Class IIa n = 95	Class IIb n = 28	Class III n = 2	Class IVD n = 11
Country of Origin					
Australia					
<i>residuals</i>	0.07	0.77	-0.86	-0.22	-0.52
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Austria					
<i>residuals</i>	1.52	-0.73	-0.77	-0.19	-0.46
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Belgium					
<i>residuals</i>	1.42	-1.05	-0.01	-0.28	-0.66
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Canada					
<i>residuals</i>	-0.26	-1.32	0.30	8.50	-0.57
<i>p-values</i>	1.00	1.00	1.00	<0.001	1.00
China					
<i>residuals</i>	-0.55	-0.01	1.29	-0.26	-0.62
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Denmark					
<i>residuals</i>	-1.11	-2.16	-0.95	-0.24	8.95
<i>p-values</i>	1.00	1.00	1.00	1.00	<0.001
England					
<i>residuals</i>	5.08	-2.87	-2.20	-0.54	-1.30
<i>p-values</i>	<0.001	0.53	1.00	1.00	1.00
Finland					
<i>residuals</i>	0.48	0.29	-0.77	-0.19	-0.46
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
France					
<i>residuals</i>	-1.35	1.11	1.02	-0.37	-0.88
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Germany					
<i>residuals</i>	0.99	-0.36	0.12	-0.56	-1.35
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00

India					
<i>residuals</i>	0.34	0.20	-0.54	-0.14	-0.33
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Ireland					
<i>residuals</i>	-0.79	1.15	-0.38	-0.10	-0.23
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Israel					
<i>residuals</i>	2.06	-3.84	0.53	-0.42	3.51
<i>p-values</i>	1.00	0.02	1.00	1.00	1.00
Italy					
<i>residuals</i>	-0.79	1.15	-0.38	-0.10	-0.23
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Japan					
<i>residuals</i>	-1.12	-0.20	1.59	-0.14	-0.33
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Lithuania					
<i>residuals</i>	-0.79	1.15	-0.38	-0.10	-0.23
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Netherlands					
<i>residuals</i>	-1.72	2.15	-0.14	-0.29	-0.70
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
New Zealand					
<i>residuals</i>	1.27	-0.87	-0.38	-0.10	-0.23
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Poland					
<i>residuals</i>	-1.12	1.64	-0.54	-0.14	-0.33
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Singapore					
<i>residuals</i>	0.34	0.20	-0.54	-0.14	-0.33
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
South Korea					
<i>residuals</i>	-1.34	-0.01	1.29	-0.26	1.15
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Spain					
<i>residuals</i>	0.34	0.20	-0.54	-0.14	-0.33

<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Sweden					
<i>residuals</i>	-1.34	-0.01	2.44	-0.26	-0.62
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Switzerland					
<i>residuals</i>	0.48	0.29	-0.77	-0.19	-0.46
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Taiwan					
<i>residuals</i>	-1.79	2.60	-0.86	-0.22	-0.52
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
United States					
<i>residuals</i>	-3.20	3.26	0.65	-0.72	-0.95
<i>p-values</i>	0.18	0.15	1.00	1.00	1.00
Medical Specialty					
Anesthesiology					
<i>residuals</i>	-0.18	0.83	-0.66	-0.17	-0.40
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Cardiovascular					
<i>residuals</i>	-2.19	1.83	1.38	-0.48	-1.16
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Clinical Chemistry					
<i>residuals</i>	-1.38	-1.51	1.08	-0.17	4.95
<i>p-values</i>	1.00	1.00	1.00	1.00	<0.001
Dental					
<i>residuals</i>	1.27	-0.87	-0.38	-0.10	-0.23
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Gastroenterology / Urology					
<i>residuals</i>	1.00	-1.05	0.50	-0.22	-0.52
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
General Hospital					
<i>residuals</i>	4.03	-3.00	-0.40	-0.55	-1.32
<i>p-values</i>	<0.001	0.17	1.00	1.00	1.00
Hematology					
<i>residuals</i>	-0.79	-0.87	-0.38	-0.10	4.38

