Cardiowise, Inc.
% Pierre Bounaud, Ph.D.
Principal Consultant
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave, Suite B-257
SAN DIEGO CA 92110

December 18, 2020

Re: K201250
Trade/Device Name: SQuEEZ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 23, 2020
Received: November 25, 2020

Dear Dr. Bounaud:

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,

For

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)*

K201250

Device Name
SQuEEZ Software

Indications for Use *(Describe)*

The SQuEEZ Software is an image analysis software application for cardiac Computer Tomography (CT) studies to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The software calculates a Stretch Quantifier for Endocardial Engraved Zones (SQuEEZ) value to highlight and color code the wall motions of the heart. Tools are provided to display regional motion properties of the heart.

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

1. Applicant/Submitter

Company Name:	Cardiowise, Inc.
Phone Number:	(479) 571-2592
Company Street Address	535 W. Research Center Blvd., Suite 135
Fax Number:	(479) 571-8814
City:	Fayetteville
State:	AR
Country:	USA
Zip Code:	72701

2. Contact Person

Full Name:	John Coats
Job Title:	CEO
Phone:	(240) 405-8312
Email:	jcoats@cardiowiseinc.com

3. Correspondent Information

Full Name:	Pierre Bounaud, Ph.D.
Job Title:	Principal Consultant
Phone:	(619) 458-9547
Email:	pbounaud@acknowledge-rs.com

4. Date of Preparation

Date of Preparation:	December 15, 2020

5. Device Information

Trade Name	SQuEEZ Software
Common or Usual Name	Picture archiving and communications system.
Classfication Name	21 CFR 892.2050
Regulatory Class	2
Product Code	LLZ

6. Predicate Device

Predicate Type	510(k) Number	Device Name	Manufacturer
Primary Device	K112531	VITREA CT MYOCARDIAL ANALYSIS	VITAL IMAGES, INC.

7. Device Description

Cardiowise SQuEEZ Software is a post processing image analysis software application for cardiac Computer Tomography (CT) studies to assist cardiologists and radiologists in assessing left ventricle function when producing a cardiac evaluation. SQuEEZ Software enables a quantitative evaluation of the regional myocardial strain using the data from an ultra-high-resolution cardiac CT scan that requires an acquisition time of as short as a single heartbeat. This is done by calculating a Stretch Quantifier for Endocardial Engraved Zones (SQuEEZ) value to highlight and color code the wall motions of the heart. The resulting analysis is graphically presented in three-dimensional color contour maps or regional graphical representations that indicate the level of strain the left ventricle experiences during the cardiac cycle.

8. Intended Use/Indications for Use

The SQuEEZ Software is an image analysis software application for cardiac Computer Tomography (CT) studies to assist cardiologists and radiologists in assessing function when producing a cardiac evaluation. The software calculates a Stretch Quantifier for Endocardial Engraved Zones (SQuEEZ) value to highlight and color code the wall motions of the heart. Tools are provided to display regional motion properties of the heart.

9. Comparison of Technological Characteristics with Predicate ·

SQuEEZ Software is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use as the predicate device cleared in K112531, i.e. software application for post-processing analysis of radiological images to assist in the assessment of the regional function of the heart muscle (myocardium).

The subject device and the device cleared in K112531 both use cardiac CT studies as input for post-processing. The device cleared in K112531 achieves its intended use by evaluating heart tissue density as an indicator of wall thickening. Transmural wall thickening happens during the ventricular relaxation-contraction process, thus indirectly representing heart wall motions. The predicate device includes tools (segmentation, color-coding, polar maps) to visualize hypo/hyperdense areas of the myocardium. The subject device creates an endocardial mesh to directly track the left ventricle movements through the same ventricular relaxation-contraction process. Form the endocardial mesh, the subject device derives a calculated value, SQuEEZ, representing local motion of the endocardial surface. The subject device includes similar visualization tools for its SQuEEZ values as the predicate device (i.e. segmentation, color-coding, polar maps).

Based on the testing performed, including software verification and validation, digital

phantom study, and animal performance testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed SQuEEZ Software are assessed to be substantially equivalent to the predicate device.

10. Performance Data

The following tests were performed to demonstrate safety based on current industry standards:

- Software testing per IEC 62304
- Non-clinical performance testing including:
    - Digital phantom study
    - Comparison to tagged MRI (magnetic resonance imaging) in acutely infarcted dogs for noninvasive regional myocardial function analysis

The results of these tests indicate that SQuEEZ Software is substantially equivalent to the predicate device.

Additionally, a peer-reviewed publication describing a study of SQuEEZ values in human subjects with normal left ventricle function was provided to support a determination of substantial equivalence for the subject device.

11. Conclusion

Based on the testing performed, including software testing, digital phantom study, and non-clinical performance testing in animals, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. The similar indications for use, technological characteristics, and performance characteristics for the proposed SQuEEZ Software are assessed to be substantially equivalent to the predicate device.