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Table S1 U.S. Food and Drug Administration-authorized cardiovascular AI tools

Device	Company	Clearance year	FDA number	Validation study	Function/key validation
HeartFlow FFRct Analysis	HeartFlow, Inc.	2016	K161772 (510k)	Nørgaard *et al.*, 2014 (70)	84% accuracy *vs.* invasive FFR; improved diagnostic performance over CCTA
HeartFlow Plaque Analysis	HeartFlow, Inc.	2022	K222901 (510k)	Narula *et al.* 2024 (71)	Prospective trial showed high agreement with IVUS
FFRangio™	CathWorks, Ltd.	2018	K182149 (510k)	Fearon *et al.* 2019 (72)	High correlation with wire FFR
EchoGo Core (Strain & EF)	Ultromics Ltd. (UK)	2019	K191171 (510k)	Karagodin *et al.*, 2021(73)	First AI for echo strain; improves early detection via strain
EchoGo Pro (CAD detection)	Ultromics Ltd. (UK)	2021	K201555 (510k)	Upton *et al.*, 2022 (74)	AI improved ischemia detection *vs.* clinicians; aided earlier CAD intervention
EchoGo Heart Failure (HFpEF AI)	Ultromics Ltd. (UK)	2022	K213857 (510k)	Akerman *et al.*, 2025 (75)	AI identified HFpEF from a single echo with high sensitivity
EchoGo Amyloidosis	Ultromics Ltd. (UK)	2024	K240860 (510k)	Slivnick *et al.*, 2025 (76)	AI for amyloidosis; validated *vs.* experts; flags amyloid from single apical-4Ch view
Caption Guidance (Caption AI)	Caption Health (Bay Labs)	2020	DEN190040 (De Novo)	Naran *et al,* 2021 (77)	AI-guided diagnostic-quality echoes
Ligence Heart	Ligence, UAB (Lithuania)	2025	K252105 (510k)	Karužas *et al.*, 2025 (78)	Reliable automated measurements; improved echo lab efficiency
LVivo Seamless & EF	DiA Imaging Analysis Ltd.	2020	K202546 (510k)	Hattub *et al.*, 2020 (79)	Automated LVEF with high agreement with sonographer values
cvi42 Auto (Auto LV Module)	Circle Cardiovascular Imaging	2022	K213998 (510k)	Snel *et al.*, 2021 (80)	Auto measurements equivalent to experts; no significant bias *vs.* manual analysis
RTHawk HeartVista AI MRI	HeartVista, Inc.	2019	K183274 (510k)	Kwong *et al.*, 2023 (81)	Improved diagnostic-quality cardiac MRI planning; reduction in scan planning time
FEops HEARTguide	FEops, N.V. (Belgium)	2021	DEN200030 (De Novo)	Claes *et al.*, 2025 (82)	Accurate prediction of TAVR valve sizing & complications; Breakthrough device for prosthetic valve planning
TAVIguide/TAVIPilot (Caranx)	Caranx Medical (France)	2025	K243884 (510k)	Tchétché *et al.*, 2025 (83)	AI planning matched expert plans; predicted optimal C-arm angles & implant depth
PhysCade System	PhysCade, Inc. (USA)	2025	K250749 (510k)	Heart Rhythm Society 2025 (abstract) (84)	PhysCade localized AF drivers comparable to experts; aims to improve ablation outcomes
Eko Analysis Software (EMAS)	Eko Health, Inc.	2020	K192004 (510k)	Chorba *et al.*, 2021(85)	High sensitivity for murmurs and AF detection
Eko Low Ejection Fraction (ELEFT)	Eko Health, Inc.	2024	K233409 (510k)	Yao *et al.*, 2020(86)	High sensitivity for EF prediction <40%
Tempus ECG-AF	Tempus AI, Inc.	2024	K233549 (510k)	Attia *et al.*, 2019 (87)	High accuracy for detecting AF

Table S1 (*continued*)

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Table S1 (*continued*)

Device	Company	Clearance year	FDA number	Validation study	Function/key validation
Tempus ECG-Low EF	Tempus AI, Inc.	2025	K250119 (510k)	Attia *et al.*, 2019 (88)	High negative predictive value for normal EF
KardiaMobile (AF Detector)	AliveCor, Inc.	2014	K132280 (De Novo)	Lowres *et al.*, 2014 (89)	High sensitivity for AF prediction
KardiaMobile 6L (Brady/Tachy)	AliveCor, Inc.	2017	K171816 (510k)	AliveCor, 2017 (internal) (90)	Cleared for brady/tachy detection; clinical studies showed high agreement with hospital ECG
Apple Watch ECG App	Apple, Inc.	2018	DEN180044 (De Novo)	Perez *et al.*, 2019 (91)	High sensitivity for AF detection
Apple Watch Irregular Rhythm	Apple, Inc.	2018	DEN180042 (De Novo)	Perez *et al.*, 2019 (92)	High sensitivity for AF detection
Samsung ECG & IRN App	Samsung Electronics	2023	K213366 (510k)	Samsung, 2023 (internal) (93)	High sensitivity for AF detection
Fitbit PPG AF Algorithm	Google (Fitbit)	2022	FDA authorization (SA)	Lubitz *et al.*, 2022 (94)	High sensitivity for AF detection
Garmin ECG App	Garmin Intl.	2023	K221774 (510k)	Garmin, 2023 (internal) (95)	High sensitivity for AF detection
Withings ScanWatch ECG	Withings	2025	K240795 (510k)	Withings, 2022 (JPM poster) (96)	High sensitivity for AF detection
Aidoc BriefCase—PE Triage	Aidoc Medical, Ltd. (Israel)	2019	K190014 (510k)	Gilad *et al.*, 2019 (multicenter) (97)	First AI PE triage tool, faster PE diagnosis by prioritizing positives
Rapid RV/ LV (Pulmonary Embolism)	RapidAI (iSchemaView)	2023	K223396 (510k)	RSNA 2022 (abstract) (98)	AI module analyzes chest CT for RV/ LV ratio—shown to measure RV/LV within 5% of radiologist values
Empatica EmbracePlus (Monitoring)	Empatica S.r.l.	2025	K242737 (510k)	Empatica, 2025 (studies) (99)	Wrist-worn AI health monitor—tracks HRV, perfusion; cleared for arrhythmia/seizure monitoring
Biovitals Analytics Engine	Biofourmis Inc. (Singapore)	2019	K183282 (510k)	Tabassian *et al.*, 2019 (100)	Cloud AI for remote monitoring—predicts HF exacerbation & arrhythmias
physIQ Heart Rhythm & Respiration	physIQ, Inc.	2019	K183322 (510k)	Raval *et al.*, 2019 (101)	AI algorithms for wearable ECG/ patch—detects AF and monitors respiratio

Summary of selected FDA-authorized/cleared AI software relevant to cardiovascular diagnosis, including manufacturer, authorization year and identifier (when available), intended use, and supporting evidence/source.

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