April 9, 2024

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

Re: K232147
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 7, 2024
Received: March 7, 2024

Dear Annemiek Bouts:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232147

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 vessels;
• Determine C-arm position for optimal imaging of cardiovascular structures;
• Quantify pressure drop in coronary vessels;
• Enhance stent visualization and measure stent dimensions;

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**

I – General Information

Submitter/Owner Name	Pie Medical Imaging BV
Address	Philipsweg 1, 6227 AJ Maastricht, The Netherlands
Phone Number	+31 43 32 81 328
Contact Person	Annemiek Bouts, Regulatory Affairs Coordinator
Email Address	reg@pie.nl
Date	08-Apr-24
Trade/Device Name	CAAS Workstation
Classification	Common Name: Radiological Image Processing Software Regulation Class: Class II Regulation Description: Angiographic X-Ray System Regulation number: 21 CFR 892.1600 Classification Product Code: QHA Additional Product Code: LLZ
Predicate Device	CAAS Workstation (K180019, Angiographic X-ray System, 21 CFR 892.1600, QHA, LLZ)

II - Device Description

CAAS Workstation is an image post-processing software package for advanced visualization and quantitative analysis in the field of cardiology or radiology and offers functionality to view X-Ray angiographic images, to segment cardiovascular structures in these images, to analyze and quantify these cardiovascular structures and to present the results in different formats.

CAAS Workstation is a client-server solution intended for usage in a network environment or standalone usage and runs on a PC with a Windows operating system. It can read DICOM X-ray images from a directory, or receive DICOM images from the X-ray or PACS system.

CAAS Workstation is composed out of the following analysis workflows: StentEnhancer and vFFR for calculating dimensions of coronary vessels, quantification of stenosis and calculating the pressure drop and vFFR value based on two 2D X-Ray angiographic images. Semi-automatic contour detection forms the basis for the analyses.

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.

III – 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 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 vessels;
- Determine C-arm position for optimal imaging of cardiovascular structures;
- Quantify pressure drop in coronary vessels;
- Enhance stent visualization and measure stent dimensions;

CAAS Workstation is intended to be used by or under supervision of a cardiologist or radiologist.

IV - Substantial equivalence

CAAS Workstation (K180019) is selected as a predicate device. This selected device has technological features and characteristics comparable to the new *CAAS Workstation* and is intended to be used by or under supervision of a cardiologist or radiologist to support clinical decision making of cardiovascular conditions.

Predicate device, CAAS Workstation (K180019), is an earlier version of the new *CAAS Workstation* product. It provides similar functionalities by means of the analysis workflows StentEnhancer and vFFR for calculating dimensions of cardiovascular structures, quantify stenosis in coronary vessels, determine C-arm position for optimal imaging of cardiovascular structures, quantify pressure drop in coronary vessels (all part of vFFR workflow) and enhance stent visualization and measure stent dimensions (StentEnhancer workflow). All these functionalities are also supported in the new *CAAS Workstation* product. Other technological features available in predicate device K180019: the analysis workflows QCA, QVA, QCA3D, LVA, RVA and IV-LINQ are not present in the new *CAAS Workstation* product.

The other differences in technological characteristics between the predicate device K180019 and the device *CAAS Workstation* are that the new *CAAS Workstation* runs from a browser and the server-side installation can be on the system itself (standalone usage) or on a server accessible through the intranet (network environment). Predicate device K180019 is only a standalone usage device. Additionally, *CAAS Workstation* can be operated using keyboard, mouse and touchscreen while predicate device K180019 could only be operated using the keyboard and mouse.

New technological characteristics in the vFFR workflow in *CAAS Workstation* include a change in the default lesion location from minimum diameter location towards the largest percentage stenosis location and a correction for the hydrostatic pressure as a function of elevation in the pressure drop quantification.

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 similar technological characteristics as the predicate device CAAS Workstation (K180019). The cardiovascular functions supported by the new *CAAS Workstation* are also provided by the predicate device K180019. Both 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.

V - Performance Data

Verification and validation of the new *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 international standards (i.e., ISO13485, ISO14971, IEC 62304, IEC 62366-1, IEC 82304-1, and ISO 15223-1).

Performance testing demonstrated that the numerical results for the analysis workflows StentEnhancer and vFFR, as already available in predicate device K180019, were comparable.

Usability testing is performed in accordance with the IEC 62366-1 standard and demonstrated that the user is able to use *CAAS Workstation* for the purpose it was developed for.

All 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 device.

VI - Conclusion

Based on the application of risk management and performance testing inherent to PMI's QA system (compliant with recognized standards as stated above) *CAAS Workstation* is as safe and effective as its predicate device 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 device.