CASIS Cardiac Simulation & Imaging Software
% Catherine Gloster
Founder and Principal Consultant- Gloster Biomedical International
Gloster Biomedical International
577 N.Hope Ave, Suite 101
SANTA BARBARA CA 93110

September 30, 2022

Re: K211611
Trade/Device Name: QIR Suite
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: August 26, 2022
Received: August 29, 2022

Dear Catherine Gloster:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K211611

Device Name
QIR SUITE

Indications for Use *(Describe)*
QIR Suite is intended to be used for viewing, post-processing, and quantitative evaluation of cardiovascular Magnetic Resonance (MR) images in a DICOM (Digital Imaging and Communication in Medicine) Standard format. The software has been validated for use on adult patients.
QIR Suite comprises QIR-MR for analysis of MR images. QIR-MR is composed of a viewer and analysis modules, and uses user inputs, standard algorithms, and/or automated deep learning detection algorithms.
QIR Suite support the following functionalities:
• Receive, store, transmit, post-process, display, and manipulate medical MR/CT images in the DICOM format (all transfer syntaxes supported including JPEG2000).
• Client/server functionalities to connect to a PACS (Picture Archiving and Communication System), to a HL7 server.
• Visualization of 2D and 2D + time of single or multiple MR datasets.
• Segmentation of regions of interest.
• Measurement of distances and areas.
• Cardiac function MR analyses for the four chambers, including ejection fraction assessment, local myocardial mass, diastolic function, thickness and thickening.
• 2D Flow studies.

Each module generates an automated report of the analysis. QIR Suite allows connection and storage of analyses on a PACS and on a HL7 server.
The software is not intended for use by patients, but rather by qualified medical professionals, experienced in examining and interpreting cardiovascular MR images to obtain diagnostic information as part of a comprehensive diagnostic decision-making process. QIR Suite cannot replace the diagnosis of a qualified practitioner and cannot be regarded as a sole medical point-of-view. The final diagnosis is the sole responsibility of the practitioner.

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) SummarySubmitter

Date prepared:	September 26, 2022
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2. Device

Trade name:	QIR Suite
Regulation Number:	21 CFR 892.2050
Regulation Name:	Medical Image Management and Processing System
Device class:	Class II
Product code:	QIH
Submission number:	K211611

3. Predicate device

QIR Suite is substantially equivalent to Segment CMR of Medviso AB (K163076). This predicate is under the same regulation as QIR Suite (Table 1). Segment CMR is a software with functionalities to analyze cardiac magnetic resonance (MR) images, similar to QIR Suite.

4. Reference Device

In addition to this primary predicate, the software CVI42 (K141480) of Circle Cardiovascular Imaging was used as a Reference Device. This software is under the same regulation as QIR Suite, and is a software to analyze cardiac magnetic resonance (MR) images, similar to QIR Suite.

5. Device description

QIR Suite is a software for quantitative analyses of cardiovascular magnetic resonance images in the DICOM format. Analyses are performed using standardized and deep-learning algorithms. QIR Suite has been validated for adult patients. QIR Suite is intended to be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images for the purpose of obtaining diagnostic information, as part of a comprehensive diagnostic decision-making process. QIR Suite cannot replace the diagnosis of a qualified practitioner and cannot be regarded as a sole medical point-of-view.

6. Indications for use

QIR Suite is intended to be used for viewing, post-processing, and quantitative evaluation of cardiovascular Magnetic Resonance (MR) images in a DICOM (Digital Imaging and Communication in Medicine) Standard format. The software has been validated for use on adult patients.

QIR Suite comprises QIR-MR for analysis of MR images. QIR-MR is composed of a viewer and analysis modules, and uses user inputs, standard algorithms, and/or automated deep learning detection algorithms.

QIR Suite support the following functionalities:

- Receive, store, transmit, post-process, display, and manipulate medical MR/CT images in the DICOM format (all transfer syntaxes supported including JPEG2000).
- Client/server functionalities to connect to a PACS (Picture Archiving and Communication System), to a HL7 server.
- Visualization of 2D and 2D + time of single or multiple MR datasets.
- Segmentation of regions of interest.
- Measurement of distances and areas.
- Cardiac function MR analyses for the four chambers, including ejection fraction assessment, local myocardial mass, diastolic function, thickness and thickening.
- 2D Flow studies.

Each module generates an automated report of the analysis. QIR Suite allows connection and storage of analyses on a PACS and on a HL7 server.

The software is not intended for use by patients, but rather by qualified medical professionals, experienced in examining and interpreting cardiovascular MR images to obtain diagnostic information as part of a comprehensive diagnostic decision-making process. QIR Suite cannot replace the diagnosis of a qualified practitioner and cannot be regarded as a sole medical point-of-view. The final diagnosis is the sole responsibility of the practitioner.

7. Comparison of technological characteristics with predicate devices

Table 1: Technological Characteristics Comparison Table

Features	**QIR Suite v4.1 (MR)**	**Segment CMR (MR)**
Trade name	QIR Suite	Segment CMR
Applicant name	CASIS	Medviso AB
Regulation Name	Medical Image Management and Processing System	Picture archiving and communication system
510(k) number	K211611	K163076
CE marked	2017 – (CE 0459)	2014 – (CE 0413)
FDA Clearance date	TBD	April 5, 2017
Regulatory Class	II	II
Product code	QIH* Automated radiological image processing software	LLZ System, image processing, radiological
Regulation	21 CFR 892.2050	21 CFR 892.2050
Manufacturer	CASIS (France)	Medviso AB (Sweden)
1. Patient population	Adult	Pediatric and Adult
2. Receive, store, transmit, post process, display and allow manipulation of medical MR images	Yes	Yes
3. Client/server functionality to connect to a PACS (Picture Archiving and Communication System) and to activate software license.	Yes	Yes
4. Visualization of 2D and 2D + time of single or multiple datasets.	Yes	Yes
5. Segmentation of regions of interest.	Yes	Yes
6. Measurement of distance and area.	Yes	Yes
7. Cardiac function analysis including ejection fraction assessment, local myocardial mass, thickness and thickening.	Yes	Yes
8. Aorta study including length and area measurements, compliance,	Yes	Yes

Features	QIR Suite v4.1 (MR)	Segment CMR (MR)
regurgitant fraction, and delay wave.		

