Circle Cardiovascular Imaging
℅ Sydney Toutant
Regulatory Affairs Manager
Suite 110 - 800 5th Ave SW
Calgary, AB T2P 3T6
Canada

December 7, 2023

Re: K232661
Trade/Device Name: Myocardial Strain Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 10, 2023
Received: November 13, 2023

Dear Sydney Toutant:

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
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.

Submission Number *(if known)*

K232661

Device Name

Myocardial Strain Software Application

Indications for Use *(Describe)*

The Myocardial Strain Software Application is intended for qualitative and quantitative evaluation of cardiovascular magnetic resonance (CMR) images. It provides measurements of 2D LV myocardial function (displacement, velocity, strain, strain rate, time to peak, and torsion); these measurements are used by qualified medical professionals, experienced in examining and evaluating CMR images, for the purpose of obtaining diagnostic information for patients with suspected heart disease as part of a comprehensive diagnostic decision-making process.

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.

Strain 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:	August 31 2023
Telephone Number:	+1 587 747 4692
Contact Person :	Sydney Toutant
Email:	sydney.toutant@circlecvi.com

II. DEVICE

Name of the Device:	Myocardial Strain Software Application
Short Brand Name:	Strain Module
Common or Usual Name:	Radiological Image Processing System
Classification Name:	Medical image management and processing system
Proposed Classification:	Device Class: II Product Code: LLZ Regulation Number: 21 CFR 892.2050

III. PREDICATE DEVICE

The predicate device is 2D Cardiac Performance Analysis MR 1.0 (2D CPA MR) manufactured by TomTec Imaging Systems GmbH and cleared under K120135.

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

IV. DEVICE DESCRIPTION

Circle's Myocardial Strain Software Application (Strain Module) is a software device that enables the analysis of CMR images acquired using SSFP cine imaging. It is designed to support physicians in the visualization, evaluation, and analysis of myocardial tissue deformation through CMR feature tracking. 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 Strain Module can be integrated into an image viewing software intended for visualization of cardiac images, such as Circle's FDA-cleared cvi42 software. The Strain Module does not interface directly with any data collection equipment, and its functionality is independent of the type of vendor acquisition equipment. The analysis results are available on-screen or can be saved for future review.

The Strain Module implements an algorithm for deformations modeling of topologies that relies on a two-dimensional (2D) version of the nearly incompressible deformable model. The deformation of the model is assumed to be completely determined by a set of control points placed on the middle curve of the myocardial wall; these points are first defined by the end-user in a reference phase, and then detected in all other phases based on the feature tracked boundaries and incompressibility constraint of the model. Once this feature tracking is complete, the Strain Module computes and reports various global and regional deformation quantities such as strains (including Global Longitudinal Strain (GLS) and Global Circumferential Strain (GCS)), strain rates, displacements, velocities, and torsion. These measurements of myocardial deformation can be made, as appropriate, in the radial, circumferential, or longitudinal directions. Note that the feature tracking and deformation quantity computation is purely mathematical; the Strain Module does not involve any artificial intelligence (AI) or machine learning (ML).

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

Strain Module 510(k) Summary

Table 1. Measurements in the Strain Module.

Measurement [units]	Description	Workflow	Application
Strain [%]	In general, myocardial strain is a measure of the deformation in shape and dimension of the heart muscle during the cardiac cycle. Mathematically Circle uses the Lagrangian strain tensor and measures the deformation with respect to the reference (end diastole) phase. The radial, circumferential and longitudinal strains are defined as the strain tensor evaluated in the radial, circumferential and longitudinal directions on the appropriate SAX or LAX slices (in 2D), respectively.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• This measurement for the global myocardium, or specific regions of myocardium, can be represented over time by Strain Curves. • Strain is also presented as an Image Overlay.
Peak Strain [%]	The maximum of the strain in absolute value, over the whole cardiac cycle.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• This measurement, on a regional basis, can be visualized and reported in Polar Maps. Note: Global peak circumferential strain and global peak longitudinal strain can be added by the user to the clinical report.
Time to Peak Strain [ms]	Trigger time elapsed from the first phase till the phase where the peak strain has been reached.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Strain Rate [1/s]	Derivative of the strain with respect to time.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Strain Curves, as above.
Peak Systolic Strain Rate [1/s]	The maximum of the strain rate in absolute value over all phases starting from the end systole till the next diastole.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Peak Diastolic Strain Rate [1/s]	The maximum of the strain rate in absolute value over all phases starting from the end diastole till the next systole.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Displacement [mm or degree]	The displacement vector represents the position of a point with respect to the position of that point in the reference (end diastole) phase. The radial (both SAX and LAX) and longitudinal (LAX)	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal	• Strain Curves, as above. Displacement is also presented as an Image Overlay.