<i>p-values</i>	1.00	1.00	1.00	1.00	<0.001
Microbiology					
<i>residuals</i>	0.34	-1.23	-0.54	-0.14	2.94
<i>p-values</i>	1.00	1.00	1.00	1.00	0.22
Neurology					
<i>residuals</i>	3.80	-2.02	-1.74	-0.44	-1.04
<i>p-values</i>	0.01	1.00	1.00	1.00	1.00
Obstetrics / Gynecology					
<i>residuals</i>	0.34	0.20	-0.54	-0.14	-0.33
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Ophthalmic					
<i>residuals</i>	0.49	0.79	-1.30	-0.33	-0.78
<i>p-values</i>	1.00	1.00	1.00	1.00	1.00
Pathology					
<i>residuals</i>	-2.13	-2.33	-1.02	-0.26	11.7
<i>p-values</i>	1.00	1.00	1.00	1.00	<0.001
Radiology					
<i>residuals</i>	-3.11	3.42	1.39	1.37	-3.54
<i>p-values</i>	0.12	0.04	1.00	1.00	0.03
Manufacturer Size					
Small					
<i>residuals</i>	-4.47	2.75	3.25	-0.71	-0.92
<i>p-values</i>	<0.001	0.06	0.01	1.00	1.00
Large					
<i>residuals</i>	4.47	-2.75	-3.25	0.71	0.92
<i>p-values</i>	<0.001	0.06	0.01	1.00	1.00

p = model significance (significant when p < 0.05).

Multivariate regression results of commonly approved products by the FDA and CE marked in Europe

Predictor	<i>b</i>	<i>b</i> 95% CI [LL, UL]	<i>sr</i> ²	<i>sr</i> ² 95% CI [LL, UL]	Fit
(Intercept)	996.28*	[38.26, 1954.30]			
CE Mark Certification Year					
2016	-294.83	[-625.99, 36.33]	.01	[-.01, .04]	
2017	-431.70*	[-766.97, -96.44]	.03	[-.01, .06]	
2018	-780.07**	[-1106.09, -454.04]	.10	[.03, .17]	
2019	-1039.31**	[-1349.32, -729.31]	.19	[.10, .29]	
2020	-893.71**	[-1340.10, -447.31]	.07	[.01, .13]	
Country of Origin					
Austria	578.95	[-4.93, 1162.82]	.02	[-.01, .04]	
Belgium	219.22	[-326.35, 764.78]	.00	[-.01, .01]	
Canada	324.84	[-259.73, 909.40]	.01	[-.01, .02]	
China	404.10	[-159.49, 967.70]	.01	[-.01, .03]	
England	96.55	[-429.77, 622.87]	.00	[-.00, .01]	
Finland	266.26	[-378.96, 911.49]	.00	[-.01, .01]	
France	343.01	[-201.25, 887.27]	.01	[-.01, .02]	
Germany	268.40	[-229.68, 766.48]	.01	[-.01, .02]	
Ireland	82.63	[-889.09, 1054.34]	.00	[-.00, .00]	
Israel	342.88	[-158.05, 843.80]	.01	[-.01, .03]	
Italy	402.11	[-459.43, 1263.64]	.00	[-.01, .02]	
Japan	295.82	[-335.17, 926.82]	.00	[-.01, .02]	
Netherlands	167.06	[-386.24, 720.37]	.00	[-.01, .01]	
New Zealand	-6.54	[-798.41, 785.33]	.00	[-.00, .00]	
South Korea	6.69	[-582.28, 595.67]	.00	[-.00, .00]	
Sweden	155.21	[-368.35, 678.78]	.00	[-.01, .01]	
Switzerland	156.87	[-600.69, 914.42]	.00	[-.00, .01]	
Taiwan	11.95	[-557.69, 581.59]	.00	[-.00, .00]	
United States	46.02	[-428.40, 520.43]	.00	[-.00, .00]	
Professional or Patient Use					
Physician	-25.26	[-343.31, 292.79]	.00	[-.00, .00]	
Medical Specialty					

Cardiovascular	-573.08	[-1213.13, 66.98]	.01	[-.01, .04]
Clinical Chemistry	-906.90*	[-1634.05, -179.75]	.03	[-.01, .06]
Dental	-465.40	[-1404.39, 473.59]	.00	[-.01, .02]
Gastroenterology/Urology	-370.31	[-1124.72, 384.11]	.00	[-.01, .02]
General Hospital	-925.90**	[-1615.91, -235.88]	.03	[-.01, .07]
Hematology	-250.90	[-1127.22, 625.42]	.00	[-.01, .01]
Microbiology	-236.40	[-1068.81, 596.01]	.00	[-.01, .01]
Neurology	-686.63*	[-1276.04, -97.23]	.02	[-.01, .06]
Obstetrics/Gynecology	-529.38	[-1625.85, 567.08]	.00	[-.01, .02]
Ophthalmic	-88.91	[-997.22, 819.39]	.00	[-.00, .00]
Radiology	-442.84	[-1069.32, 183.63]	.01	[-.01, .03]
Manufacturer Size				
Small	26.88	[-161.12, 214.88]	.00	[-.00, .00]
Regulatory Pathway				
510(k)	166.20	[-305.18, 637.57]	.00	[-.01, .01]
de novo	356.06	[-300.59, 1012.71]	.01	[-.01, .02]