8. Performance Data

QIR Suite was subjected to extensive testing, verification, and validation during all stages of its development. According to "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*", QIR Suite is a medical device software with a "moderate" level of concern, a level of concern identical to its predicates.

8.1 Verification and Validation Testing

Verification and Validation testing is an integral part of CASIS software development process. QIR Suite has been tested according to specifications from the user need requirements.

Software Requirement Specifications (SRSs) describe the functionalities to be implemented based on the product requirements. The Software Design Specifications (SDSs) describe how the requirements in the SRS are implemented. Before each new release, a series of automated Unit Tests are performed to ensure proper integration of all requirements, and that all SDS met the SRS. An exhaustive list of Software Integration Tests and Software Verification Tests were outlined in the Software Test Plan including the expected outcome of each test. The execution of the validation confirmed that all tests met their acceptance criteria. Therefore, the software has been validated. Manual testing, including formative and summative evaluations, were performed by CASIS's engineers and a team of physicians and collaborators.

8.2 Performance Testing and Substantial Equivalence

Extensive testing was performed with QIR Suite and the predicates SEGMENT CMR to demonstrate that the output of each function of QIR Suite was substantially equivalent to the output of its predicate. Testing was performed using data of patients' database from the US and Europe, with three brands of equipment (Siemens, Philips and GE) and with images acquired with 1.5 or 3 Tesla magnetic field.

Each point in the Table 1 "Technological Characteristics Comparison Table » was evaluated against one of the predicates. Segment CMR was used for features 1 to 6; Circle CVI42 was used for features 7 and 8. Deep learning algorithms used in QIR Suite were evaluated against a ground truth.

To validate quantitative parameters, measurements using patient examinations were performed on QIR Suite and on one of the predicates. The values were then compared in either or both of the following ways.

For each parameter, the measurements obtained in QIR Suite and in the predicate were plotted, with the QIR Suite value on the y axis and the CVI42 value on the x axis. A linear fit was then performed and a correlation coefficient R^2 was calculated. For all measurements, a correlation coefficient above 0.95 was considered in good agreement. Furthermore, the absolute mean difference was calculated as follow. For each parameter, the absolute difference in percent between measurements in QIR Suite and in the predicate was calculated, then the average of the differences was measured. An absolute mean difference between data under 10% was considered excellent.

Measurements were performed on a dataset comprised of MR images from patients from Europe, the USA, and India. These data were recorded using 3 different manufacturers (Siemens, Philips, and GE), and at different magnetic field intensity (1.5 and 3T). Due to anonymization, the pathologies and demographics of the patients were not known.

For each comparison, the correlation coefficient between measurements performed in QIR Suite and the predicate was systematically above 0.97, with an average correlation above 0.99. For all parameters, the absolute mean differences were well under 10%.

For the distance measurements, the absolute mean difference between QIR Suite and Segment CMR showed a variation of 0.8% over 11 measurements, and the area measurements in both software showed a variation of 2.8% over 10 measurements.

For all the cardiac function parameters, the absolute mean difference between QIR Suite and CVI42 is well under 5%, which is within the acceptable margin of error (acceptance criteria ≤10%). The minimum correlation coefficient was 0.9792 and most R^2 were above 0.99, with an average correlation coefficient over all reported values of 0.9954.

For all the 2D flow parameters, the absolute mean difference between QIR-MR and CVI42 was under 10%, which is within the acceptable margin of error. The minimum correlation coefficient was 0.9590 and most R^2 were above 0.99, with an average correlation coefficient over all reported values of 0.9907.

The Deep Learning algorithms were evaluated using a Dice coefficient. The DICE coefficient evaluates the proximity between the algorithm outcome and the ground truth. For instance, a DICE value of 1 would mean no differences between the outcome of the algorithm and the ground truth. DICE measurements performed on large testing datasets gave a mean score of 0.893 and 0.888 for the AG and AG+ algorithms respectively, and 0.908 for the Fast algorithm. These values are closed to previously published results.

The performance testing demonstrated the safety and effectiveness of QIR Suite and demonstrated that the QIR Suite is substantially equivalent to legally marketed predicated devices Segment CMR.

8.3 Clinical performance testing

The subject of this premarket submission did not require clinical studies to support substantial equivalence.

9. Conclusions

QIR Suite and its predicate Segment CMR are support tools for analysis of cardiovascular MR images. These medical device softwares provide the clinician with relevant clinical data to support diagnoses. All analysis functionalities provided by QIR Suite are also provided by the predicate devices, and their Intended Use and Indications for Use are similar.

The main difference between QIR Suite and Segment CMR is in the patient population. QIR Suite's intended population is adults only, whereas Segment CMR also include pediatric patients. This difference does not raise safety or effectiveness concerns; and is clearly stated in QIR Suite's Intended Use and Instruction for Use.

Based on these analyses, we conclude that QIR Suite can be considered substantially equivalent to the predicate devices in Intended Use, Indications for Use, patient population, environment of use, technology characteristics, specifications, and performance. **We conclude that QIR Suite is as safe and effective as the predicate devices Segment CMR. QIR Suite performs in accordance with its Intended Use as well than the legally marketed predicate devices currently on the market Segment CMR.**