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

December 3, 2018

Re: K181825
Trade/Device Name: CAAS MR Solutions
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 4, 2018
Received: October 9, 2018

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181825

Device Name
CAAS MR Solutions

Indications for Use *(Describe)*
CAAS MR Solutions features segmentation of cardiovascular structures and enables 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.

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

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K181825

510(k) Summary **CAAS MR Solutions** **Pie Medical Imaging BV**

Submitter/Owner Name	Pie Medical Imaging BV
Address	Philipsweg 1, 6227 AJ Maastricht, The Netherlands
Phone Number	+31 43 32 81 328
Fax Number	+31 43 32 81 329
Contact Person	Annemiek Bouts, Regulatory Affairs Coordinator
Email Address	reg@pie.nl
Preparation Date	27-Sep-18

Trade Name	CAAS MR Solutions	
Common Name	CAAS MR Solutions	
Classification	Regulation Name:	Image Processing System
	Regulation Class:	Class II
	Regulation number:	21 CFR 892.2050
	Classification Product Code:	LLZ

Predicate Device

- CAAS MRV (K162112, Image Processing System, 21 CFR 892.2050, LLZ)
- CAAS MR Flow (K090155, Image Processing System, 21 CFR 892.2050, LLZ)
- CAAS MR 4D Flow (K162376, Image Processing System, 21 CFR 892.2050 LLZ)
- MR-CT VVA (K140587, Image Processing System, 21 CFR 892.2050, LLZ)

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 found DICOM MR images into patients, studies and series.

CAAS MR Solutions is composed out of analysis workflows of its previously cleared devices: CAAS MRV, CAAS MR Flow and CAAS MR 4D Flow. CAAS MR Solutions comprises their respective functionalities for viewing and quantification of cardiovascular MR images. In addition, CAAS MR Solutions offers new functionality for signal intensity analysis of the myocardium and for MR parametric maps for T1 relaxation. The CAAS MR Solutions product has a moderate level of concern.

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

Intended Use

CAAS MR Solutions is a modular software product intended to be used by or under supervision of a cardiologist or radiologist in order to aid in reading and interpreting cardiovascular MR images and to visualize and evaluate blood flow in cardiovascular structures to support clinical decision making.

Indications for Use

CAAS MR Solutions features segmentation of cardiovascular structures, enables 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.

Substantial equivalence
Four devices have been selected as predicates devices for CAAS MR Solutions: CAAS MRV, CAAS MR Flow, CAAS MR 4D Flow and MR-CT VVA. All selected devices have technological features and characteristics comparable to CAAS MR Solutions and are intended to be used or under supervision of a cardiologist or radiologist to support clinical decision making of cardiovascular conditions.

CAAS MR Solutions provides functionalities for segmentation of cardiovascular structures (i.e. the heart) semi-automatically, automatically or manually and for quantification of the functional and regional parameters of the heart ventricles. Further it offers functionality to quantify MR parametric maps for T2 and T2* relaxation values. All these functionalities are also supported by the predicate device CAAS MRV.

CAAS MR Solutions features 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. These functionalities are supported by the predicate devices CAAS MR Flow for 2D MR images (single plane, velocity-encoded) and CAAS MR 4D Flow for 4D MR images (multi-slice, multi-phase, velocity-encoded).

CAAS MR Solutions provides functionality for signal intensity analysis of the myocardium which is supported by MR-CT VVA. Further it offers functionality to quantify MR parametric maps for T1 relaxation values which is also supported by MR-CT VVA.

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 devices CAAS MRV (K162112), CAAS MR Flow (K090155), CAAS MR 4D Flow (K162376) and MR-CT VVA (K140587). 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.

Performance Data
Verification and validation of the CAAS MR Solutions showed that the system requirements – derived from the intended use and indications for use – as well as risk control measures were implemented correctly and that the device meets its specifications including conformance to the following standards:

- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- NEMA PS 3.1 – 3.20 (2016), Digital Imaging and Communication in Medicine (DICOM)
- IEC 62304 Ed 1.1, 2015-06, Medical device software – Software life cycle processes
- IEC 62336-1 Ed 1.0 2015-02, Medical devices - Application of usability engineering to medical devices
- ISO 13485:2016, Medical devices – Quality Management Systems

For each analysis workflow in CAAS MR Solutions a validation approach is created and the proper functioning of the algorithms is validated.

- Equivalence in numerical results for the analysis workflows already available in the predicate devices CAAS MRV, CAAS MR Flow and CAAS MR 4D Flow was demonstrated with regression testing.
- The validation of the new functionalities for signal intensity analysis workflow and the T1 mapping quantification demonstrated that the results meet the accuracy and reproducibility requirements.
- Usability testing is performed in accordance with IEC62366 which demonstrated that the user is able to use CAAS MR Solutions for the purpose it was developed for.

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

Conclusion
Based on the application of risk management and performance testing inherent to PMI's QA system (compliant with recognized standards as stated above) we conclude that CAAS MR Solutions is as safe and effective as its predicate devices in terms of intended use, 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 devices.