May 23, 2019

Pie Medical Imaging B.V.
℅ Annemiek Bouts
Regulatory Affairs Coordinator
Philipsweg 1
6227 AJ Maastricht, Limburg
THE NETHERLANDS

Re: K180019
Trade/Device Name: CAAS Workstation
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: Class II
Product Code: QHA, LLZ
Dated: March 28, 2018
Received: April 2, 2018

Dear Annemiek Bouts:

This letter corrects our substantially equivalent letter of May 3, 2018.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180019

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;
- Quantify pressure drop in coronary vessels;
- 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.

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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510(k) Summary **CAAS Workstation** **Pie Medical Imaging BV**

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	Annemiek Bouts, Regulatory Affairs Coordinator
Email Address	annemiek.bouts@pie.nl
Preparation Date	23-May-19

Trade Name	CAAS Workstation	
Common Name	CAAS (Cardiovascular Angiographic Analysis System)	
Classification	Regulation Name:	Angiographic X-ray System
	Regulation Class:	Class II
	Regulation number:	21 CFR 892.1600
	Classification Product Code:	QHA
	Subsequent Product Code:	LLZ
Predicate Device	CAAS Workstation (K151780, Angiographic X-ray System, 21 CFR 892.1600, IZI, LLZ) CAAS (K052988, Image Processing System, 21 CFR 892.2050, LLZ)	

Device Description

The CAAS Workstation is designed as a stand-alone software package to run on a PC with a Windows operating system. It can read DICOM X-ray images from an directory, or received from the X-ray or PACS system. Intravascular images (such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in DICOM format can be read from a directory, or received from the intravascular imaging console or PACS system. IVUS images can also be received real-time as a video stream from an intravascular imaging console via a DVI streamer. The CAAS Workstation product has a moderate level of concern.

CAAS Workstation is composed out of the following analysis workflows: QCA, QCA3D, QVA, LVA, RVA, StentEnhancer and IV-LINQ of the previously cleared predicate device CAAS Workstation (K151780) 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 IVUS and OCT) is added by means of the analysis module IV-LINQ.

In the newly added vFFR workflow the user can calculate the pressure drop and a vFFR value on coronary vessels. To obtain these values for a specific lesion in a coronary vessel, the user has to start with a QCA3D detection using two angiographic images. In each of these images a classic 2D coronary detection is performed after which a reconstruction of the coronary segment is obtained in 3D space. Based on the 3D reconstruction and the user input of systolic and diastolic aortic root blood pressure, the pressure drop and the vFFR values can be assessed. The functionality is based on a combination of the QCA3D workflow available in predicate device CAAS Workstation (K151780) and technology available in the predicate device CAAS (K052988).

Results can be displayed on the screen, printed or saved in a variety of formats to hard disk, network, PACS system or CD. Results and clinical images with overlay can also be printed as a hardcopy and 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;
- Quantify pressure drop in coronary vessels;
- 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.

Substantial equivalence

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 Manufacturer 510(k) number	CAAS Workstation Pie Medical Imaging K180019	CAAS Workstation Pie Medical Imaging K151780	CAAS Pie Medical Imaging K052988
Intended Use and Indications for Use			
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 in diagnoses and for assistance during intervention of cardiovascular conditions.	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 in diagnoses and for assistance during intervention of cardiovascular conditions.	The intended use of CAAS is: • Quantification of coronary artery dimensions; • Quantification of peripheral arteries and aorta; • Quantification of left and right ventricles; • Management of data resulting of the quantitative analysis. CAAS is used online or offline in hospitals and offline for research purposes. In hospitals, the software will be used by cathlab personnel under supervision of cardiologists and radiologists. In research institutes, the users are principal investigators and other research personnel operating under supervision of cardiologists and radiologists as well.
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;	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;	CAL Calculate the pixel size of the image to be analysed. MEAS Perform basic length, angle and density measurements. QCA Detect the contour of the coronary vessel in the angiographic X-ray image - Calculate the dimensions of the coronary artery segment.

