February 11, 2026

Ai4medimaging Medical Solutions S.A.
℅ Sandra Soniec
Managing Director
Meditec Consulting GmbH
Obermoosstrasse 23
Boll, Berne 3067
Switzerland

Re: K252084
Trade/Device Name: AI4CMR v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: January 15, 2026
Received: January 15, 2026

Dear Sandra Soniec:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252084

Please provide the device trade name(s).

AI4CMR v2.0

Please provide your Indications for Use below.

AI4CMR software is designed to report cardiac function measurements (ventricle volumes, ejection fraction, indices, etc.) from 1.5T and 3T magnetic resonance (MR) scanners. AI4CMR uses artificial intelligence to automatically segment and quantify the different cardiac measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making. The user incorporating AI4CMR into their DICOM application of choice is responsible for implementing a user interface.
AI4CMR also supports clinical diagnostics by calculating flow measurements of vascular structures in 2D phase-encoded cardiac MR images.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

1 General Information

510(k) Sponsor	AI4MedImaging Medical Solutions S.A.
Address	Rua do Parque Poente, lt 32 4705-002 Sequeira, Braga Portugal
Correspondence Person	Sandra Soniec Senior consultant meditec Consulting GmbH, Switzerland
Contact Information	Email: soniec@meditec-consulting.ch Phone: +41 31 535 3193
Date Prepared	February 10, 2026

2 Subject Device

Proprietary Name	AI4CMR v2.0
Common Name	AI4CMR
Classification Name	Automated radiological image processing software
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH, LLZ
Regulatory Class	II

3 Predicate and Reference Device

Proprietary Name (Predicate Device)	AI4CMR v1.0
Premarket Notification	K220624
Common Name	AI4CMR
Classification Name	Automated radiological image processing software
Regulation Number	21 CFR 892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH
Regulatory Class	II

Proprietary Name (Reference Device)	cvi42 Software Application
Manufactured by	Circle Cardiovascular Imaging, Inc.
Premarket Notification	K242781
Common Name	cvi42
Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Regulation Name	Medical Image Management and Processing System
Product Code	QIH, LLZ
Regulatory Class	II

4 Device Description

AI4CMR v2.0 is a cloud-based solution designed to integrate to any third-party DICOM viewer application where the DICOM viewer serves as the user interface and the interface to a PACS or scanner for AI4CMR. AI4CMR is implemented as a plug-in to the DICOM viewer by the user and automatically processes and analyses cardiac MR images received by the DICOM viewer to quantify relevant cardiac function metrics as well as analytical flow quantification and makes the information available to the user at the user's discretion.
The following are the cardiac function metrics quantified and reported by the software:

Quantitative Analysis
The subject device performs the following:
Cardiac function measurements in cine sequences

- Anatomy and tissue segmentation
- LV/RV stroke volume
- LV/RV cardiac output
- LV/RV ejection fraction
- LV/RV end-diastolic volume
- LV/RV end-systolic volume

Analytical flow quantification in 2D Phase-Contrast Sequences (2DFlow)

- Total Forward/Backward Net Volumes
- Regurgitation Fraction
- Effective Volume per Minute
- Maximum Velocity
- Pressure Gradient
- Flow values

Reporting
The subject device enables the following metrics to be reported as desired by the user:
Cardiac function measurements

- LV/RV stroke volume
- LV/RV cardiac output
- LV/RV ejection fraction
- LV/RV end-diastolic volume
- LV/RV end-systolic volume
- LV myocardial mass
- LV/RV end-systolic frame

- LV/RV end-diastolic frame
- LV/RV end-systolic volume index
- LV/RV end-diastolic volume index
- LV/RV stroke volume index
- Myocardium mass index
- Cardiac index

Analytical flow measurements (2DFlow)

- Total Forward Volume
- Total Backward Volume
- Total Volume
- Total Net Positive Volume
- Total Net Negative Volume
- Regurgitation Fraction
- Volume per Minute
- Effective Volume per Minute
- Maximum Pressure Gradient
- Maximum Velocity
- Minimum Velocity
- Maximum Mean Velocity
- Maximum Flow
- Minimum Flow

5 Indications for Use

AI4CMR software is designed to report cardiac function measurements (ventricle volumes, ejection fraction, indices, etc.) from 1.5T and 3T magnetic resonance (MR) scanners. AI4CMR uses artificial intelligence to automatically segment and quantify the different cardiac measurements. Its results are not intended to be used on a stand-alone basis for clinical decision-making. The user incorporating AI4CMR into their DICOM application of choice is responsible for implementing a user interface. AI4CMR also supports clinical diagnostics by calculating flow measurements of vascular structures in 2D phase-encoded cardiac MR images.

6 Comparison of Technological Characteristics

Feature, Function	Subject device AI4CMR v2.0	Predicate Device AI4CMR v1.0 (K220624)	Reference Device Circle cvi42 (2D Flow feature) (K242781)	Comparison
Operating System	cross-platform	cross-platform	cross-platform	Same
Platform	client-server	client-server	client-server	Same
Scanners	Both 1.5T and 3.0T	Both 1.5T and 3.0T	Both 1.5T and 3.0T	Same
Image Input	Supports DICOM 3.0	Supports DICOM 3.0	Supports DICOM 3.0	Same
Data Acquisition Protocol for flow and volume analysis	Cardiovascular images: multi-phase, multi-slice acquired from MRI scanners	Cardiovascular images: multi-phase, multi-slice acquired from MRI scanners	Cardiovascular images: multi-phase, multi-slice acquired from MRI scanners	Same
Workflows	Basic 2D, Basic 3D, 2D Phase Contrast	Basic 2D, Basic 3D	Basic 2D, Basic 3D, 2D Phase Contrast, additional 2D Flow	Similar
Image Display Mode	N/A	N/A	N/A	Same
Image Navigation Tools	N/A	N/A	N/A	Same
3D image review	N/A	N/A	N/A	Same
Cardiac View	N/A	N/A	N/A	Same
Orientation Label	N/A	N/A	N/A	Same
Cross-reference indicator	No	No	No	Same
View DICOM Data	Yes, users can view the DICOM information about the patient, study and current image via the	Yes, users can view the DICOM information about the patient, study and current image via the	Yes, users can view the DICOM information about the patient, study and current image via the	Same

Feature, Function	Subject device AI4CMR v2.0	Predicate Device AI4CMR v1.0 (K220624)	Reference Device Circle cvi42 (2D Flow feature) (K242781)	Comparison
	third-party viewer	third-party viewer	third-party viewer	
Secondary Capture	N/A	N/A	N/A	Same
Segmentation of region of interest	Automatic	Automatic	Automatic	Same
Phase Error Correction	No	No	No	Same
Quantitative Analysis, Flow	Yes, 2D Phase Contrast	No	Similar, comparative Performance Evaluation confirmed equivalence	Similar
Quantitative Analysis, Area	No	No	No	Same
Quantitative Analysis, Distance	No	No	No	Same
Quantitative Analysis, Volume in 4D Flow Workflow	No	No	No	Same
Directional/vector display of the blood particle travel	No	No	No	Same
Flow quantification of valves	No	No	No	Same
Automatic selection of the Temporal Landmark time points	No	No	No	Same

7 Model Card

Model Overview	Model Name: 2D Flow Segmentation Version: 1.0.0 Developer / Manufacturer: AI4CMR Model Category: Convolutional Neural Network (U-Net architecture) Primary Function: Automated segmentation of major cardiac vessels on 2D flow CMR (PC-MRI) images. Regulatory Classification: Class II, System, Image Processing, Radiological Short Description: The model uses a U-Net convolutional neural network to generate pixel-wise segmentation masks of cardiac vessels (aorta, pulmonary artery) on phase-contrast MRI images. The segmentation supports calculation of flow and velocity profiles and quantification.
Intended Users	AI4CMR shall be used by qualified medical professionals, experienced in examining and evaluating magnetic resonance images as a support tool that provides relevant clinical information. The software is not intended to determine or recommend a course of action or treatment for a patient.
Indications for Use	AI4CMR supports clinical diagnostics by calculating flow measurements of vascular structures in 2D phase-encoded cardiac MR images. Its results are not intended to be used on a stand-alone basis for clinical decision-making.
Model Summary	AI4CMR uses a convolutional neural network–based segmentation model to outline vascular structures on magnitude and phase images. A user-selected seed point localizes the vessel, and generated contours may be manually edited by the clinician. The model is “locked,” meaning it does not adapt or change with new input data.
AI-based 2D Flow Segmentation – Model Development	The AI-based vessel segmentation model was developed using retrospective clinical data comprising 167 cardiac MR cases from 61 adult subjects (32% female, 68% male; age range 17–89 years, mean age 62), obtained from a tertiary Western European hospital. Images were acquired using standard cardiac MR 2D phase-contrast flow imaging protocols on 1.5T and 3T scanners. The dataset included both normal and pathological cases (e.g., cardiomyopathies, aortic disease, and valvular disease) and preserved real-world variability in anatomy, motion artifacts, and image quality, with no exclusions based solely on image quality. An expert reader (EACVI level III) independently annotated all cases using standard segmentation guidelines to ensure consistency and algorithm generalizability, with intra-reader reliability maintained by following established standards.

	In total, 296 vessel samples (ascending aorta, descending aorta, and pulmonary artery) were included. Data were stratified by vessel type and split at the subject level into training, validation, and independent test sets (70%/15%/15% of subjects), with all vessels and repeated acquisitions from each subject assigned exclusively to a single dataset to prevent data leakage. Segmentation performance was evaluated using the Dice Similarity Coefficient (DSC), with values greater than 0.70 defined a priori as the acceptance criterion based on established evidence of clinically usable vessel delineation. On the independent test set, the model achieved DSC values of 0.952 for the ascending aorta, 0.957 for the descending aorta, and 0.952 for the pulmonary artery, exceeding the predefined acceptance threshold. Model generalizability was further supported through multi-vendor evaluation across Siemens, GE, and Philips MRI systems and comparison with a legally marketed reference device.
Performance Summary	Performance was evaluated using internally validated datasets and independent multi-center data. Segmentation Performance: • Dice: 0.95 • Precision: 0.96 • Recall: 0.95 Agreement With Predicate/Reference Measurements: (In multi-vendor, multi-center evaluation) • Total Forward Volume (TFV): ICC 0.95 • Total Backward Volume (TBV): ICC 0.82 • Maximum Velocity (Vmax): ICC 0.95
Generalizability	The model was evaluated on images from multiple centers and major MRI vendors, covering a broad range of adult patient presentations. Validation included diverse flow encoding settings and scanner configurations.
Limitations	• Not validated on pediatric patients under 18 years • Not designed for 4D flow MRI • Not validated on congenital anomalies with extreme vessel distortion • Performance may decrease on images with very low signal-to-noise ratio or poor contrast.
Warnings & Precautions	• The segmentation results must be reviewed and, if necessary, corrected by a qualified clinician. • Segmentation inaccuracies may lead to incorrect flow quantification. • Not intended to provide a diagnosis or replace expert clinical judgment.

User Interaction	• The user provides a seed point to identify the target vessel. • Segmentation contours are displayed on magnitude and phase images. • Manual editing tools allow correction or refinement of the AI-generated contours.
Version History	Version 1.0, Initial Release

8 Performance Data

Safety and performance of AI4CMR v2.0 were evaluated and verified in accordance with software design specifications and applicable performance standards through software verification and validation activities. Software validation was performed in accordance with IEC 62304:2006+A1:2015 and applicable FDA guidance, including *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Non-clinical verification and validation demonstrated that the device meets its design requirements and intended use and is as safe and effective as the predicate device, with risks managed through a formal risk management process. Performance evaluation comparing AI4CMR v2.0 with the legally marketed reference device cvi42 (K242781), using both synthetic and real-world phase-contrast CMR datasets, demonstrated consistent agreement across vendors for three primary flow measurements—total forward volume (TFV), total backward volume (TBV), and maximum velocity (Vmax)—with intraclass correlation coefficients of 0.95, 0.82, and 0.95, respectively.

The additional 2D Flow outputs are not independent measurements but are deterministic mathematical derivatives of these validated core metrics. Technical validation of the AI-based vessel segmentation demonstrated robustness against manual reference annotations (mean Dice Similarity Coefficient of 0.857), supporting accurate and reproducible flow quantification under realistic clinical variability.

Clinical validation was not required for this modification, as the feature provides deterministic quantitative measurements without diagnostic interpretation. Safety and effectiveness are adequately supported through non-clinical performance testing, multi-vendor evaluation, and agreement with the legally marketed reference device. These results adequately support a determination of substantial equivalence in accordance with 21 CFR 807.100(b)(2)(ii)(B).

9 Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, the AI4CMR v2.0 raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy, and performance.