K123970

solutions in cardiovascular analysis

PIE MEDICAL IMAGING

510(k) Summary **CAAS IntraVascular** **[QA858]v2.0**

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Preparation Date: 20 December 2012

FEB 6 2013

Trade Name: CAAS IntraVascular

Common Name: CAAS IntraVascular

Classification Name: Picture Archiving and Communications System

Regulation Class: Class II (21 CFR, part 892.2050, LLZ)

Predicate Device: echoPlaque Intra Vascular Analysis Software (K092842)

Device Description: CAAS IntraVascular is a stand-alone software application intended to run on a PC with a Windows operating system. CAAS IntraVascular is designed for viewing and analyzing DICOM data from intravascular ultrasound (IVUS) and optical coherence tomography (OCT) studies. CAAS Intravascular provides (semi-)automatic detection of vessel and stent structures and quantitative analysis of the dimensions of these structures. CAAS IntraVascular is designed for use in clinical practice to support the physician to diagnose the patient.

Intended Use: CAAS IntraVascular has been developed to review and analyze intravascular images. The software is used by or under supervision of a cardiologist or radiologist.

Indications for use: Based on intravascular ultrasound (IVUS) and/or optical coherence tomography (OCT) images CAAS IntraVascular enables quantification of artery and/or stent dimensions.

Technological Characteristics Comparison: The underlying technology of the subject device is similar to the predicate device. Both the subject device and predicate device can import intravascular DICOM data, display this data in similar ways and provide similar contour definition, vessel analysis and measurement methods. The technological comparision table shows the equivalence between CAAS IntraVascular and the predicated device.

	New Device	Predicate Device
Data type	• IVUS and OCT data in DICOM format (vendor independent)	• IVUS data in DICOM format (vendor independent)

	New Device	Predicate Device
Import of Patient Data	• Manual through keyboard • Automatic import with image file • Study List creation	• Manual through keyboard • Automatic import with image file
Image display	• Cross-sectional views • Longitudinal reconstruction • 3D OCT reconstruction	• Cross-sectional views • Longitudinal reconstruction • 3D IVUS view
Contour definition	Lumen, EEM and stent contour • Automatic • Manual	Lumen, EEM and stent contour • Automatic • Manual
Vessel analysis	• Stenosis analysis • Plaque analysis • Stent analysis	• Stenosis analysis • Plaque analysis • Stent analysis
Image assessment	• Linear (length and diameter), angular and ROI measurements • Volume measurements	• Linear (length and diameter), angular and ROI measurements • Volume measurements
Storage of Results	• Printout • Reanalysis • Digital PDF report • XML export • DICOM PDF report	• Printout • Reanalysis • Digital Word report • XML export
Operating System	• MS Windows	• MS Windows

Performance Data

Testing includes software verification and validation. The tests were made to evaluate CAAS IntraVascular and yield accuracy and precision results within the predetermined specifications.

Substantial Equivalence

CAAS IntraVascular is substantial equivalent to the predicate device in terms of intended use, indications for use, technological characteristics, measurements and operating environment of the predicate device. All found differences raise no new safety and effectiveness issues or concerns.

Conclusion

The testing reported in this 510(k) establishes that CAAS IntraVascular is substantial equivalent to the predicate device 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 Center – WO66-G609
Silver Spring, MD 20993-0002

February 6, 2013

Pie Medical Imaging BV
C/O Florie Daniels
Regulatory Affairs Coordinator
BECANUSSTRAAT 13D
6212 BX MAASTRICHT
THE NETHERLANDS

Re: K123970
Trade/Device Name: CAAS Intra Vascular
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 20, 2012
Received: December 26, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123970

Device Name: CAAS IntraVascular

Indications for Use:

Based on Intravascular ultrasound (IVUS) and/or optical coherence tomography (OCT) images CAAS IntraVascular enables quantification of artery and/or stent dimensions.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123970