November 21, 2025

iCardio.ai
Joseph Sokol
CEO
8601 Beverly Blvd
Floor 2
West Hollywood, California 90048

Re: K251293
Trade/Device Name: CardioVision™
Regulation Number: 21 CFR 870.2200
Regulation Name: Adjunctive Cardiovascular Status Indicator
Regulatory Class: Class II
Product Code: QUO
Dated: April 25, 2025
Received: April 25, 2025

Dear Joseph Sokol:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251293

Device Name
CardioVision™

Indications for Use *(Describe)*
The iCardio.ai CardioVision™ AI is an automated machine learning–based decision support system, indicated as a diagnostic aid for patients undergoing an echocardiographic exam consisting of a single PLAX view in an outpatient environment, such as a primary care setting.

When utilized by an interpreting clinician, this device provides information that may be useful in detecting moderate or severe aortic stenosis. iCardio.ai CardioVision™ AI is indicated in adult populations over 21 years of age. Patient management decisions should not be made solely on the results of the iCardio.ai CardioVision™ AI analysis. iCardio.ai CardioVision™ AI analyzes a single cine-loop DICOM of the parasternal long axis (PLAX).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

1. Summary

Submitter's Name	iCardio.ai
Address	8601 Beverly Blvd, West Hollywood, CA 90048 Re: Joseph Sokol
Contact Person	Joseph Sokol
Title	CEO
Telephone Number	310-614-7904
Email	joseph@icardio.ai
Date Summary Prepared	November 21, 2025
Device Proprietary Name	CardioVision™
Model Number	V 1.0.0
Common Name	CardioVision
Regulation Number	21 CFR §870.2200
Regulation Name	Adjunctive Cardiovascular Status Indicator
Product Code	QUO
Device Class	Class II
Predicate Device	Trade name: EchoGo™Heart Failure Manufacturer: Ultromics Limited; 4630 Kingsgate Cascade Way, Oxford Business Park South, Oxford, Oxfordshire, United Kingdom, OX4 2SU Regulation Number: 21 CFR §870.2200 Regulation Name: Adjunctive Cardiovascular Status Indicator Device Class: Class II Product Code: QUO 510(k) Number: K222463 510(k) Clearance Date: November 23, 2022

2. Device Description

The iCardio.ai CardioVision™ AI is a standalone image analysis software developed by iCardio.ai Corporation, designed to assist in the review of echocardiography images. It is intended for adjunctive use with other physical vital sign parameters and patient information, but it is not intended to independently direct therapy. The device facilitates determining whether an echocardiographic exam is consistent with aortic stenosis (AS), by providing classification results that support clinical decision-making.

The iCardio.ai CardioVision™ AI takes as input a DICOM-compliant, partial or full echocardiogram study, which must include at least one parasternal long-axis (PLAX) view of the heart and at least one full cardiac cycle. The device uses a set of convolutional neural networks (CNNs) to analyze the image data and estimate the likelihood of moderate or severe aortic stenosis. The output consists of a binary classification of "none/mild" or "moderate/severe," indicating whether the echocardiogram is consistent with moderate or severe aortic stenosis. In cases where the image quality is insufficient, the device may output an "indeterminate" result.

The CNNs and their thresholds are fixed prior to validation and do not continuously learn during standalone testing. These models are coupled with pre- and post-processing functionalities, allowing the device to integrate seamlessly with pre-existing medical imaging workflows, including PACS, DICOM viewers, and imaging worklists. The iCardio.ai CardioVision™ AI is intended to be used as an aid in diagnosing AS, with the final diagnosis always made by an interpreting clinician, who should consider the patient's presentation, medical history, and additional diagnostic tests.

3. Indications for use:

The iCardio.ai CardioVision™ AI is an automated machine learning–based decision support system, indicated as a diagnostic aid for patients undergoing an echocardiographic exam consisting of a single PLAX view in an outpatient environment, such as a primary care setting.

When utilized by an interpreting clinician, this device provides information that may be useful in detecting moderate or severe aortic stenosis. iCardio.ai CardioVision™ AI is indicated in adult populations over 21 years of age. Patient management decisions should not be made solely on the results of the iCardio.ai CardioVision™ AI analysis. iCardio.ai CardioVision™ AI analyzes a single cine-loop DICOM of the parasternal long axis (PLAX).

4. Substantial Equivalence

As does the predicate device, EchoGo Heart Failure 1.0, the iCardio.ai CardioVision™ software works with digital imaging and communications in medicine (DICOM) echocardiography images to provide adjunctive information on a patient's cardiovascular condition. Both devices are machine learning-based software products that receive DICOM inputs, perform image processing operations, and return results to assist clinicians in diagnosing cardiovascular conditions. The iCardio.ai CardioVision™ AI specifically aids in the detection of aortic stenosis, while the EchoGo Heart Failure 1.0 aids in detecting heart failure with preserved ejection fraction (HFpEF). Both devices are intended to be used by interpreting clinicians as diagnostic aids, where patient management decisions should not be made solely on the results produced by either system.

