June 30, 2025

Mycardium AI Limited
% Michael Pogose
Director of Quality Assurance and Regulatory Affairs
Hardian Health Ltd t/a Hardian Health
c/o Galloways, 3rd Floor 21 Perrymount Road
Haywards Heath, RH16 3T
United Kingdom

Re: K250670
Trade/Device Name: EchoConfidence (USA)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 30, 2025
Received: June 2, 2025

Dear Michael Pogose:

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,

for

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.

510(k) Number *(if known)*
K250670

Device Name
EchoConfidence (USA)

Indications for Use *(Describe)*
EchoConfidence is Software as a Medical Device (SaMD) that displays images from a Transthoracic Echocardiogram, and assists the user in reviewing the images, making measurements and writing a report.

The intended medical indication is for patients requiring review or analysis of their echocardiographic images acquired for their cardiac anatomy, structure and function. This includes automatic view classification; segmentation of cardiac structures including the left and right ventricle, chamber walls, left and right atria and great vessels; measures of cardiac function; and Doppler assessments.

The intended patient population is both healthy individuals and patients in whom an underlying cardiac disease is known or suspected; the intended patient age range is for adults (>= 22 years old) and adolescent in the age range 18 – 21 years old.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K250670

510(k) Summary

Prepared on: 2025-06-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Mycardium AI Limited
Applicant Address	The Spine 2 Paddington Village Liverpool L7 3FA United Kingdom
Applicant Contact Telephone	07812167512
Applicant Contact	Mr. Michael Walker
Applicant Contact Email	michael.walker@mycardium.com
Correspondent Name	Hardian Health Ltd t/a Hardian Health
Correspondent Address	c/o Galloways, 3rd Floor 21 Perrymount Road Haywards Heath RH16 3T United Kingdom
Correspondent Contact Telephone	+44 7958656882
Correspondent Contact	Mr. Michael Pogose
Correspondent Contact Email	mike@hardianhealth.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	EchoConfidence (USA)
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K210791	us2ai	QIH
K191171	EchoGo Core	QIH

Device Description Summary

21 CFR 807.92(a)(4)

EchoConfidence is Software as a Medical Device (SaMD) that displays images from a Transthoracic Echocardiogram, and assists the user in reviewing the images, making measurements and writing a report.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

EchoConfidence is Software as a Medical Device (SaMD) that displays images from a Transthoracic Echocardiogram, and assists the user in reviewing the images, making measurements and writing a report.

The intended medical indication is for patients requiring review or analysis of their echocardiographic images acquired for their cardiac anatomy, structure and function. This includes automatic view classification; segmentation of cardiac structures including the left and right ventricle, chamber walls, left and right atria and great vessels; measures of cardiac function; and Doppler assessments.

The intended patient population is both healthy individuals and patients in whom an underlying cardiac disease is known or suspected; the intended patient age range is for adults (>= 22 years old) and adolescent in the age range 18 – 21 years old.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Age: It is acknowledged that the CDRH typically defines adults as individuals greater than or equal to 22 years of age, and those between the ages of 18-21 as older adolescents, which may require special consideration. However, numerous SCMR and American College of Cardiology consensus statements and clinical practice guidelines for a number of cardiac pathologies define children as anyone below the age of 18 years of age, and adults greater than or equal to 18 years of age, with no special consideration or expected differences between those aged 18-21 vs. >= 22 years of age. As such, this subgroup was not independently evaluated within the clincial evaluation of EchoConfidence: adults have been considered to be people >= the age of 18 years.

Technological Comparison 21 CFR 807.92(a)(6)

Both devices are intended to be used to segment and quantify structural and functional measure of the heart from cardiac echo images. Both utilise artificial intelligence to segment and analyse the echo scans. The patient population and the intended users are the same. However, the similar device does not allow for the manual editing of contours, provide automatic view classification and provides a limited number of outputs, when compared to the subject device. These limitations, however, are independent of the output variables and will not impact the accuracy of these measures. With these factors in mind, the subject device demonstrates an equivalence to the predicate device, with respect to the technical characteristics.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing included the use of data obtained through the internal risk management process, software verification and validation testing, usability engineering, internal validation. Testing was conducted to verify compliance with specified requirements in accordance with EN ISO 14971, IEC 62304, IEC 62366-1 and IEC 62366-2.

The primary acceptance criteria are based on a comparison of “mean absolute error” (MAE) of the AI against the 3 human expert reads against the “mean absolute error” of the 3 human experts against each other.

This is calculated for every one of the 200 patient cases. The difference between the MAE of the AI against the 3 human experts and the 3 human experts against each other is then calculated for each case. The central tendency of the distribution of these differences is summarized by the median, and bootstrapped confidence intervals are calculated and then it is expressed as a percentage of the 3 human expert MAE.

The primary criteria for acceptance are that the upper 95% confidence interval is less than +25%. In the majority of cases the point estimate is substantially below 0% (i.e. the AI agrees with the humans more than they agree with each other.

The 200 echocardiographic cases were collected from 200 different patients. As a note, a single comprehensive echocardiogram from a single patient often consists of multiple video and image acquisitions (often in excess of 100 vidoes and images, and in very detailed studies may exceed even 300 acquisitions). From these different videos and images of the heart, multiple measurements are made on this image (EchoConfdience contains over 100 measurements).

Geographic Location: all cases were delivered via a US Echocardiography CoreLab. In addition, our three human experts were US accredited and US based employed by the US CoreLab.

Demographic Breakdown: the demographic breakdown of the 200 cases is tabulated in the Instructions for Use, with subgrouping by age ranges, gender, ethnicity, cardiac pathologies, ultrasound equipment vendor and model, year of scan and qualitative image quality. In addition, whilst in many cases the statistical power is reduced within a subgroup, the entire primary analysis has been performed and reported for each of the 20 subgroups. The reporting shows that the point estimation is such that the AI agrees with the human experts better than the humans agree with themselves: that the upper 95% confidence interval is also <0%, and well below the +25% criterion standard; across the subgroups, whilst there is increased noise and wider confidence intervals (as would be expected with fewer cases), the finding is consistent amongst the subgroups.

The use of +25% as the criterion standard for the upper 95% confidence interval on the estimate of the difference between the AI MAE and the expert human MAE is from publicly available documentation on the us2ai predicate (K210791) in which the manufacturer utilized the same criterion standard but based on a parametric rather than non-parametric derived estimate of the “variability”.

Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per the FDA Guidance documents "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submission for Management of Cybersecurity in Medical Devices".

The reference standard was derived by having each of the 3 human experts independently perform the measurements for each echo as if they were performing it for clinical use. A physician, again as would be consistent with clinical practice, reviewed and adjusted if needed ~10% of the measurements. The analysis process for the primary endpoint, because it calculates the mean absolute error of the AI from the human experts and each of the human experts from each other, preserves the individual measurements of each expert and doesn't average it. Bland-Altman analysis was reported, based on averages of the human experts' measurements.

The data used in the validation study was derived from a US based CoreLab that did not supply any training data. These data were derived from non-public data sources. Furthermore, the data used is kept on a servers controlled by the CoreLab. This prevents the validation test data entering the training dataset.

The dataset used for development and internal testing was derived from a separate source and not from the US based CoreLab. Within our development dataset we name files after a hash of the source DICOM and source patients are specifically tagged as being either used for training or internal testing.

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, EchoConfidence raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness.