iCardio.ai
Roman Sandler
Co-founder, CTO
1875 Century Park East
Suite 1800
Los Angeles, California 90067

October 10, 2024

Re: K241430
Trade/Device Name: EchoMeasure
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: September 6, 2024
Received: September 6, 2024

Dear Roman Sandler:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241430

Device Name

EchoMeasure

Indications for Use *(Describe)*

iCardio.ai EchoMeasure is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making.

iCardio.ai EchoMeasure is indicated for use in adult patients.

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.

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1 Summary

Submission Number	K241430
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	October 2, 2024
Device Proprietary Name	EchoMeasure
Model Number	V 1.0.0
Common Name	EchoMeasure
Regulation Number	21 CFR 892.2050
Regulation Name	Medical image management and processing system
Product Code	QIH
Device Class	Class II
Predicate Device	Trade name: Libby™ Echo:Prio Manufacturer: Dyad Medical, Inc; 215 Brighton Avenue, Suite 203 Boston, MA 02134 Regulation Number: 21 CFR 892.2050 Regulation Name: Medical image management and processing system Device Class: Class II Product Code: QIH 510(k) Number: K220956 510(k) Clearance Date: July 20, 2022

2 Device Description

iCardio.ai EchoMeasure is a software device used to process previously acquired DICOM-compliant transthoracic cardiac ultrasound images. The software provides automated view classification and quality check of images to then provide several automated estimation of cardiac anatomical measurements and quantities.

iCardio.ai EchoMeasure is a comprehensive software application that seamlessly integrates image pre-processing and quality check of standard cardiac ultrasound views and provides automated measurements of standard cardiac parameters and measurements.

iCardio.ai EchoMeasure is designed to sort through and determine the eligibility criteria for downstream processing, including image quality, and appropriate cardiac view. The following pre-processing steps are considered in making a determination about image eligibility for processing:

- Echocardiographic view classification
- Echocardiographic view overall image quality
- End-Diastolic and End-Systolic frame identification

iCardio.ai EchoMeasure automatically sorts through and recognizes these key parameters to then allow an image to pass for automated processing for measurement of several cardiac parameters, including:

1. Left Ventricular Volume (A2C, A4C, and Biplane; Systole and Diastole)
2. Left Ventricular Diameter (Systole and Diastole)
3. Right Ventricular Diameter
4. Posterior Wall Thickness
5. Aortic Annulus Diameter
6. Left Ventricular Outflow Tract Diameter
7. Sinus of Valsalva Diameter
8. Sinotubular Junction Diameter
9. Left Atrium Dimension
10. Interventricular Septal Thickness

Machine learning based view detection, quality grading, key frame selection, automated keypoint detection and segmentation form the basis of the software's automated analysis.

iCardio.ai EchoMeasure output is intended for consumption by 3rd party software and hardware vendors. Additionally iCardio.ai has a native browser interface for reviewing the report summary as well as a functionality to download the available report in PDF format. The iCardio.ai EchoMeasure browser interface allows the end user to view both 2D image and cine loops determined by the software and to review the automated measurements

produced. It is the option of the reviewing clinician to accept, reject, edit, or ignore the output provided by iCardio.ai EchoMeasure.

A report, automatically generated from the calculated parameters, is returned to the interpreting clinician. This software device aims to aid diagnostic review and analysis of echocardiographic data, patient record management, and reporting. It also features tools for organizing and displaying quantitative data from cardiovascular images acquired from ultrasound scanners. It is exclusively for use by qualified clinicians.

3 Indication for use:

iCardio.ai EchoMeasure is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making.

iCardio.ai EchoMeasure is indicated for use in adult patients.

4 Substantial Equivalence

As does the predicate device, the iCardio.ai EchoMeasure software works with digital imaging and communications in medicine (DICOM) echocardiography images and can be deployed on a secure cloud server or on-premise server. Both devices are software products that receive DICOM inputs, perform image processing operations and return results.

The following table shows a summary of the similarities and differences:

Characteristic	**Subject Device: iCardio.ai EchoMeasure**	**Predicate Device: Libby™ Echo:Prio**
Regulation	21 CFR 892.2050	21 CFR 892.2050
Product Code	QIH	QIH
Intended Use	Identical	Quantification of cardiovascular function from an echocardiogram

Indications for use	iCardio.ai EchoMeasure is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making. iCardio.ai EchoMeasure is indicated for use in adult patients.	Libby Echo:Prio is software that is used to process previously acquired DICOM-compliant cardiac ultrasound images, and to make measurements on these images in order to provide automated estimation of several cardiac measurements. The data produced by this software is intended to be used to support qualified cardiologists, sonographers, or other licensed professional healthcare practitioners for clinical decision-making. Libby Echo:Prio is indicated for use in adult patients.
Anatomical Site	Identical	Cardiovascular Structures
Modality	Identical	Ultrasound
Intended Users	Identical	Accredited echocardiographers and sonographers
Intended Patient Population	Identical	Adults
Hardware Component?	No	No
Machine learning-based algorithm	Yes	Yes
Operates on DICOM clips	Yes	Yes
Echocardiogram images	Yes	Yes

on device report		
Auto-view classification	Yes	Yes
Image-quality Checks	Yes	No Information
Measurements	1. Left Ventricular Volume (A2C, A4C, and Biplane; Systole and Diastole) 2. Left Ventricular Diameter (Systole and Diastole) 3. Right Ventricular Diameter 4. Posterior Wall Thickness 5. Aortic Annulus Diameter 6. Left Ventricular Outflow Tract Diameter 7. Sinus of Valsalva Diameter 8. Sinotubular Junction Diameter 9. Left Atrium Dimension 10. Interventricular Septal Thickness	1. Ejection Fraction 2. Left Ventricle Volume (A2C, A4C, Biplane; Systole and Diastole)
Contours/Keypoints overlaid on echocardiogram images	Yes	Yes
User confirmation / rejection of result	Yes	Yes
Manual editing of automated result by user	No	Yes