$$R^2 = .660^{**}$$

Note. A significant *b*-weight indicates the semi-partial correlation is also significant. *b* represents unstandardized regression weights. *sr*² represents the semi-partial correlation squared. *LL* and *UL* indicate the lower and upper limits of a confidence interval, respectively.

* indicates $p < .05$. ** indicates $p < .01$.

Sensitivity analysis with excluded outliers for commonly approved devices by the FDA and CE marked in Europe

Predictor	<i>b</i>	<i>b</i> 95% CI [LL, UL]	<i>sr</i> ²	<i>sr</i> ² 95% CI [LL, UL]	Fit
(Intercept)	772.69	[-117.01, 1662.39]			
CE Mark Certification Year					
2016	-210.32	[-518.37, 97.72]	.01	[-.01, .03]	
2017	-329.66*	[-642.83, -16.48]	.02	[-.01, .05]	
2018	-680.72**	[-985.27, -376.17]	.08	[.02, .14]	
2019	-904.19**	[-1198.00, -610.39]	.15	[.07, .24]	
2020	-845.53**	[-1257.36, -433.70]	.07	[.01, .12]	
Country of Origin					
Austria	499.33	[-39.92, 1038.58]	.01	[-.01, .04]	
Belgium	185.22	[-317.51, 687.94]	.00	[-.01, .01]	
Canada	334.24	[-204.11, 872.59]	.01	[-.01, .02]	
China	385.49	[-133.62, 904.59]	.01	[-.01, .03]	
England	94.03	[-390.66, 578.72]	.00	[-.00, .01]	
Finland	280.57	[-313.67, 874.81]	.00	[-.01, .02]	
France	342.90	[-158.32, 844.11]	.01	[-.01, .03]	
Germany	319.66	[-139.79, 779.10]	.01	[-.01, .03]	
Ireland	276.46	[-623.92, 1176.85]	.00	[-.01, .01]	
Israel	321.13	[-140.31, 782.57]	.01	[-.01, .03]	
Italy	249.65	[-547.61, 1046.90]	.00	[-.01, .01]	
Japan	333.78	[-247.64, 915.19]	.01	[-.01, .02]	
Netherlands	191.30	[-318.39, 701.00]	.00	[-.01, .01]	
New Zealand	-15.54	[-744.80, 713.71]	.00	[-.00, .00]	
South Korea	-14.66	[-557.17, 527.84]	.00	[-.00, .00]	
Sweden	340.34	[-151.12, 831.79]	.01	[-.01, .03]	
Switzerland	16.00	[-685.39, 717.39]	.00	[-.00, .00]	
Taiwan	13.07	[-511.52, 537.66]	.00	[-.00, .00]	
United States	26.25	[-410.76, 463.26]	.00	[-.00, .00]	
Professional or Patient Use					
Physician	125.12	[-177.80, 428.05]	.00	[-.01, .01]	
Medical Specialty					

Cardiovascular	-627.83*	[-1217.93, -37.73]	.02	[-.01, .05]
Clinical Chemistry	-879.70*	[-1549.49, -209.92]	.03	[-.01, .06]
Dental	-443.47	[-1308.27, 421.32]	.00	[-.01, .02]
Gastroenterology/Urology	-433.99	[-1129.51, 261.53]	.01	[-.01, .02]
General Hospital	-892.76**	[-1528.43, -257.09]	.03	[-.00, .07]
Hematology	-303.97	[-1111.45, 503.50]	.00	[-.01, .01]
Microbiology	-217.72	[-984.36, 548.91]	.00	[-.01, .01]
Neurology	-443.77	[-1000.72, 113.19]	.01	[-.01, .03]
Obstetrics/Gynecology	-438.13	[-1448.97, 572.70]	.00	[-.01, .01]
Ophthalmic	-117.60	[-954.20, 719.00]	.00	[-.00, .00]
Radiology	-511.37	[-1089.37, 66.63]	.01	[-.01, .04]
Manufacturer Size				
Small	89.02	[-87.03, 265.07]	.00	[-.01, .02]
Regulatory Pathway				
510(k)	152.73	[-281.42, 586.88]	.00	[-.01, .01]
de novo	465.08	[-142.23, 1072.38]	.01	[-.01, .03]

$$R^2 = .687^{**}$$

Note. A significant *b*-weight indicates the semi-partial correlation is also significant. *b* represents unstandardized regression weights. *sr*² represents the semi-partial correlation squared. *LL* and *UL* indicate the lower and upper limits of a confidence interval, respectively.

