DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Pie Medical Imaging B.V.
% Ms. Florie Daniels
Regulatory Affairs Coordinator
Philipsweg 1
Maastricht, Limburg 6227 AJ
THE NETHERLANDS

February 6, 2015

Re: K143044
Trade/Device Name: CAAS A-Valve
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 6, 2015
Received: January 12, 2015

Dear Ms. Daniels:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K143044

Device Name
CAAS A-Valve

Indications for Use *(Describe)*
CAAS A-Valve has been developed to support the interventionalist during or in preparation of treatment of the aortic root. Based on angiographic X-ray images an analysis is performed:

To assist in C-arm projection selection to optimize visualization during treatment;
To calculate dimensions of the aortic root corrected for out-of-plane magnification and foreshortening errors;
To provide an objective and reproducible grading method for aortic regurgitation based on time versus density curves extracted from an aortogram.

The software is used by or under supervision of a cardiologist or radiologist. When the results provided by CAAS A-Valve are used in a clinical setting to support diagnoses or for assistance during intervention 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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Contact Person:	Florie Daniels, Regulatory Affairs Coordinator
Email Address	Florie.Daniels@pie.nl
Preparation Date	20 October 2014

Trade Name	CAAS A-Valve
Common Name	CAAS A-Valve
Regulation Class	Class II (21 CFR, part 892.2050, LLZ)
Classification Name	Picture Archiving and Communications System
Predicate Devices	CAAS A-Valve (K113076) CAAS (K052988)

Device Description

CAAS A-Valve is a stand-alone software application, intended to run on a PC with a Windows operating system. The images for analysis can be read from a directory or from an X-ray system or PACS through a command line interface. The results can be displayed on the screen, printed or saved in a variety of formats to a hard disk, network, PACS system or CD. Results and clinical images with overlay can also be printed as a hardcopy.

CAAS A-Valve consists of two separate workflows, Optimal Projection and qRA (quantitative Regurgitation Analysis).

With CAAS A-Valve – Optimal Projection, angiographic images of the aortic root can be analyzed to determine a good projection for visualization of the aortic root and to perform basic measurements. As input for analysis, two angiographic images of the aortic root can be selected. On both images the contour of the aortic root is defined manually by the user. The 2D aortic root contours in each image are used to generate a 3D reconstruction of the aortic root. By indicating the right coronary cusp in both projections the software determines the recommended projection (PRL projection). This projection can be used to acquire an aortogram with the cusps in a line and all cusps visible. Additionally it is possible to perform diameter and length measurements based on the 3D reconstruction.

The Optimal Projection workflow is 510(k) cleared under K113076.

CAAS A-Valve – qRA is used to determine aortic regurgitation (also referred to as aortic insufficiency). This is done based on a multi-frame image showing the aortic root and the left ventricle while contrast liquid is injected in the aorta during the X-ray acquisition; also known as an aortogram.

The user draws the contour of the aortic root and the left ventricle and indicates the basal plane. Next a static background, which is obtained from the images before contrast injection, is subtracted resulting in an image sequence in which the intensities correlate to the amount of contrast liquid. Based on this image sequence combined with the user input, time versus contrast density curves are calculated and visualized for both the aortic root and the left ventricle. The ratio between the area under the curve of the aortic root and the area under the curve of the left ventricle represents the amount of contrast liquid flowing from the aortic root to the left ventricle and is a measure for regurgitation. Additionally a dynamic color map is shown for the left ventricle. This color map is achieved by showing the accumulative area under the curve at each image frame as a movie with the same frame rate as used during the acquisition of the multi-frame image.

CAAS A-Valve is designed for use in clinical practice to support the physician during or in preparation of treatment of the aortic root.

Intended Use

CAAS A-Valve has been developed to support the interventionalist during or in preparation of treatment of the aortic root.
Based on angiographic images CAAS A-Valve quantifies:

- Dimensions of the aortic root and assists in C-arm positioning;
- Time versus density curves of the ventricle.

