November 15, 2024

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

Re: K242062
Trade/Device Name: 1CMR Pro
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: October 18, 2024
Received: October 18, 2024

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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
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)*

K242062

Device Name

1CMR Pro

Indications for Use *(Describe)*

1CMR Pro is software that displays, analyses and transfers DICOM cardiovascular images acquired in Cardiovascular Magnetic Resonance (CMR) scanners, specifically structure, function and flow in the heart and major vessels using multi-slice, multi-phase, multi-parametric and velocity encoded CMR images. It is compatible with 1.5T and 3T CMR acquisitions.

The intended patient population is both known healthy patients and patients in whom an underlying cardiac disease is suspected. The standard viewing tools are indicated for all patients. The AI analysis components are not intended for use in patients with a known congenital cardiac abnormality, children (Age<18), or individuals with pacemakers (even if MRI compatible).

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.

510(k) #: K242062

510(k) Summary

Prepared on: 2024-11-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Mycardium AI Limited
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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	1CMR Pro
Common Name	Medical image management and processing system
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Product Code(s)	QIH, LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220624	AI4CMR	LLZ
K213998	Device Trade Name Cvi42 auto	QIH

Device Description Summary

21 CFR 807.92(a)(4)

1CMR Pro is software that displays, analyses and transfers DICOM cardiovascular images acquired in Cardiovascular Magnetic Resonance (CMR) scanners, specifically structure, function and flow in the heart and major vessels using multi-slice, multi-phase, multi-parametric and velocity encoded CMR images. It is compatible with 1.5T and 3T CMR acquisitions.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

1CMR Pro is software that displays, analyses and transfers DICOM cardiovascular images acquired in Cardiovascular Magnetic Resonance

(CMR) scanners, specifically structure, function and flow in the heart and major vessels using multi-slice, multi-phase, multi-parametric and velocity encoded CMR images. It is compatible with 1.5T and 3T CMR acquisitions.
The intended patient population is both known healthy patients and patients in whom an underlying cardiac disease is suspected. The standard viewing tools are indicated for all patients. The standard viewing tools are indicated for all patients. The AI analysis components are not intended for use in patients with a known congenital cardiac abnormality and children (Age<18) or pacemakers (even if MRI compatible).

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 1CMR Pro: adults have been considered to be people >= the age of 18 years.

Technological Comparison 21 CFR 807.92(a)(6)

There is a minor difference with the primary predicate - 1CMR Pro provides a user interface to allow users to view analysis whereas the predicate, AI4CMR, requires the user incorporating it into their DICOM application of choice to be responsible for implementing a user interface - however the intended use for Cardiac MRI image analysis is the same.

There is a minor difference with the secondary predicate - the secondary predicate device can also be used on CT images and can be used for calcium scoring and to confirm the presence or absence of physician identified lesions - however the use with Cardiac MRI (CMR) images is the same.

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.

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”.

1CMR Pro was clinically validated through non-clinical performance testing on independent validation datasets, to confirm acceptable accuracy and precision of the output measurements and segmentations.

The accuracy of 1CMR Pro was tested on a dataset of 64 adults (ranging between 18 and 84 years, 39% female, with a mixture of cardiac pathologies [healthy, dilated cardiomyopathy, hypertrophic cardiomyopathy, myocardial infarction, left ventricular hypertrophy]), using images collected on either 1.5T or 3T scanners (range of Siemens, Philips, and GE). This comprised 3 types of assessment: DICE scores, Accuracy and Precision. This was done by 3 independent US based truthers, all with >5 years experience.

Results: DICE scores: DICE scores were used for the LV short axis contours. The AI was superior to truthers (In brief, AI vs. Truther overall DICE scores averaged 0.90 compared to Truther vs. Truther DICE scores average 0.89). Both humans and AI were more variable at the base of the heart.

Results: Accuracy: Accuracy was assessed for 14 variables: volumes (LV and RV: EDV, ESV, SV; LA, RA), LV mass, function (LVEF, RVEF, TAPSE, MAPSE, GLS). The AI passed all assessments and the majority of analyses showed that the AI exceeded that of the truthers. There were variations in the performance: the LV was more accurate than the RV, analysis in health more accurate than in disease. There were no differences by age or ethnicity. Performance was higher for Siemens vs non Siemens scanners – note the sample size was smaller for non-Siemens scanners (53 vs. 11 [8 Philips + 3 GE]).

The precision of 1CMR was tested on a dataset of 110 adults (ranging from 22 to 72 years, 35% female, with a mixture of cardiac pathologies, scanned twice.

Results: Precision: Precision was performed for LV variables. The AI passed was superior to humans for all measurements and prior FDA cleared software. Results include:
AI vs Clinician coefficient of variation (CoV) for LVEF: 4.3±0.3% vs 7.0±0.6%, p<0.001,
AI vs Clinician CoV for LVmass: 3.8±0.3% vs 4.6±0.3%, p<0.001,
AI vs Clinician CoV for LVEDV: 4.9±0.4% vs 6.2±0.5% p=0<0.001,
AI vs Clinician CoV for LVESV: (5.4 (4.3-6.4%) vs 11.4 (6.5-15.6%, p=0.008).

In addition, 1CMR Pro was assessed against other cleared software (Circle CVI v 5.13). The testing here used no human editing. 1CMR Pro exceeded the performance in every measured variable:
LVEF: 4.2% (95% CI: 3.5-5.0%) vs 10.4% (95% CI: 6.8-14.0%), $p<0.001$;
LV mass: 4.2% (95% CI: 3.5-5.0%) vs 10.4% (95% CI: 6.8-14.0%), $p<0.001$;
LVEDV: 5.4% (95% CI: 4.3-6.4%) vs 11.4 (95% CI: 6.5-15.6%), $p=0.008$).

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, 1CMR Pro raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness.