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

May 16, 2022

Re: K212376
Trade/Device Name: Caas Qardia
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 14, 2022
Received: April 18, 2022

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 (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/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 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 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software 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)*
K212376

Device Name
Caas Qardia

Indications for Use *(Describe)*
Standalone software for medical image analysis intended for advanced visualization and quantitative analysis in adult populations to support physicians with diagnostics by means of enabling segmentation, quantification, review, and reporting of cardiac structures based on multi-dimensional echocardiographic images. Caas Qardia facilitates the following use:

- Segmentation of cardiovascular structures
- Calculation of quantitative indices describing cardiovascular function and structure

When the results provided by Caas Qardia are used in a clinical setting to support clinical decision making, 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.

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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
Preparation Date	14-Apr-22
Trade Name	Caas Qardia
Common Name	Caas Qardia
Classification	Regulation Name: Image Processing System Regulation Class: Class II Regulation Number: 21 CFR 892.2050 Classification Product Code: LLZ
Predicate Device	TomTec Arena (K201632, Image Processing System, 21 CFR 892.2050, LLZ)

II - Device Description

Caas Qardia is an image post-processing software package for diagnostic echocardiography, which offers functionality to view echocardiographic images, to segment cardiovascular structures in these images, to analyze and quantify these cardiovascular structures and to present the analysis results in different formats.

Caas Qardia is a web-based solution for diagnostic echocardiography, intended for usage in a network environment or standalone usage. *Caas Qardia* is composed of the following key analysis features:

- Study selection (from PACS server or local data)
- Image viewing
- Left ventricular ejection fraction analysis
- Left ventricular strain analysis
- Cardiac geometric measurements and velocity measurements
- Reporting
- Export of results

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.

III – Intended Use and Indications for Use

Intended Use

Standalone diagnostic bioimaging software is intended to measure and visualize cardiovascular structures.

Indications for Use

Standalone software for medical image analysis intended for advanced visualization and quantitative analysis in adult populations to support physicians with diagnostics by means of enabling segmentation, quantification, review, and reporting of cardiac structures based on multi-dimensional echocardiographic images. *Caas Qardia* facilitates the following use:

- Segmentation of cardiovascular structures
- Quantification and reporting of cardiovascular function and structure

When the results provided by *Caas Qardia* are used in a clinical setting to support clinical decision-making, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical decision- making.

IV - Substantial equivalence comparison

The Tomtec Arena clinical software package (K201632) was selected as a predicate device specifically for its ability for review, quantification and reporting of cardiovascular structures and function based on echocardiographic images. Unlike Tomtec Arena, which can be used for cardiovascular, fetal and abdominal on medical data acquired with different modalities, *Caas Qardia* can only be used for the analysis of cardiovascular structures in adult populations acquired with echocardiographic images. The Tomtec Arena device, amongst others, consists of analysis workflows for left ventricular ejection fraction analysis, left ventricular strain analysis, cardiac performance analysis (geometric and velocity measurements) and features like image viewing and reporting similar to the *Caas Qardia* device.

The selected device has technological features and characteristics comparable to *Caas Qardia* and is intended to be used or under supervision of a medical specialist to support clinical decision making of cardiovascular conditions.

The basic features and technology of the new *Caas Qardia* product are the same in terms of intended use and indications for use and have the same technological characteristics as the predicate device Tomtec Arena (K201632).

Both *Caas Qardia* and Tomtec Arena (K201632) software applications use the same types of data (echocardiographic images) and operating principles for the user and technology regarding data import, contour definition, image display and storage of results.

V – Performance Data

Caas Qardia was developed and tested according to PMI's design and test procedures and has been extensively tested for safety and performance. Non-clinical verification and validation of the *Caas Qardia* showed that the system requirements – derived from indications for use – as well as risk control measures were implemented correctly, and that the device meets its specifications including conformance to the following recognized consensus standards:

Consensus standard	**Recognition number**
ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices	5-125
IEC 62304:2015 – Medical Device Software – Software Life Cycle Processes	13-79
IEC 62366-1:2015 – Medical Devices – Application of Usability Engineering to Medical Devices	5-114
NEMA PS 3.1-3.20 (2016) – Digital Imaging and Communication in Medicine (DICOM)	12-300
IEC 82304-1:2016 – Health Software – Part 1: General Requirements for Product Safety	13-97

In addition, *Caas Qardia* is compliant with the international standard ISO13485:2016.

Usability testing is performed in accordance with IEC62366 which demonstrated that the user is able to use *Caas Qardia* for the purpose it was developed for.

Performance testing to demonstrate substantial equivalence to the predicate device was conducted. ED and ES volume calculation and EF determination, directly resulting from segmented contours on clinical images are compared to ED and ES volumes and EF resulting from manually annotated ED and ES contours. The acceptance criteria for ED and ES volume, and EF calculations were as follows: A Pearson correlation of 0.7 or higher, an ICC of at least 0.6 and a bias not more than one pooled standard deviation from zero from the comparison with literature. For all values these acceptance criteria were met.

The global longitudinal strain was evaluated on clinical datasets by performing a comparative test of the results against the predicate device. The acceptance criteria for global longitudinal strain were as follows: A Pearson correlation of 0.7 or higher and an ICC of at least 0.6. For all values these acceptance criteria were met.

Inter- and intra-observer variability was evaluated for the ED and ES volume calculation, EF determination and global longitudinal strain (GLS) calculation. Both intra- and inter-observer variability demonstrated acceptable performance with a Pearson correlation higher than 0.9.

The verification and validation results demonstrate the safety and effectiveness of *Caas Qardia* in relation to its intended use and indications for use and therefore *Caas Qardia* can be considered as safe and effective as its predicate devices.

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) the conclusion is that *Caas Qardia* is as safe and effective as its predicate devices in terms of 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.