Circle Cardiovascular Imaging
% Kyle Mayr
Director – Regulatory Affairs & Quality Management Systems
Suite 1100 - 800 5th Ave SW
Calgary, AB T2P 3T6
CANADA

June 7, 2024

Re: K241038
Trade/Device Name: Cardiac CT Function Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 15, 2024
Received: April 16, 2024

Dear Kyle Mayr:

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).

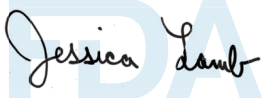
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless 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,



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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241038

Device Name

Cardiac CT Function Software Application

Indications for Use *(Describe)*

The Cardiac CT Function Software Application is indicated to be used with multi-phase, multi-slice cardiovascular CT angiography images to assist qualified medical professionals in assessing and evaluating cardiac function. CT Function includes manual and semi-automatic heart segmentation of 2 chambers (LV and RV) and calculation of cardiac function metrics including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and LV myocardial mass.

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.

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CT Function Module 510(k) Summary

The following 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device Act 1990 and 21 CFR 807.92(c).

I. SUBMITTER

Submitter's Name:	Circle Cardiovascular Imaging, Inc.
Address:	Suite 1100 – 800 5th Ave SW, Calgary, AB, Canada, T2P 3T6
Date Prepared:	June 5th, 2024
Telephone Number:	+1 587 686-0787
Contact Person :	Kyle Mayr
Email:	kyle.mayr@circlecvi.com

II. DEVICE

510(k):	K241038
Name of the Device:	Cardiac CT Function Software Application
Short Brand Name:	CT Function Module
Common or Usual Name:	Automated Radiological Image Processing System
Classification Name:	Medical image management and processing system
Proposed Classification:	Device Class: II Product Code: QIH, LLZ Regulation Number: 21 CFR 892.2050

III. PREDICATE DEVICE

The predicate device is Vitrea CT Multi-Chamber Cardiac Functional Analysis (CFA) manufactured by Vital Images, Inc. and cleared under K141302.

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Circle's Cardiac CT Function Software Application ("CT Function Module" or "CT Function", for short) is a software device that enables the analysis of cardiac images acquired using computed tomography (CT) scanners. It is designed to support physicians in the visualization, evaluation, and analysis of heart function through the calculation of parameters such as volume and mass. The device is intended to be used as an aid to the existing standard of care and does not replace existing software applications that physicians use. The CT Function Module does not interface directly with any data collection equipment, and its functionality is dependent on the type of vendor acquisition equipment. The analysis results are available on-screen or can be saved for future review.

CT Function consists of multiplanar reconstruction (MPR) views and 3D rendering of the original CT data. The module displays three MPR views that the user can freely adjust to any position and orientation. Lines and regions of interest (ROIs) can be manually drawn on these MPR images for quantitative measurements.

The CT Function Module implements an Artificial Intelligence / Machine Learning (AI/ML) algorithm to detect and segment heart structures and post-processing methods to convert the heart segments to editable surfaces. All surfaces generated by the system are editable and users are advised to verify and correct any errors; if desired, users can also perform segmentation of the cardiac structures manually using surface contour generation tools.

The device allows users to perform the measurements listed in Table 1.

CT Function Module 510(k) Summary

Table 1. Measurements in CT Function. "" indicates the measurement is available in the LV only. Note that measurement may also be indexed to patient BSA or height.*

Measurement [units]	Description	Display
End Diastolic Volume (EDV) [mL]	LV/RV cavity volume at the phase defined as the ED.	• On Screen Data Panel • CT Function Report
End Systolic Volume (ESV) [mL]	LV/RV blood volume at the phase defined as the ES.	• On Screen Data Panel • CT Function Report
Stroke Volume (SV) [mL]	The volume of blood pumped out of the LV/RV during each cardiac contraction; represented by the differences of EDV and ESV.	• On Screen Data Panel • CT Function Report
Ejection Fraction (EF) [%]	Percentage of the total amount of blood in the LV/RV that is pumped out in each cardiac cycle; calculated by dividing the SV by EDV.	• On Screen Data Panel • CT Function Report
Cardiac Output (CO) [L/min]	The amount of blood pumped by the heart in a minute; calculated by multiplying the SV and heart rate.	• On Screen Data Panel • CT Function Report
Cardiac Index (CI) [L/min/m^2]	An indexed hemodynamic parameter that relates the CO in one minute to body-surface area (calculated from gender, height, and weight); obtained by dividing the CO by BSA.	• On Screen Data Panel • CT Function Report
End Diastolic Mass (EDM)* [g]	LV myocardial mass at the phase defined as the ED; calculated by multiplying the myocardial volume in ED phase with myocardial density (1.05 g/mL).	• On Screen Data Panel • CT Function Report
End Systolic Mass (ESM)* [g]	LV myocardial mass at the phase defined as the ES; calculated by multiplying the myocardial volume in ES phase with myocardial density (1.05 g/mL).	• CT Function Report
End Diastolic and End Systolic Mass (EDESM)* [g]	Mean LV myocardial mass; calculated as the average of the LV EDM and LV ESM.	• CT Function Report