5 Performance Data

The EchoMeasure software was developed and tested in accordance with iCardio.ai's design control processes and has been subjected to extensive safety and performance testing. Verification and validation testing was conducted to demonstrate the substantial equivalence of the subject device to the predicate. The objective of the iCardio.ai EchoMeasure standalone study was to demonstrate successful device performance using rational, prospectively-defined success criteria for each endpoint. Based on the 95% CI for

the bivariate linear regression coefficient slope (BLRSC), each endpoint was designed to estimate the "worst-case" error for a specific group of linear and volumetric measurements. The error was defined as the difference between the software output and the mean of three (3) clinician-derived annotations. Based on these criteria, it was possible to confirm that the estimated worst-case BLRSC was above a certain threshold.

The results show that the performance of the iCardio.ai EchoMeasure software device was validated to meet the predetermined accuracy limits of the study for all measurements.

This was a retrospective, standalone performance study using data sampled from two independent clinical sites from two different US states to assure a wide sample of imaging data and patient demographics. Data included 200 comprehensive echocardiography studies from 200 distinct patients. A single DICOM was selected for the relevant view (either PLAX, A2C, or A4C) based on the view-confidence score. No data from these sites was used for the training or tuning of the algorithm. Patient demographic information on the dataset can be seen in Fig. 1. The dataset included 92 (46%) males and 108 (54%) females. It included data from GE and Teratech ultrasound machines.

	patient_age	patient_height	patient_weight	patient_bmi
count	200.0	200.0	200.0	200.0
mean	61.6	66.6	195.44	30.92
std	17.52	4.22	50.06	7.25
min	22.0	59.0	85.0	16.6
25%	48.0	63.0	158.75	25.67
50%	64.5	66.5	185.0	29.75
75%	74.25	70.0	225.25	34.97
max	92.0	77.0	394.0	67.62

Fig. 1: Patient demographic information

Ground truth annotations were established using manual measurements and segmentations performed by experienced clinicians (using the mean of three experienced US-based cardiac sonographers per case to establish the Ground Truth). The sonographers used in the standalone study were independent of those sonographers used to annotate the training data.

The output showed very good agreement with the established Ground Truth. In no instance did the worst-case BLRSC for a given measurement (calculated based on the 95% confidence interval) fall below the predetermined, minimum allowable BLRSC threshold. Additional metrics including median absolute error, median percent error, Pearson correlation, Spearman correlation, and Individual Equivalence Coefficient were also evaluated and detailed results are reported in labeling.

Subgroup analyses also revealed that the worst-case BLRSC rarely exceeded the prescribed accuracy/error limits for any subgroup investigated, including based on age, gender, weight, BMI, or Ultrasound scanner manufacturer. These data support that there appears to be no biased performance of the software related to a particular set of imaging characteristics or subject demographic variables. Finally, no hazardous situations occurred during the study, and no apparent safety risk to subjects were identified.

Study Conclusion: According to the statistical analysis of the results from this standalone software performance study, the investigation was successful. The subject population evaluated in this study was representative of the target population that the iCardio.ai EchoMeasure software was designed to be applied on (i.e. the US population).

The results of this study show that the performance of the software met the success criteria. The results also show that the results of the software are not systematically different within specific subgroups of subjects or ultrasound manufacturers.

A summary of the results can be found in the Table 1 below:

Table 1: Model Performance Summary

Tool	Metric	Value [95% CI]
Aortic Annulus Diameter	BLRSC	0.952 [0.829, 1.082]
Left Ventricular Outflow Tract Diameter	BLRSC	1.112 [0.970, 1.255]
Sinus of Valsalva Diameter	BLRSC	0.932 [0.848, 1.015]
Sinotubular Junction Diameter	BLRSC	0.773 [0.676, 0.869]
Left Atrial Diameter	BLRSC	0.888 [0.830, 0.944]
Left Ventricular Diameter (Systole)	BLRSC	0.860 [0.776, 0.945]
Left Ventricular Diameter (Diastole)	BLRSC	0.791 [0.710, 0.869]
Right Ventricular Diameter (Diastole)	BLRSC	0.786 [0.715, 0.854]
Interventricular Septal Thickness	BLRSC	0.833 [0.731, 0.934]
Posterior Thickness	BLRSC	0.785 [0.664, 0.904]
Left Ventricular Volume (A4C-Systole)	BLRSC	1.059 [0.977, 1.158]
Left Ventricular Volume (A4C-Diastole)	BLRSC	0.943 [0.869, 1.013]
Left Ventricular Volume (A2C-Systole)	BLRSC	0.936 [0.777, 1.048]
Left Ventricular Volume (A2C-Diastole)	BLRSC	1.005 [0.917, 1.096]
Biplane Left Ventricular Volume (Systole)	BLRSC	0.906 [0.795, 0.993]
Biplane Left Ventricular Volume (Diastole)	BLRSC	0.972 [0.893, 1.054]

6 Conclusion

iCardio.ai EchoMeasure is substantially equivalent to the predicate device. The subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences between subject and predicate device in indications and output do not alter the intended use of the device and do not raise new or different questions regarding its safety and effectiveness when used as labeled. The software verification and validation testing data, including the standalone software performance assessment study data, support the safety of the devices and demonstrate that the iCardio.ai EchoMeasure software should perform as intended in the specified use conditions. Therefore, iCardio.ai EchoMeasure is substantially equivalent to the predicate.