The software is used by or under supervision of a cardiologist or radiologist.

Indications for Use

CAAS A-Valve has been developed to support the interventionalist during or in preparation of treatment of the aortic root.
Based on angiographic X-ray images an analysis is performed:

- To assist in C-arm projection selection to optimize visualization during treatment;
- To calculate dimensions of the aortic root corrected for out-of-plane magnification and foreshortening errors;
- To provide an objective and reproducible grading method for aortic regurgitation based on time versus density curves extracted from an aortogram.

The software is used by or under supervision of a cardiologist or radiologist. When the results provided by CAAS A-Valve are used in a clinical setting to support diagnoses or for assistance during intervention of cardiovascular conditions, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical decision making.

Technological Characteristics Comparison

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

	New Device	Predicate Device	Predicate Device
Device name	CAAS A-Valve	CAAS A-Valve	CAAS
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Pie Medical Imaging
510(k) number	Unknown	K113076	K052988
Data type	• X-Ray Angiography data in DICOM format (vendor independent)	• X-Ray Angiography data in DICOM format (vendor independent)	• X-Ray Angiography data in DICOM format (vendor independent)
Import of Patient Data	• Manual through keyboard • Automatic import with image file	• Manual through keyboard • Automatic import with image file	• Manual through keyboard • Automatic import with image file
Contour Definition	• Manual Contour Definition	• Manual Contour Definition	• Manual and Automatic Contour Definition
Image Display	• 2D X-Ray image • 3D Reconstruction	• 2D X-Ray image • 3D Reconstruction	• 2D X-Ray image • n/a

	New Device	Predicate Device	Predicate Device
Device name	CAAS A-Valve	CAAS A-Valve	CAAS
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Pie Medical Imaging
510(k) number	Unknown	K113076	K052988
Image Assessment	• Optimal projection • Diameter and length measurements • Time versus density curves of the left ventricle • Grading method for Aortic Regurgitation • Color map based on curves	• Optimal projection • Diameter and length measurements • n/a • n/a • n/a	• n/a • Diameter and length measurements • Densitometry and density measurements • n/a • n/a
Storage of Results	• Printout • Images • XML	• Printout • Images • XML	• Printout • Images • XML
Operating System	• Ms Windows	• Ms Windows	• Ms Windows

Substantial Equivalence

Compared to the predicate devices:

- CAAS A-Valve (K113076)
  The intended use and indications for use of the predicate device CAAS A-Valve (K113076) are modified to include the quantification of time versus density curves of the ventricle which had been added in the new device CAAS A-Valve. Like the predicate device CAAS A-Valve (K113076), the subject device is intended to support the interventionalist during and in preparation of treatment of the aortic root.
  All technological characteristics, except the quantification of time versus density curves of the ventricle, of the subject device are the same as the cleared predicate device CAAS A-Valve (K113076).
- CAAS (K052988)
  Quantification of time versus density curves for regurgitation analysis is technologically similar to the densitometry measurements of the predicate device CAAS (K052988) however extended over time. Furthermore parameters derived from the curves, i.e. a grade for Aortic Regurgitation and a dynamic color map, are calculated.

Conformance Standards

The device complies with the following conformance standards:

- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- NEMA PS 2.1 – 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

Performance Data

System requirements – derived from the intended use and indications for use – as well as risk control measures are verified by System Testing.
Additionally numerical accuracy and reproducibility is verified and validated for the following analysis results:

- Optimal C-arm projection;
- Dimensions of the aortic root;
- Time versus density curves.
- Aortic regurgitation grade;

The test results demonstrate safety and effectiveness of CAAS A-Valve in relation to its intended use and that CAAS A-Valve is considered as safe and effective as the predicate devices.

Conclusion	The testing reported in this 510(k) demonstrated that CAAS A-Valve is substantially equivalent to the predicate devices in terms of intended use, indications for use, technological characteristics, measurements and operating environment. As such CAAS A-Valve is considered as safe and effective as its predicate devices and performs as well as its predicate devices.