Characteristic	**Subject Device: iCardio.ai CardioVision**	**Predicate Device: EchoGo Heart Failure (K222463)**
Regulation	21 CFR 870.2200	21 CFR 870.2200
Product Code	QUO	QUO
Intended Use	Providing adjunctive information on a patient's cardiovascular condition (diagnostic aid for aortic stenosis).	Providing adjunctive information on a patient's cardiovascular condition (diagnostic aid for Heart Failure with Preserved Ejection Fraction (HFpEF)).
Indications for use	The iCardio.ai CardioVision™ AI is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing limited screening echocardiographic exams in an outpatient environment, such as a primary care setting. When utilized by an interpreting clinician, this device provides information that may be useful in detecting moderate or severe aortic stenosis. iCardio.ai CardioVision™ AI is indicated in adult populations over 21 years of age. Patient management decisions should not be made solely on the results of the iCardio.ai CardioVision™ AI analysis. iCardio.ai CardioVision™ AI takes as input a single cine-loop dicom of the parasternal long axis (PLAX) view of the heart, or a full echocardiographic study that includes a PLAX cine loop.	EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF). EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis. EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50%.
Anatomical Site	Identical	Cardiovascular

Modality	Identical	Ultrasound
Intended Users	Identical	The clinician interpreting the report produced by EchoGo Heart Failure 1.0 and making a diagnostic decision.
Intended Patient Population	Adults over age 21	Adults over age 25
Hardware Component?	No	No
Machine learning-based algorithm	Yes	Yes
Operates on DICOM clips	Yes	Yes
Echocardiogram images on device report	Yes	Yes
Auto-view classification	Yes	No Information
Conditions diagnosed	1. Aortic stenosis	1. heart failure with preserved ejection fraction (HFpEF)
Operating platform	Hosted on iCardio platform or on third party infrastructure	Hosted on Ultromics' platform or on third party infrastructure
Pre-clinical Performance Testing	Identical	No animal studies were conducted
Bench Performance Testing	Identical	Technical validation, numerical stability, and regression testing.
Clinical Performance Testing	Validated on a US cohort population, comprising 6+ independent clinical sites representative of the intended use population.	Validated on a US cohort population, comprising 8 independent clinical sites representative of the intended use population.

5. Performance Data

Nonclinical Testing/Software Assessment:

The CardioVision™ software was developed and tested in accordance with iCardio.ai's design control processes and has undergone rigorous safety and performance evaluations. Verification and validation testing were conducted to demonstrate substantial equivalence to the predicate device. Testing was executed under an automated prospective Validation Plan utilizing a traceability matrix to map Design Input Requirements (e.g., RR-series) directly to verification results. This risk-based validation spanned Unit, Intercomponent, and End-to-End testing, subjecting the system to normal use as well as abnormal and edge-case scenarios to demonstrate that the software consistently fulfills its operating parameters.

Clinical Testing

The primary objective of the standalone study was to evaluate the software's ability to detect aortic stenosis using predefined success criteria for sensitivity, specificity, and AUROC. Performance was assessed by comparing the software's outputs against ground truth annotations established by board-certified echocardiographers.

This retrospective, multi-center performance study evaluated 650 echocardiography studies from 608 subjects sourced from 12 independent clinical sites across the United States. The dataset reflects a broad distribution of patient ages, heights, weights, and BMI values. Subgroup analyses confirmed consistent performance across available demographic and imaging-related subgroups, including age, weight, BMI, clinical site, ultrasound machine manufacturers, and disease severity (moderate/severe). Subgroup analyses were unable to be performed with gender or race demographics due to anonymization of data. No data from these sites were used in the training or tuning of the algorithm. The dataset included scans acquired on ultrasound systems from GE, Teratech, Siemens, and Mindray. Scans were not included from handheld ultrasound systems.

Ground truth annotations were derived from echocardiographic assessments performed by experienced Level III echocardiographers, with a majority vote approach used in cases of

disagreement. The study evaluated the software's performance in distinguishing between None/Mild and Moderate/Severe aortic stenosis.

A human factors validation study was conducted to evaluate the usability of CardioVision™ AI for detecting moderate or severe aortic stenosis. All participants successfully completed the critical task of results interpretation without errors.

Study Results

The key performance metrics to evaluate the ability for CardioVision™ to produce an output that is consistent with moderate/severe and normal/mild readings are summarized in Table 1. Seven (7) out of 650 studies (1.077%) were rejected by the device for poor image quality. The full confusion matrix is shown in Figure 1.