V. INTENDED USE / INDICATIONS FOR USE

Intended Use

The Cardiac CT Function Software Application is intended for qualitative and quantitative evaluation of cardiovascular CT images in a DICOM Standard format, to calculate and display cardiac function metrics (e.g. end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and LV myocardial mass).

Indications for Use

The Cardiac CT Function Software Application is indicated to be used with multi-phase, multi-slice cardiovascular CT angiography images to assist qualified medical professionals in assessing and evaluating cardiac function. CT Function includes manual and semi-automatic heart segmentation of 2 chambers (LV and RV) and calculation of cardiac function metrics including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and LV myocardial mass.

VI. COMPARISON WITH PREDICATE DEVICE

The detailed analysis of the subject device and the predicate device (shown in **Table 2** and **Table 3**) demonstrates that the subject device is substantially equivalent in indications for use / intended use, technological characteristics, functionality, and operating principles with the predicate (K141302). Of the three characteristics (technical, biological, and clinical) required for the demonstration of equivalence, biological characteristics are not applicable since both the subject device and predicate device are software as a medical device applications with no tangible component interfacing with the body.

Table 2. Intended use and indications comparison.

	Subject Device *CT Function Module (K241038)* Manufactured by Circle	**Predicate Device** *Vitrea CT Multi-Chamber CFA (K141302)* Manufactured by Vital Images
Intended Use	The Cardiac CT Function Software Application is intended for qualitative and quantitative evaluation of cardiovascular CT images in a DICOM Standard format, to calculate and display cardiac function metrics (e.g., end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and LV myocardial mass).	The Vitrea CT Multi-Chamber CFA option is intended to be used with CT studies of the heart to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The CT Multi-Chamber CFA option includes semi-automatic heart segmentation including three chambers (left ventricle, right ventricle, and left atrium) segmentation, including identification of long axis and mitral valve boundaries across multiple phases; calculation of global metrics, including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, stroke index, and myocardial mass; and calculation of regional metrics; including wall motion, percentage of wall thickening, regional ejection fraction, and polar plots.
Indications for Use	The Cardiac CT Function Software Application is indicated to be used with multi-phase, multi-slice cardiovascular CT angiography images to assist qualified medical professionals in assessing and evaluating cardiac function. CT Function includes manual and semi-automatic heart segmentation of 2 chambers (LV and RV) and calculation of cardiac function metrics including end diastolic volume, end systolic volume, stroke volume, ejection fraction, cardiac output, cardiac index, and LV myocardial mass.	

Table 3. Regulatory and technological features comparison.

