510(k) Summary	CAAS Workstation	[GEN1632]v2.0

Submitter/Owner Name	Pie Medical Imaging BV
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Contact Person:	Florie Daniels, Product Registration Coordinator
Email Address	Florie.Daniels@pie.nl
Preparation Date	24-Dec-2013
Trade Name	CAAS Workstation
Common Name	Cardiovascular Angiography Analysis System (CAAS)
Classification	Classification Name: Angiographic X-ray System
	Regulation Class: Class II
	Regulation number: 21 CFR 892.1600
	Classification Product Code: IZI
	Subsequent Product Code: LLZ
Predicate Devices	CAAS (K052988)
	CAAS QxA3D (K100292)
	IC-PRO System (K110256)

Device Description
CAAS Workstation is designed as a stand-alone modular software product for viewing and quantification of X-ray angiographic images intended to run on a PC with a Windows operating system. CAAS Workstation contains the analysis modules QCA, QCA3D, QVA, LVA, RVA and StentEnhancer.
The analysis modules QCA, QCA3D, QVA, LVA and RVA contain functionality of the previously cleared predicate devices CAAS (K052988) and CAAS QxA3D (K100292) for calculating dimensions of coronary and peripheral vessels and the left and right ventricles, quantification of stenosis, performing density measurements and determination of optimal C-arm position for imaging of vessel segments. Semi-automatic contour detection forms the basis for the analyses.
Functionality to enhance the visualization of a stent and to measure stent dimension is added by means of the analysis module StentEnhancer. This functionality is based on the StentOptimizer module of the IC-PRO System (K110256).
The quantitative results CAAS Workstation support diagnosis and intervention of cardiovascular conditions.
The analysis results are available on screen, and can be exported in various electronic formats.
The functionality is independent of the type of vendor acquisition equipment.

Intended Use
CAAS Workstation 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 X-Ray images to support diagnoses and for assistance during intervention of cardiovascular conditions.

Indications for Use   CAAS Workstation features segmentation of cardiovascular structures, 3D reconstruction of vessel segments based on multiple angiographic images, measurement and reporting tools to facilitate the following use:
- Calculate the dimensions of cardiovascular structures;
- Quantify stenosis in coronary and peripheral vessels;
- Quantify the motion of the left and right ventricular wall;
- Perform density measurements;
- Determine C-arm position for optimal imaging of cardiovascular structures;
- Enhance stent visualization and measure stent dimensions.

CAAS Workstation is intended to be used by or under supervision of a cardiologist or radiologist.When the results provided by CAAS Workstation are used in a clinical setting to support diagnoses and 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 predicate and subject device is given the table below.

	New Device	Predicate Device	Predicate Device	Predicate Device
Device name	CAAS Workstation	CAAS	CAAS QxA3D	IC-PRO System
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Pie Medical Imaging	Paieon
510(k) number	-	K052988	K100292	K110256
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)	• X-Ray Angiography data in DICOM format (vendor independent)
Import of Patient Data	• Manual through keyboard • Command line interface	• Manual through keyboard • Command line interface	• Manual through keyboard • Command line interface	• Manual through keyboard • Command line interface
Contour Definition	• Manual and semi-automatic centerline definition based contour detection of coronary and peripheral vessel • Manual and semi-automatic left ventricular contour definition • Manual right ventricular contour definition • Manual stent contour definition • Contour correction and restriction	• Manual and semi-automatic centreline definition based contour detection of coronary and peripheral vessel • Manual and semi-automatic left ventricular contour definition • Manual right ventricular contour definition • Contour correction and restriction	• Manual and semi-automatic centreline definition based contour detection of coronary and peripheral vessel • Contour correction and restriction	• Manual stent contour definition • Contour correction
Image Display	• 2D X-Ray image • 3D coronary vessel reconstruction	• 2D X-Ray image	• 2D X-Ray image • 3D coronary and peripheral vessel reconstruction	• 2D X-Ray image
Image Assessment	• Manual and automatic calibration • Basic length, diameter, density and angle measurements • Vessels and ventricle dimensions (diameters, areas, volumes) • Automatic and manual stenosis assessment • 3D coronary vessel reconstruction • Left and right	• Manual and automatic calibration • Basic length, diameter, density and angle measurements • Vessels and ventricle dimensions (diameters, areas, volumes) • Automatic and manual stenosis assessment • Left and right ventricular wall motion • Left ventricular	• Automatic calibration • Automatic and manual stenosis assessment • 3D coronary and peripheral vessel reconstruction	• Enhanced stent visualization • Stent dimensions

	New Device	Predicate Device	Predicate Device	Predicate Device
Device name	CAAS Workstation	CAAS	CAAS QxA3D	IC-PRO System
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Pie Medical Imaging	Paieon
510(k) number	-	K052988	K100292	K110256
	ventricular wall motion • Left ventricular myocardium dimensions • Enhanced stent visualization • Stent dimensions	myocardium dimensions		
Storage of Results	• Printout • Images • XML • DICOM SC • PDF	• Printout • Images • XML • DICOM SC • DICOM SR	• Printout • Images • XML • DICOM SC • DICOM SR	• Printout • Images •
Operating System	• Windows	• Windows	• Windows	• Windows

All technological characteristics of the subject device are similar to the cleared predicate devices.

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

Performance Data   System requirements – derived from the intended use and indications for use – as well as risk control measures are verified by system testing.
For each analysis module a validation approach is created and the proper functioning of the algorithms is validated.
For analysis modules already implemented in earlier versions of CAAS regression testing is performed to verify equivalence in numerical results.
The test results demonstrate safety and effectiveness of CAAS Workstation in relation to its intended use and that CAAS Workstation is considered as safe and effective as the predicate devices.

Substantial Equivalence   The analysis modules QCA, QVA, LVA, RVA in the previously cleared device 'CAAS' (K052988) and the analysis module QCA3D in the previously cleared device 'CAAS QxA3D' (K100292) are available in CAAS Workstation and are similar in terms of intended use and indications for use and in functionality.
The analysis module 'StentEnhancer' has been added in CAAS Workstation and is similar in terms of intended use, indications for use and technology as the StentOptimizer module available in 'The IC-PRO System' (K110256).

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

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

March 25, 2014

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

Re: K133993
Trade/Device Name: CAAS Workstation
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI, LLZ
Dated: December 24, 2013
Received: December 26, 2013

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 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. 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,

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)*
K133993

Device Name
CAAS Workstation

Indications for Use *(Describe)*
CAAS Workstation features segmentation of cardiovascular structures, 3D reconstruction of vessel segments based on multiple angiographic images, measurement and reporting tools to facilitate the following use:
- Calculate the dimensions of cardiovascular structures;
- Quantify stenosis in coronary and peripheral vessels;
- Quantify the motion of the left and right ventricular wall;
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- Enhance stent visualization and measure stent dimensions.
CAAS Workstation is intended to be used by or under supervision of a cardiologist or radiologist. When the results provided by CAAS Workstation are used in a clinical setting to support diagnoses and 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*