	displacements are expressed in mm and the circumferential (SAX) displacement is presented in degree.	• LAX-Radial	
Peak Displacement [mm or degree]	The maximum of the displacement in absolute value, over the whole cardiac cycle (expressed in mm for radial and longitudinal, and in degree for circumferential displacements).	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Time to Peak Displacement [ms]	Trigger time elapsed from the first phase till the phase where the peak displacement has been reached.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Velocity [mm/s or degree/s]	Derivative of the displacement with respect to time (expressed in mm/s or degree/s, as appropriate). The circumferential velocity represents an angular velocity.	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Strain Curves, as above.
Peak Systolic Velocity [mm/s or degree/s]	The maximum of the velocity in absolute value over all phases starting from the end diastole till the next systole (expressed in mm/s or degree/s, as appropriate).	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Peak Diastolic Velocity [mm/s or degree/s]	The maximum of the velocity in absolute value over all phases starting from the end systole till the next end diastole (expressed in mm/s or degree/s, as appropriate).	• SAX-Circumferential • SAX-Radial • LAX-Longitudinal • LAX-Radial	• Polar Maps, as above.
Torsion [deg/cm]	The difference in rotation between the apical and basal slices divided by the distance between apical and basal slices. Note that circumferential displacement represents an angle.	• SAX-Circumferential	• Strain Curves, as above.
Torsion Rate [deg/(cm*s)]	The difference in rotational velocity between apical and basal slices divided by the distance between the apical and basal slices. Note that circumferential velocity represents an angular velocity.	• SAX-Circumferential	• Strain Curves, as above.

V. INTENDED USE / INDICATIONS FOR USE

Intended Use

The Myocardial Strain Software Application is intended for qualitative and quantitative evaluation of cardiovascular MR images in a DICOM Standard format. As prerequisite, the user confirms endocardial and epicardial contours in a reference phase, and the software tracks features over the cardiac cycle and computes 2D myocardial deformation and movement (e.g., strain, displacement, velocity).

Indications for Use

The Myocardial Strain Software Application is intended for qualitative and quantitative evaluation of cardiovascular magnetic resonance (CMR) images. It provides measurements of 2D LV myocardial function (displacement, velocity, strain, strain rate, time to peak, and torsion); these measurements are used by qualified medical professionals, experienced in examining and evaluating CMR images, for the purpose of obtaining diagnostic information for patients with suspected heart disease as part of a comprehensive diagnostic decision-making process.

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 (K120135). 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.

Strain Module 510(k) Summary

Table 2. Intended use and indications comparison.

	Subject Device *Strain Module* Manufactured by Circle	**Predicate Device** *2D CPA MR (K120135)* Manufactured by TomTec
Intended Use	The Myocardial Strain Software Application is intended for qualitative and quantitative evaluation of cardiovascular MR images in a DICOM Standard format. As prerequisite, the user confirms endocardial and epicardial contours in a reference phase, and the software tracks features over the cardiac cycle and computes 2D myocardial deformation and movement (e.g., strain, displacement, velocity).	2D CPA MR software is intended for quantification of the myocardial deformation (strain) and movement (displacement / velocity) for digital magnetic resonance images. Possible quantification results are velocity, displacement, strain, strain rate, time-to-peak and phase. Prerequisite is to draw a contour (endocard or endocard and epicard) in a digital magnetic resonance image. Based on this manual drawn contour, the SW calculates with a tracking algorithm the borders' displacement.
Indications for Use	The Myocardial Strain Software Application is intended for qualitative and quantitative evaluation of cardiovascular magnetic resonance (CMR) images. It provides measurements of 2D LV myocardial function (displacement, velocity, strain, strain rate, time to peak, and torsion); these measurements are used by qualified medical professionals, experienced in examining and evaluating CMR images, for the purpose of obtaining diagnostic information for patients with suspected heart disease as part of a comprehensive diagnostic decision-making process.	2D Cardiac Performance Analysis is intended for cardiac quantification based on magnetic resonance images. It provides measurements of myocardial function (displacement, velocity, strain, strain rate) that is used for diagnostic purposes of patients with suspected heart disease.

Table 3. Regulatory and technological features comparison.

Feature	**Subject Device** *Strain Module* Manufactured by Circle	**Predicate Device** *2D CPA MR (K120135)* Manufactured by TomTec
Device Class	II	II
Product Code	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	cine MR images (vendor independent)	cine MR images (vendor independent)
Prerequisites	Endocardial and epicardial contours in reference phase(s).	Contours (endocardial, or endocardial and epicardial) in a digital magnetic resonance image
Myocardial deformation assessment technique	Feature tracking (FT)	Feature tracking (FT)
Comprehensive functional assessment of myocardial function	Yes	Yes
2D functional analysis of myocardial deformation	Yes	Yes
Express parameters in their spatial directions (e.g., circumferential, longitudinal radial)	Yes	Yes
Overlay of tracked contour and graphical displays for measured parameters	Yes	Yes
Myocardial Function Global and Regional Measurements	• Displacement • Velocity • Strain • Strain Rate • Time to Peak • Torsion	• Displacement • Velocity • Strain • Strain Rate • Time to Peak
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.

Strain 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 Outputs

The tracking performance and the clinically relevant Global Longitudinal and Global Circumferential strains were validated using a complimentary combination of simple and realistic phantoms, real MRI data, and analytical solutions. The tracking performance was evaluated with simple analytical phantoms generated with variable input parameters; the deformation field generated by the strain module was evaluated on realistic phantoms with artificially imposed known deformation field and perturbations; and the performance of the constrained tissue tracking algorithm was also compared to manual tracking in ES phase by three expert readers. The computation of the deformation metrics from the tracked deformations were evaluated analytically.

VIII. CONCLUSION

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