* indicates $p < .05$. ** indicates $p < .01$.

Sensitivity analysis with continuous CE marking year variables for commonly approved devices by the FDA and CE marked in Europe

Predictor	<i>b</i>	<i>b</i> 95% CI [LL, UL]	<i>sr</i> ²	<i>sr</i> ² 95% CI [LL, UL]	Fit
(Intercept)	473685.64**	[365298.85, 582072.43]			
CE Mark Certification Year	-234.69**	[-288.35, -181.03]	.34	[.22, .46]	
Country of Origin					
Austria	566.13	[-14.04, 1146.29]	.02	[-.01, .05]	
Belgium	250.58	[-288.64, 789.80]	.00	[-.01, .02]	
Canada	379.02	[-198.11, 956.15]	.01	[-.01, .03]	
China	383.95	[-184.30, 952.19]	.01	[-.01, .03]	
England	164.15	[-352.56, 680.86]	.00	[-.01, .01]	
Finland	300.48	[-332.89, 933.85]	.00	[-.01, .02]	
France	383.73	[-160.45, 927.90]	.01	[-.01, .03]	
Germany	352.01	[-140.62, 844.65]	.01	[-.01, .03]	
Ireland	141.66	[-823.82, 1107.15]	.00	[-.00, .00]	
Israel	384.45	[-114.72, 883.61]	.01	[-.01, .03]	
Italy	428.61	[-411.81, 1269.03]	.00	[-.01, .02]	
Japan	344.00	[-290.78, 978.78]	.01	[-.01, .02]	
Netherlands	231.85	[-310.83, 774.53]	.00	[-.01, .02]	
New Zealand	123.80	[-653.38, 900.97]	.00	[-.00, .01]	
South Korea	13.41	[-567.93, 594.74]	.00	[-.00, .00]	
Sweden	235.94	[-275.03, 746.92]	.00	[-.01, .02]	
Switzerland	171.13	[-560.21, 902.46]	.00	[-.01, .01]	
Taiwan	36.55	[-525.07, 598.16]	.00	[-.00, .00]	
United States	104.13	[-366.49, 574.75]	.00	[-.01, .01]	
Professional or Patient Use					
Physician	-31.41	[-346.18, 283.37]	.00	[-.00, .00]	
Medical Specialty					
Cardiovascular	-474.98	[-1083.86, 133.90]	.01	[-.01, .03]	
Clinical Chemistry	-832.86*	[-1537.05, -128.68]	.02	[-.01, .06]	
Dental	-401.68	[-1327.19, 523.82]	.00	[-.01, .02]	
Gastroenterology/Urology	-370.97	[-1132.40, 390.45]	.00	[-.01, .02]	
General Hospital	-893.25*	[-1572.98, -213.53]	.03	[-.01, .07]	

Hematology	-230.28	[-1115.66, 655.10]	.00	[-.01, .01]
Microbiology	-200.78	[-1039.08, 637.52]	.00	[-.01, .01]
Neurology	-641.24*	[-1211.98, -70.50]	.02	[-.01, .06]
Obstetrics/Gynecology	-293.92	[-1366.21, 778.37]	.00	[-.01, .01]
Ophthalmic	-65.60	[-968.37, 837.16]	.00	[-.00, .00]
Radiology	-397.32	[-1011.08, 216.43]	.01	[-.01, .03]
Manufacturer Size				
Small	70.67	[-108.37, 249.70]	.00	[-.01, .01]
Regulatory Pathway				
510(k)	207.64	[-251.38, 666.66]	.00	[-.01, .02]
de novo	317.50	[-329.90, 964.90]	.00	[-.01, .02]

$R^2 = .634^{**}$

Note. A significant *b*-weight indicates the semi-partial correlation is also significant. *b* represents unstandardized regression weights. sr^2 represents the semi-partial correlation squared. *LL* and *UL* indicate the lower and upper limits of a confidence interval, respectively.

* indicates $p < .05$. ** indicates $p < .01$.