February 1, 2024

Pie Medical Imaging B.V.
Annemiek Bouts
Regulatory Affairs Coordinator
Philipsweg 1
Maastricht, Limburg 6227 AJ
Netherlands

Re: K232007
Trade/Device Name: CAAS MR Solutions
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 18, 2023
Received: December 18, 2023

Dear Annemiek Bouts:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232007

Device Name
CAAS MR Solutions

Indications for Use *(Describe)*
Standalone software for medical image analysis intended for advanced visualization and quantitative analysis for diagnostics in the field of cardiology or radiology by means of segmentation of cardiovascular structures and enabling the analysis of blood flow in the heart and large vessels based on multi-slice, multi-phase and velocity encoded MR images as well as measurement and reporting tools by providing the following functionality:

- Segmentation of cardiovascular structures and calculation of quantitative results
- Support signal intensity analysis for the myocardium
- Quantification of MR parametric maps (such as T1, T2, T2* relaxation)
- Visualization and quantification of blood flow velocity and directions

When the results provided by CAAS MR Solutions are used in a clinical setting to support diagnoses, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical decision making.

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) Summary **CAAS MR Solutions** **Pie Medical Imaging BV**

I – General Information

Submitter/Owner Name	Pie Medical Imaging BV
Address	Philipsweg 1, 6227 AJ Maastricht, The Netherlands
Phone Number	+31 43 32 81 328
Contact Person	Annemiek Bouts, Regulatory Affairs Coordinator
Email Address	reg@pie.nl

Preparation Date	06-Jul-23	
Trade Name	CAAS MR Solutions	
Common Name	CAAS MR Solutions	
Classification	Regulation Name:	Medical Image Management and Processing System
	Regulation Class:	Class II
	Regulation Number:	21 CFR 892.2050
	Classification Product Code:	LLZ
Predicate Devices	**Primary predicate device:** CAAS MR Solutions (K181825, 21 CFR 892.2050, LLZ)	
	Secondary predicate device: Segment CMR (K163076, 21 CFR 892.2050, LLZ)	

II - Device Description

CAAS MR Solutions is an image post-processing software package which offers functionality to import DICOM MR images, to segment cardiovascular structures in these images, to visualize and evaluate blood flow in cardiovascular structures, to analyze and quantify these cardiovascular structures and to present the analysis results in different formats.

CAAS MR Solutions is designed as a stand-alone software package to run on a PC with a Windows operating system. It can read DICOM MR images from an accessible file system, hard disk (local directory), or (indirectly) received from the MR or PACS system. CAAS MR Solutions provides the functionality to import the DICOM MR images and to organize the loaded DICOM MR images into patients, studies, and series.

CAAS MR Solutions comprises functionalities for viewing and quantification of cardiovascular MR images, segmentation of cardiovascular structures and calculation of quantitative results, for signal intensity analysis of the myocardium, for quantification of MR parametric maps and for visualization and quantification of blood flow velocity and directions.

Results can be displayed on the screen, printed, or saved in a variety of formats to hard disk, network or PACS system. Results and clinical images with overlay can also be printed as a hardcopy and exported in various electronic formats.

III – Intended Use and Indications for Use

Intended Use

Standalone diagnostic bioimaging software is intended to measure and visualize cardiovascular structures.

Indications for Use

Standalone software for medical image analysis intended for advanced visualization and quantitative analysis for diagnostic in the field of cardiology or radiology by means of segmentation of cardiovascular structures and enabling the analysis of blood flow in the heart and large vessels based on multi-slice, multi-phase and velocity encoded MR images as well as measurement and reporting tools by providing the following functionality:

- Segmentation of cardiovascular structures and calculation of quantitative results
- Support signal intensity analysis for the myocardium
- Quantification of MR parametric maps (such as T1, T2, T2* relaxation)
- Visualization and quantification of blood flow velocity and directions

When the results provided by CAAS MR Solutions are used in a clinical setting to support diagnoses, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical decision making.

IV - Substantial equivalence comparison

The devices CAAS MR Solutions (K181825) and Segment CMR (K163076) have been selected as predicate devices for *CAAS MR Solutions*. The selected devices have technological features and characteristics comparable to CAAS MR Solutions and are intended to be used by or under supervision of a cardiologist or radiologist to support clinical decision making of cardiovascular conditions.

The predicate device, CAAS MR Solutions (K181825), is an earlier version of the current *CAAS MR Solutions* product. The indications for use of the two devices are similar. The two products provide the same functionalities for segmentation of cardiovascular structures semi-automatically, automatically, or manually and for quantification of the functional and regional parameters of the heart ventricles. Further they offer functionality for signal intensity analysis of the myocardium and for quantification of MR parametric maps for T1, T2 and T2* relaxation values. Additionally, they both feature functionalities for segmentation of the blood vessels and analysis and quantification of the blood flow in vessels and through heart valves in phase-contrast MR images semi-automatically, automatically, or manually. All these functionalities are supported in both the new *CAAS MR Solutions* product and the predicate device CAAS MR Solutions (K181825).

The difference between the previous generation of the *CAAS MR Solutions* product, CAAS MR Solutions (K181825) and the current device is the addition of a workflow for strain analysis on MR images. The selected predicate device, Segment CMR (K163076), offers similar functionality for strain analysis. Selection of images, delineation of myocardial walls, correction of myocardial contours, feature tracking, and type of calculated results for the strain analysis workflow in the predicate device are similar to the new strain analysis workflow in the *CAAS MR Solutions* product.

The basic features and technology of the new *CAAS MR Solutions* product are the same in terms of intended use and indications for use and have the same technological characteristics as the predicate device CAAS MR Solutions (K181825). Therefore, the predicate device CAAS MR Solutions (K18125) is selected as the primary predicate device. The newly added analysis workflow for strain analysis in *CAAS MR* Solutions is similar to the function provided by Segment CMR (K163076). Therefore, this device is chosen as secondary predicate device. All software applications use the same types of data and operating principles for the user and technology regarding data import, contour definition, image display and storage of results.

V - Performance Data

Verification and validation of the *CAAS MR Solutions* showed that the system requirements – derived from indications for use – as well as risk control measures were implemented correctly, and that the device meets its specifications including conformance to the international recognized process standards (i.e., ISO 13485, ISO 14971, IEC 62304, IEC 62366-1, and IEC 82304).

For the strain analysis workflow in *CAAS MR Solutions* software verification and validation testing were conducted and documented:

- The verification and validation of the new strain analysis workflow demonstrated that the results meet the accuracy and reproducibility requirements.
- Usability testing is performed in accordance with IEC62366 which demonstrated that the user could use the strain analysis workflow in *CAAS MR Solutions* for the purpose it was developed for.

Equivalence in numerical results for the analysis workflows already available in the predicate device CAAS MR Solutions (K181825) was demonstrated with regression testing.

The verification and validation results demonstrate the safety and effectiveness of *CAAS MR Solutions* in relation to its intended use and indications for use and therefore *CAAS MR Solutions* can be considered as safe and effective as its predicate devices.

VI - Conclusion

Based on the application of risk management and performance testing inherent to PMI's QA system (compliant with recognized standards as stated above) the conclusion is that *CAAS MR Solutions* is as safe and effective as its predicate device in terms of indications for use, technological characteristics, measurements, and operating environment and does not raise any new issues related to safety and effectiveness compared to the predicate device.