K113076

JAN 30 2012

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Preparation Date	22 December 2011

Trade Name	CAAS A-Valve
Common Name	Cardiovascular Angiography Analysis System CAAS A-Valve
Regulation Class	Class II (21 CFR, part 892.2050, LLZ)
Predicate Devices	CAAS QxA 3D, cleared under K100292 IC-Pro, cleared under K110256

Device Description

The CAAS A-Valve is a stand-alone software application intended to run on a PC with a Windows operating system. The CAAS A-Valve is designed for objective, accurate and reproducible assessment of the aortic root geometry from a set of angiographic X-ray images from different projections.

On each of the 2D images the aortic root is segmented. The segmented 2D aortic root contours in each image are used to generate a 3D reconstruction of the aortic root. A number of analysis results can be calculated:

1. Optimal C-arm projection to optimize visualization during treatment;
2. Dimensions of the aortic root.

Results are corrected for out-of-plane magnification and foreshortening errors.

Intended Use

CAAS A-valve has been developed to support the interventionalist during or in preparation of treatment of the aortic root. CAAS A-Valve quantifies dimensions of the aortic root and assists in C-arm positioning based on a set of angiographic images. 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 a set of 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.

Performance Data

CAAS A-Valve is developed, tested, validated and produced under the same Quality Assurance system applicable to the development and production of products currently marketed by Pie Medical Imaging.

Substantial Equivalence

The intended use and technological characteristics of CAAS A-Valve are substantial equivalent to a combination of the intended use and technological characteristics of the predicate devices.

Conclusion	The testing reported in this 510(k) establishes that CAAS A-Valve is substantial equivalent to a combination of predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Florie Daniels
Product Registration Coordinator
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JAN 30 2012

Re: K113076
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: December 22, 2011
Received: December 28, 2011

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K113076

Device Name: CAAS A-Valve

Indications for Use:

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- To calculate dimensions of the aortic root corrected for out-of-plane magnification and foreshortening errors.

Prescription Use ____√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113076