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 11, 2016

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

Re: K151780
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: February 1, 2016
Received: February 8, 2016

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,

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)*
K151780

Device Name
CAAS Workstation

Indications for Use *(Describe)*
CAAS Workstation features segmentation of cardiovascular structures, 3D reconstruction of vessel segments and catheter path 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;
- Co-registration of angiographic X-Ray images with IVUS and OCT images.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Submitter/Owner Name	Pie Medical Imaging BV
Address	Philipsweg 1, 6227 AJ Maastricht, The Netherlands
Phone Number	+31 43 32 81 328
Fax Number	+31 43 32 81 329
Contact Person:	Florie Daniels, Regulatory Affairs Coordinator
Email Address	Florie.Daniels@pie.nl
Preparation Date	26-Jun-2015

Trade Name	CAAS Workstation
Common Name	Cardiovascular Angiographic Analysis System
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 Workstation (K133993, Angiographic X-ray System, 21 CFR 892.1600, IZI, LLZ) Volcano Angio-IVUS Mapping system (K060483, Echocardiograph, 21 CFR 870.2330 , IYO, IZI)
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 of the previously cleared predicate device CAAS Workstation (K133993) for calculating dimensions of coronary and peripheral vessels and the left and right ventricles, quantification of stenosis, performing density measurements, determination of optimal C-arm position for imaging of vessel segments and functionality to enhance the visualization of a stent and to measure stent dimension. Semi-automatic contour detection forms the basis for the analyses. Functionality to co-register X-ray angiographic images and intravascular imaging techniques (such as intravascular ultrasound and optical coherence tomography) is added by means of the analysis module IV-LINQ. With co-registration a common frame of intravascular imaging techniques with X-ray angiographic images is provided using a three-dimensional model. This functionality is based on the Volcano Angio-IVUS Mapping system (K060483). In the IV LINQ workflow the user has to select two angiographic X-ray images in DICOM format. The user indicates a catheter path starting at the imaging tip. This path can be optimized manually by adding, deleting or moving control points on the drawn path. After the catheter path is drawn in both angiographic X-ray images, a 3D reconstruction of the catheter path is calculated.

The user then has to select one IVUS or OCT dataset in DICOM format or the data is streamed from the intravascular imaging console with a DVI streamer. The IVUS or OCT pullback must be acquired using a motorized pullback device. After the 3D catheter path from X-ray angiographic images is calculated and the IVUS or OCT pullback is loaded, IV-LINQ co-registers each IVUS or OCT frame with a position on the 3D catheter path using a distance mapping algorithm. On intravascular images diameter and area measurements can be performed.

The quantitative results of 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, co-registering 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 and catheter path 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;
- Co-registration of angiographic X-Ray images with IVUS and OCT images.

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**
Device name	CAAS Workstation	CAAS Workstation	Angio-IVUS Mapping System
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Volcano Corp.
510(k) number	-	K133993	K060483
Data type	• X-Ray Angiography data in DICOM format (vendor independent) • IVUS data as videostream or in DICOM format (vendor independent) • OCT data as DICOM format only (vendor independent)	• X-Ray Angiography data in DICOM format (vendor independent)	• X-Ray Angiography data in DICOM format (vendor independent) • IVUS data in DICOM format
Import of Patient Data	• Manual through keyboard • Command line interface	• Manual through keyboard • Command line interface	• Manual through keyboard
Centerline Definition	• Manual and semi-automatic centerline definition based contour detection of coronary and	• Manual and semi-automatic centerline definition based contour detection of coronary and	

	New Device	Predicate Device	Predicate Device
Device name	CAAS Workstation	CAAS Workstation	Angio-IVUS Mapping System
Manufacturer	Pie Medical Imaging	Pie Medical Imaging	Volcano Corp.
510(k) number	-	K133993	K060483
	peripheral vessel • Manual and semi-automatic left ventricular contour definition • Manual right ventricular contour definition • Manual stent contour definition • Contour correction and restriction • Manual catheter path definition	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 centerline / catheter path definition
Image Display	• 2D X-Ray image • 3D reconstruction based on 2 X-Ray images • 2D intravascular image • Longitudinal intravascular reconstruction	• 2D X-Ray image • 3D reconstruction based on 2 X-Ray images	• 2D X-Ray image • 3D reconstruction based on 2 X-Ray images • 2D intravascular image • Longitudinal intravascular reconstruction
Image Assessment X-Ray	• 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 myocardium dimensions • Enhanced stent visualization • Stent dimensions • Providing a common frame of reference for IVUS and OCT data with X-ray angiographic data	• 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 myocardium dimensions • Enhanced stent visualization • Stent dimensions	• Manual and automatic calibration • Basic length, diameter, density and angle measurements • Providing a common frame of reference for IVUS data with X-ray angiographic data
Image Assessment – IVUS / OCT	• Basic diameter and area measurements		• Basic diameter and area measurements
Storage of Results	• Printout • Images • DICOM SC • XML • PDF	• Printout • Images • DICOM SC • XML • PDF	• Printout • Images • DICOM SC
Operating System	• Windows	• Windows	• Windows

Besides IVUS images, also OCT images can be co-registered with IV LINQ. IV LINQ bases image co-registration on the length of the intravascular imaging pullback (either IVUS or OCT). This is similar as the basis for image co-registration in the predicate device Angio-IVUS Mapping System (K060483), which uses the length of the IVUS pullback. The length of an OCT pullback is calculated using the same acquisition information as for IVUS. For IVUS DICOM and IVUS video stream data the calculation of length is also based on the same acquisition information.
The differences in technological characteristics of the subject device compared to the predicate devices therefore do not effect the safety and effectivess of the device.

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 Workstation regression testing is performed to verify equivalence in numerical results. The validation of the distance mapping algorithm used in IV LINQ demonstrated that the length on which co-registration is based, meets the accuracy and reproducibility requirements. Usability testing is performed to validate the IV-LINQ workflow of CAAS Workstation and demonstrated that the user is able to use IV LINQ for the purpose it was developed for. 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 workflows QCA, QVA, LVA, RVA, QCA3D and StentEnhancer in the previously cleared device CAAS Workstation (K133993) are available in CAAS Workstation and are the same in terms of intended use and indications for use and have the same technological characteristic. The difference between these two devices is that the analysis workflow 'IV-LINQ' has been added in CAAS Workstation. With the addition of the IV LINQ workflow, the new CAAS Workstation is, like the predicate CAAS Workstation (K133993), intended to support the interventional cardiologist and radiologist with diagnoses and assist them during intervention of cardiovascular conditions. IV-LINQ has similar intended use and indications for use as the Angio-IVUS Mapping System (K060483). Technologically similar 3D reconstruction and distance mapping methods are used to provide co-registration in Angio-IVUS Mapping System as are used in IV-LINQ. Besides IVUS also OCT images can be co-registered with IV LINQ. OCT images are two-dimensional images created using back-reflecting light versus back-reflected sound waves in IVUS imaging. The image processing of OCT and IVUS images in IV LINQ is considered technologically similar and as such does not affect the safety and effectiveness of the device when used as labeled. There is no difference in the clinical use of IV LINQ, which is providing a common frame of reference, related to the use of OCT images versus IVUS images and the clinical use is therefore considered the same as for the predicate Angio-IVUS Mapping System (K060483).
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.