Feature	**Subject Device** *CT Function Module (K241038)* Manufactured by Circle	**Predicate Device** *Vitrea CT Multi-Chamber CFA (K141302)* Manufactured by Vital Images
Device Class	II	II
Product Code(s)	QIH, LLZ	LLZ
Regulation Name	Medical image management and processing system	Picture Archiving and Communications System
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
DICOM Compliant?	Yes	Yes
Input Data Type	Multi-phase, multi-slice cardiac CT angiography images (vendor independent)	Multi-phase, multi-slice cardiac CT angiography images
Multi-chamber semi-automatic segmentation	Semi-automatic determination of epicardial and endocardial contours, via segmentation of the LV cavity, LV myocardium, and RV cavity in the ED and ES phases using Machine Learning techniques.	Semi-automatic determination of epicardial and endocardial contours, via segmentation of LV chamber and myocardium, RV chamber, and LA chamber.
Tools	• Provides manual contour editing tools if adjustments are needed • Default views automatically aligned to contours to aid typical image review process • Report	• Provides image editing tools if adjustments are needed • Visualization presets and automated steps for typical image review procedures • Report
Views	• 2D image viewing with real-time Window/Level, Zoom, and Pan • 3D and Multi-Planar Reformatting (MPR) view • Automatic industry standard oblique views of the heart (SAX, 2 chamber, and 4 chamber) • Volume Rendering • Phase Navigator • Review Heart in Motion	• 2D image viewing with real-time Window/Level, Zoom, and Pan • 3D and Multi-Planar Reformatting (MPR) view • Maximum Intensity Projection • Automatic industry standard Oblique views of the heart • Volume Rendering • Phase Navigator • Review Heart in Motion
Identification of cardiac phases and landmarks in loaded DICOM datasets	• Automatic determination of ED and ES phases by volume • Manually select/correct ED • Manually select/correct ES • Automatically identifies/orients to long axis view across multiple phases • Automatically identifies/orients basal cut plane close to the mitral valve	• Automatic determination of ED and ES phases by volume • Provides ability to select Diastolic phase • Provides ability to select Systolic phase • Automatically identifies the long axis across multiple phases • Automatically identifies the plane of the Mitral valve
Automated calculation and display of cardiac parameters	• End Diastolic Volume (EDV) • End Systolic Volume (ESV) • Stroke Volume (SV) • Ejection Fraction (EF) • Cardiac Output (CO) • Myocardial Mass (EDM, ESM, EDESM) [in the LV Only]	• End Diastolic Volume (EDV) • End Systolic Volume (ESV) • Stroke Volume (SV) • Stroke Index (SI) • Ejection Fraction (EF) • Cardiac Output (CO)

CT Function Module 510(k) Summary

Feature	**Subject Device** *CT Function Module (K241038)* Manufactured by Circle	**Predicate Device** *Vitrea CT Multi-Chamber CFA (K141302)* Manufactured by Vital Images
	• Cardiac Index (CI)	• Myocardial Mass • Wall Motion • Percent Wall Thickening • Myocardial Volume (MV) • Myocardial Index • Myocardial Mass Index • Regional Ejection Fraction (EF) • Outputs a Polar Map • Time/Volume Graph • Cardiac Index (CI) • Regurgitation Fraction • Cyclic Volume Change • Reservoir Volume
Operating System	Microsoft Windows Apple macOS	Microsoft Windows

VII. PERFORMANCE DATA AND TESTING

Performance testing was conducted to verify compliance with specified design requirements in accordance with ISO 13485:2016, IEC 62304:2015, ISO 14971:2019, and DICOM standards.

Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per the FDA Guidance *"Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submission"*. No clinical studies were necessary to support substantial equivalence.

CT Function Module has been tested according to the specifications that are documented in a Master Software Test Plan. Testing is an integral part of Circle Cardiovascular Imaging Inc.'s software development as described in the company's product development process.

Validation of Machine Learning Derived Outputs

The Machine Learning (ML) algorithms of CT Function Module have been trained and tested on images acquired from major vendors of CT imaging devices. All data used for validation were not used during the development of the ML algorithms. Image information for all samples was anonymized and limited to ePHI-free DICOM headers. The validation data was sourced from 9 different sites, with 90% of the data sampled from US sources. All performance testing results met Circle's pre-defined acceptance criteria.

For cardiac CT function analysis, the acceptance criteria were pre-defined to evaluate the performance of the ML-based segmentation of Left Ventricle (LV) cavity, LV myocardium, and Right Ventricle (RV) cavity. The mean volume prediction error (Mean Absolute Error in predicted volumetric measures, or MAE), 3D Hausdorff Distance (HD), and Dice coefficient were used to evaluate the performance of the segmentation. Overall, comparable performance was achieved on all variability factors including scanner vendors, scanner tube current, pixel resolution, slice thickness, age group, and gender.

Compared to a reference standard established from three expert readers, the ML-based model is capable of segmenting the LV cavity with less than 10% difference in MAE, a Dice coefficient above 86%, a HD below 9.5 mm, and an EF bias of 1.3% with a 95% confidence interval of [-12, 14]. Similarly, the RV cavity is segmented with less than 18% MAE, a Dice coefficient above 85%, a HD below 18 mm, and an EF bias of -5.5% with a 95% confidence interval of [-15, 4.4]. Lastly, the LV myocardium is segmented with less than 17% MAE, a Dice coefficient above 82%, and a HD below 15 mm.

VIII. CONCLUSION

The information submitted in this premarket notification, including the performance testing and predicate device comparison, support the safety and effectiveness of the CT Function Module as compared to the predicate device when used for the defined intended use.