	• Determine C-arm position for optimal imaging of cardiovascular structures; • Enhance stent visualization and measure stent dimensions; • Quantify pressure drop in coronary vessels; • 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.	• 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.	QVA Detect the contour of the peripheral vessel in the angiographic X-ray image - Calculate the dimensions of the peripheral vessel segment. LVA Delineate the outline of the left ventricular wall automatically and/or manually in angiographic X-ray images – either monoplane or biplane analysis; absolute measurements of left ventricular volumes; calculations of derived parameters; quantification of the motion of the left ventricular wall; estimations of the dimensions of the myocardial wall. RVA Delineate the outline of the right ventricular wall semi-automatically and/or manually in angiographic X-ray images – either monoplane or biplane analysis; absolute measurements of right ventricular volumes based on several established models for children and adults; calculations of derived parameters; quantification of the motion of the right ventricular wall.
Technological Characteristics			
Data type	• X-Ray angiography in DICOM format (vendor independent); • IVUS and OCT data in DICOM format (vendor independent); • IVUS data as video stream	• X-Ray angiography in DICOM format (vendor independent); • IVUS and OCT data in DICOM format (vendor independent;) • IVUS data as video stream	• X-Ray angiography in DICOM format (vendor independent); • n/a • n/a
Import of patient data	• Manual through keyboard; • Command line interface	• Manual through keyboard; • Command line interface	• Manual through keyboard; • Command line interface
Contour definition	• Manual and semi-automatic centreline definition based contour detection of coronary and peripheral vessels; • 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	• Manual and semi-automatic centreline definition based contour detection of coronary and peripheral vessels; • 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	• Manual and semi-automatic centreline definition based contour detection of coronary and peripheral vessels; • 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
Image display	• 2D X-ray image; • 3D reconstruction based on 2 X-ray images; • 2D intravascular image; • Longitudinal intravascular	• 2D X-ray image; • 3D reconstruction based on 2 X-ray images; • 2D intravascular image; • Longitudinal intravascular	• 2D X-ray image • n/a • n/a • n/a

	reconstruction	reconstruction	
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; • Left and right ventricular wall motion; • Left ventricular myocardium dimensions; • Enhanced stent visualization; • Stent dimensions; • Pressure drop calculation in coronary vessels; • Providing 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; • n/a • Providing 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; • n/a • n/a • Pressure drop calculation in coronary vessels (in stenotic flow reserve and hemodynamic data functionality); • n/a
Storage of results	• Printout; • Images; • XML; • DICOM SC; • PDF • n/a	• Printout; • Images; • XML; • DICOM SC; • PDF • n/a	• Printout; • Images; • XML; • DICOM SC; • n/a • DICOM SR
Operating system	• Windows	• Windows	• Windows

The basic features and technology of the new CAAS Workstation are the same in terms of intended use and indications for use and have the same technological characteristics as the predicate devices CAAS Workstation (K151780) and CAAS (K052988). The cardiovascular functions supported by the CAAS Workstation are a combination of functions provided by the predicate devices K151780 and K052988. All software applications use the same types of data and operating principles for the user and technology regarding data import, contour definition, image display and storage of results.

Performance Data

Verification and validation of the CAAS Workstation showed that the system requirements – derived from the intended use and indications for use – as well as risk control measures were implemented correctly and that the device meets its specifications including conformance to the following standards:

- ISO 14971:2007, Medical devices – Application of risk management to medical devices
- NEMA PS 3.1 – 3.20 (2016), Digital Imaging and Communication in Medicine (DICOM)
- IEC 62304 Ed 1.1, 2015-06, Medical device software – Software life cycle processes
- IEC 62336-1 Ed 1.0 2015-02, Medical devices - Application of usability engineering to medical devices

For each analysis workflow in CAAS Workstation a validation approach is created and the proper functioning of the algorithms is validated.

- Equivalence in numerical results for the analysis workflows already available in predicate device K151780 was demonstrated with regression testing.
- To demonstrate a proper integration of the functionality 'quantification of pressure drop in coronary vessels' from predicate device K052988 into CAAS Workstation, a series of X-ray angiographic datasets with known pressure drops were analysed and compared with K052988 and the new CAAS Workstation. The functionality 'quantification of pressure drop in coronary vessels' in the new CAAS Workstation is based on a 3D coronary reconstruction out of 2 angiographic images. In the predicate device K052988, which uses a method based on a single angiographic image, the results were generated for both the angiographic images as used for the 3D reconstruction. The results for the pressure drop were compared and differences (mean and standard deviation) of the calculated pressure drops with respect to known pressure drops of the used datasets were

calculated. A Pearson correlation between the known and calculated pressure drop values was also performed. This demonstrated that the quantification of pressure drop in coronary vessels in the new CAAS Workstation is improved compared to the predicate device K052988.

The verification and validation results demonstrate the safety and effectiveness of CAAS Workstation in relation to its intended use and therefore CAAS Workstation can be considered as safe and effective as its predicate devices.

Conclusion

Based on the application of risk management and performance testing inherent to PMI's QA system (compliant with recognized standards as stated above) we conclude that CAAS Workstation is as safe and effective as its predicate devices in terms of intended use, indications for use, technological characteristics, measurements and operating environment and does not raise any new issues related to safety and effectiveness compared to the predicate devices.