DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 21, 2016

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

Re: K162112
Trade/Device Name: CAAS MRV
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 13, 2016
Received: July 29, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162112

Device Name
CAAS MRV

Indications for Use *(Describe)*
CAAS MRV features segmentation of cardiovascular structures on different types of MR images as well as measurement and reporting tools to facilitate the following use:
• Quantitative functional and regional analyses of the heart ventricles
• Quantification of T2 and T2* relaxation values
CAAS MRV is intended to be used by or under supervision of a cardiologist or radiologist. When the results provided by CAAS MRV are used in a clinical setting to support diagnosis of cardiovascular conditions, 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.

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Preparation Date	19-Sep-16

Trade Name	CAAS MRV
Common Name	CAAS MRV
Classification:	Classification Name: Image Processing System Regulation Class: Class II Regulation number: 21 CFR 892.2050 Classification Product Code: LLZ
Predicate Devices	- CAAS MRV (K060941, Image Processing Systems, 21 CFR 892.2050, LLZ) - Medis MR-CT VVA (K140587, Image Processing Systems, 21 CFR 892.2050, LLZ)
Device Description	CAAS MRV is designed as a stand-alone modular software package for viewing and quantification of cardiovascular MR images intended to run on a PC with a Windows operating system. The images for analysis can be read from CD, hard disk or from a PACS system and CAAS MRV provides the functionality to scan the contents of a specific directory and to organize the found DICOM MR images into patients, studies and series. CAAS MRV contains several analysis workflows of the previously cleared predicate device CAAS MRV (K060941) for quantification of the functional and regional parameters of the heart ventricles. Contour detection performed automatically, semi-automatically or manually forms the bases for the analyses. Functionality to quantify T2 and T2* relaxation values is added by means of the analysis module Tissue Mapping. For this specific feature, Medis MR-CT VVA is used as a predicate device. This feature is implemented in MR-CT VVA and is very similar in both control and presentation, to the CAAS MRV feature, and yields the same results. The quantitative results of CAAS MRV support diagnosis of cardiovascular conditions. The analysis results are available on screen and can be saved to hard-disk to enable re-analysis of the data. Also, the analysis results can be exported in various electronic formats. The functionality is independent of the type of vendor acquisition equipment.
Intended Use	CAAS MRV 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 to support diagnosis of cardiovascular conditions.

Indications for Use

CAAS MRV features segmentation of cardiovascular structures on different types of MR images as well as measurement and reporting tools to facilitate the following use;

- Quantitative functional and regional analyses of the heart ventricles;
- Quantification of T2 and T2* relaxation values

CAAS MRV is intended to be used by or under supervision of a cardiologist or radiologist. When the results provided by CAAS MRV are used in a clinical setting to support diagnoses of cardiovascular conditions, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical decision making.

Technological Comparison

A comparison of the technological characteristics of the predicate and subject device is given the table below.

	New Device	**Predicate Device**	**Predicate Device**
Device name	CAAS MRV 4.2	CAAS MRV (3.0)	MR-CT-VVA
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Medis
510(k) number	-	K060941	K140587
Images supported	Vendor-independent DICOM MR images (specific requirements depend on type of analysis, but image viewing is possible on all MR images)	Vendor-independent DICOM MR images (specific requirements depend on type of analysis, but image viewing is possible on all MR images)	Vendor-independent DICOM MR images (specific requirements depend on type of analysis, but image viewing is possible on all MR images)
Image asssessment	• Manual and automatic contour detection • Functional and regional analysis analysis of the heart ventricles • Analysis of T2 and T2* relaxation values	• Manual and automatic contour detection • Functional analysis of LV and RV	***(other assessment features not relevant for equivalence)*** • Analysis of T2 and T2* relaxation values
Image display and manipulation	• 2D MR image • Pan/zoom; magnify; maximize and minimize, scroll through slice stack; adjust window level, contrast, brightness	• 2D MR image • Pan/zoom; magnify; maximize and minimize, scroll through slice stack; adjust window level, contrast, brightness	• 2D MR image • 3D volume reconstruction • Pan/zoom; magnify; maximize and minimize, scroll through slice stack; adjust window level, contrast, brightness
Correction types	• Manual contour correction/propagation	• Manual contour correction/propagation	• Manual contour correction/propagation
Result visualization	• Numerical • Graph • Bulls Eye View	• Numerical • Graph • Bulls Eye View	• Numerical • Graph • Bulls Eye View • 3D view
Storage of Results	• Printout • PDF • DICOM SC • XML • Images (PNG, JPEG) • Session state (reanalysis)	• Printout • DICOM SC • CSV/spreadsheet • Images (PNG, JPEG)	• Printout • Images • XML • DICOM SC • PDF • HTML
Operating System	• Windows	• Windows	• Windows

Conformance Standards

The device complies with the following conformance standards:

- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- NEMA PS 3.1 – 3.20 (2011), Digital Imaging and Communication in Medicine (DICOM) Set. (Radiology)
- IEC 62304 First edition 2006-05, Medical device software – Software life cycle processes
- IEC 62336:2007, Medical devices - Application of usability engineering to medical devices

Performance Data	System requirements – derived from the intended use and indications for use – as well as risk control measures are verified by system testing. System testing showed that the system requirements were implemented correctly. For each analysis workflow a validation approach is created and the proper functioning of the algorithms is validated. For analysis workflows already implemented in earlier versions of CAAS MRV regression testing is performed to verify equivalence in numerical results. The validation of the tissue mapping algorithms used in the new analysis workflow Tissue Mapping demonstrated that the quantification of the tissue relaxation values (T2 and T2*) meet the accuracy and reproducibility requirements. Usability testing is performed a according with IEC 62366 to validate all analysis workflows of CAAS MRV and demonstrated that the user is able to use CAAS MRV for the purpose it was developed for. The test results demonstrate safety and effectiveness of CAAS MRV in relation to its intended use and that CAAS MRV is considered as safe and effective as the predicate devices.
Substantial Equivalence	The analysis workflows Functional Analysis in the previously cleared device CAAS MRV (K060941) is available in CAAS MRV and is similar in terms of intended use and indications for use and have the same technological characteristic and clinical use. The difference between these two devices is that the analysis workflow 'Tissue Mapping' has been added in CAAS MRV. With the addition of the Tissue Mapping workflow, the new CAAS MRV is, like the predicate CAAS MRV (K060941), intended to support the interventional cardiologist and radiologist with diagnoses. The Tissue Mapping workflow has a similar intended use and indications for use as the same functionality present in the MR-CT VVA System (K0140587). The feature is very similar in both control and presentation and yields the same results.
Conclusion	From the comparison table and substantial quivalence analysis it can be concluded that CAAS MRV is substantially equivalent to a combination of the predicate devices. Based on the application of risk management and performance testing inherent to PMI's quality system (compliant with recognized standards) CAAS MRV can be considered as safe and effective as its predicate devices and does not raise any new issues related to safety and effectiveness as compared to its predicate devices.