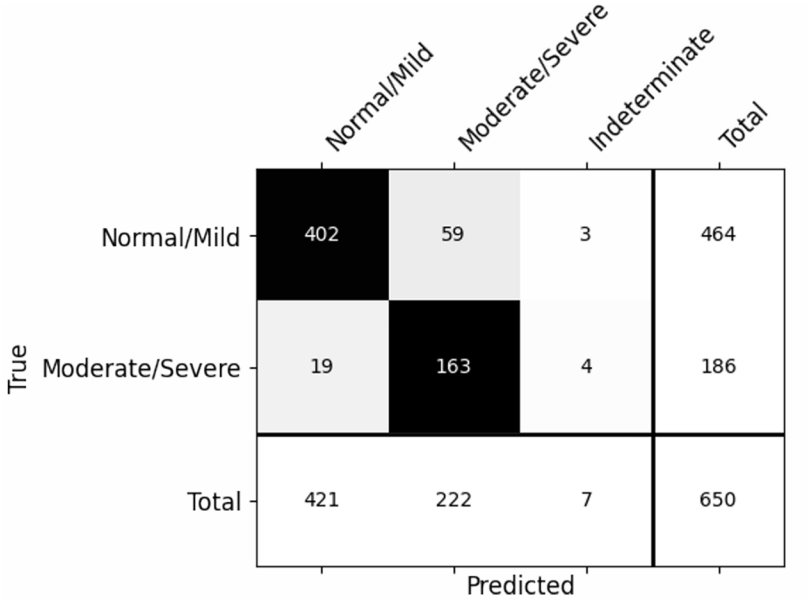

Figure 1: CardioVision™ Confusion Matrix

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Metric	Value
Dataset Size	643
Rejection Rate (%)	1.077
AUROC	0.945
Sensitivity	0.896 (95% Wilson score CI: [0.8427 , 0.9321])
Specificity	0.872 (95% Wilson score CI: [0.8384 , 0.8995])
PPV	0.734 (95% Wilson score CI: [0.673, 0.787])
NPV	0.955 (95% Wilson score CI: [0.931, 0.971])

Table 1: CardioVision™ Performance Results Summary.

Sensitivity quantifies the proportion of true Moderate/Severe aortic stenosis cases correctly identified by the algorithm, representing the software's ability to minimize false-negative classifications. Specificity, conversely, measures the algorithm's capacity to correctly classify individuals without Moderate/Severe aortic stenosis, thereby limiting false-positive results. Without indeterminate outputs, the sensitivity was estimated to be 89.6% (95% Wilson score CI: 84.3%-93.2%), and the specificity was estimated to be 87.2% (95% Wilson score CI: 83.8%-90.0%). When including indeterminate outputs (i.e. rejections) in the sensitivity and specificity calculations, the sensitivity was estimated to be 0.876 (95% Wilson score CI: [0.8213, 0.9162]) and the specificity was estimated to be 0.866 (95% Wilson score CI: [0.8324 , 0.8943]). The combination of high sensitivity and specificity reinforces its substantial equivalence to the predicate device. These predictive values reflect expected performance at this prevalence; real-world performance may vary depending on the underlying disease prevalence in the population.

These levels of sensitivity and specificity exceed the predefined success criteria and those of the predicate device, supporting the claim of substantial equivalence.

Subgroup analyses were performed across patient demographics including age, BMI, and weight as well as ultrasound manufacturer, PLAX subview, and clinical site. See sensitivity and specificity point estimates in Figure 3.

Subgroup	N	Sensitivity	Specificity
B-Mode View			
PLAX Standard	432	0.874	0.888
PLAX Aortic Cusps	127	0.943	0.824
PLAX Paracardial	84	0.885	0.845
Age			
21-44	165	1.000	0.994
45-64	162	0.769	0.926
65-114	316	0.915	0.706
Weight (lb)			
70-174	237	0.875	0.860
175-219	239	0.962	0.888
220-549	166	0.860	0.862
BMI			
16-25	186	0.875	0.877
26-31	251	0.928	0.857
32-76	203	0.877	0.891
Manufacturer			
GE	311	0.883	0.845
Siemens	43	1.000	0.947
Teratech	285	0.909	0.881
Mindray	4	-	-
Site			
OMM	311	0.895	0.843
PRO	120	0.944	0.961
JAC	16	-	-
VIE	10	-	-
VIR	63	0.667	0.870
SAN	97	0.897	0.824
PEN	2	-	-
IMA	22	1.000	0.812
PRI	1	-	-
HAR	1	-	-

Figure 3: Subgroup Analysis Results

No hazardous situations were observed during the study, and no safety risks to subjects were identified.

Study Conclusion: The statistical analysis of the standalone study confirmed that CardioVision™ met the predefined success criteria for sensitivity, specificity. The sensitivity and specificity levels demonstrate that the device is substantially equivalent to the predicate device.

6. Conclusion

iCardio.ai CardioVision™ is substantially equivalent to the predicate device, EchoGo Heart Failure 1.0. The subject device has the same intended use, similar technological characteristics, and principles of operation as the predicate device. The primary difference between the subject and predicate device is the pathology being assessed: iCardio.ai CardioVision™ is intended for detecting aortic stenosis, while EchoGo Heart Failure 1.0 is intended for detecting heart failure with preserved ejection fraction (HFpEF). These differences in the assessed conditions do not alter the intended use of the device and do not raise new or different questions regarding its substantial equivalence when used as labeled. The software verification and validation testing, including clinical performance data, support that iCardio.ai CardioVision™ is substantially equivalent to the predicate in the specified use conditions. Therefore, iCardio.ai CardioVision™ is substantially equivalent to the predicate.