K082526

MRI Cardiac Services, Inc

510(k) Summary

JAN - 5 2009

Submitter:
MRI Cardiac Services, Inc
8 West Third Street, M-9
Winston Salem, NC 27101
336-831-1908 (v)
336-727-0919 (f)

Date Prepared:
August 31, 2008

Contact Person(s)

Scott Huber, President
336-831-1908 x 3 (v)
336-727-0919 (f)
scott.huber@provaimages.com

Dwight Ball, VP Operations
336-831-1908 x 5 (v)
336-727-0919 (f)
dwight.ball@provaimages.com

Device Trade Name:
CardioVue Quantitative Analysis™ **(CVQ)**

Device Common Name
Cardiovascular magnetic resonance image analysis software

Classification Name:
Class II – System, Image Processing

Product Code / Regulation Number:
LLZ / 892.2050

Substantially Equivalent To:

MRI-Mass and MRI-Flow
Medis Medical Imaging Systems BV
Schuttersveld 9
2316 XG Leiden
The Netherlands

Device Description:
CVQ is an add-on module to the proprietary software included in the CardioVue™ workstation (K060840.) **CVQ** provides clinical quantitative data by analyzing multi-slice, multi-phase DICOM compatible cardiovascular MR images. Functional and blood flow analysis is performed using 2D, 3D and 4D data sets using standard algorithms and user input. MR images may be imported from various sources including images stored on a CardioVue™ workstation, portable media, network storage devices, PACS, and other vendors systems and supports cardiovascular MR images from all of the major MRI scanner vendors. **CVQ** can be used for the immediate analysis of cardiovascular MR images at the time of the patient study (real-time) or after the study (post processing.)

Intended Use:
CVQ is intended to be used by a qualified cardiologist, radiologist or other licensed professional healthcare practitioners to assist them in making their diagnosis. It uses tools for the rapid analysis DICOM-compliant cardiovascular MR images to provide clinically relevant quantitative data on ventricular function such as left and right ventricular volumes, ejection fractions, stroke volumes, peak ejection and filing rates, myocardial mass, regional wall thickness, fractional thickening and wall motion. It also provides quantitative data on blood flow and velocity in the arterial vessels and at the heart valves. It is intended to be a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Technological Comparison to Predicate Device:
The proposed and predicate devices are both devices that can be used for the analysis of multi-slice, multi-frame and phase encoded DICOM-compliant MR image data sets. Both complete their analysis of these data sets using standard algorithms and user inputs to delineate the myocardial and arterial vascular wall from surrounding tissue and blood (wall contours.) Both render wall contours either fully automatically, semi-automatically, manually or in combination providing clinically relevant data. Both devices allow user input to recalculate rendered numeric output based on a qualified user's expertise. The proposed and predicate device can be operated from a personal computer. **CVQ** is an integrated module of CardioVue 1.0 (K060840) and has substantially equivalent features and specifications to the predicate device.

Laboratory and Clinical Testing:
CVQ is a an integrated custom software module of the CardioVue ™ medical image management device (K060840) intended for analyzing DICOM-compliant cardiovascular images acquired from MRI scanners. **CVQ** does not in any way alter the images. Images from MRI scanners have been proven and accepted clinically.

CVQ is used for real-time image analysis and quantification of cardiovascular images providing clinically relevant numeric computations that support a cardiologist or radiologist in their diagnosis of heart disease. **CVQ** contains no image digitizers and uses only lossless compression. On this basis, MRI Cardiac Services, Inc. believes that clinical investigation is not necessary.

Extensive testing of the software package will be performed by programmers, by non-programmers, quality assurance staff and by potential customers prior to commercial release. (see test plan in Section 6.) We conclude that the subject device, **CVQ** is as safe and effective as the predicate device and posses no new questions of safety and effectiveness.

Adverse Affects on Health:
The potential hazards are identified in the Hazard Analysis and are controlled by:

- Designing controls directed at the cause and/or
- Introducing protective measures and/or
- Warning the Users

All identified hazards are mitigated to minor levels of concern.

8 West Third Street. M-9 Winston Salem, NC 27101
(p) 336-831-1908 (f) 336-727-0919 scott.huber@provaimages.com

See Summary of Safety and Effectiveness on the following page.

Conclusions:
We conclude that the subject device **CVQ** is as safe and effective as the predicate device and poses no new questions of safety and effectiveness. **CVQ** performs in accordance with its intended use as well as the Medis MRI-Mass and MRI-Flow cardiovascular MRI image analysis products currently on the market. MRI Cardiac Services, Inc considers the features of the **CVQ** to be substantially equivalent to the subset of features in common with the MRI-Mass (510(k) 994283) and MRI-Flow (510(k) 994282) and that the subset of features is not effected by the operation of CardioVue ™ (K060840) of which it is an integrated module.

8 West Third Street. M-9 Winston Salem, NC 27101
(p) 336-831-1908 (f) 336-727-0919 scott.huber@provaimages.com

MRI Cardiac Services, Inc

Summary of Safety and Effectiveness

The intended use **CVQ** is for analyzing DICOM-compliant cardiovascular MRI selected and pushed to it from CardioVue (K060840). **CVQ** can be used for real-time image analysis to aid a licensed and qualified cardiologist, radiologist or other clinician in their diagnosis and determination of cardiovascular function and blood flow. It is a support tool that provides relevant data for the clinician that is evaluating a patient's cardiovascular system using functional data such as ejection fraction, stoke volumes and cardiac output. The image analysis provided by **CVQ** makes the images more clinically useful for the physician in making his diagnosis. **CVQ** does **not** in any way alter the MRI imaging data in the analytical process. **CVQ** provides assistance to a professionally trained physician and all of the information is subject to his/her oversight and control. Any potential hazard and /or reduction in effectiveness that may be due to the failure of the hardware or software components of **CVQ** will be mitigated by the user of the device.

CVQ runs on standard off-the-shelf Intel-based PC hardware and Microsoft Windows XP operating system software. The use of these industry standard components provide for maximum availability and reliability making **CVQ** more effective for its intended use. The predicate device also uses an Intel-based PC and another industry standard operating system, Unix. The current versions of these industry standard products used for the operation **CVQ** are of greater effectiveness and any safety concerns caused by failure of the off-the-shelf components and the **CVQ** software component are no greater than the predicate device.

See Substantial Equivalence Chart and copies of the 510(k) Premarket Notification summaries for the predicate devices on the following pages of this Section for comparison to the intended use **CVQ** and discussions of hazard and safety concerns.

8 West Third Street. M-9 Winston Salem, NC 27101
(p) 336-831-1908 (f) 336-727-0919 scott.huber@provaimages.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2009

Mr. Scott Huber
President
MRI Cardiac Services, Inc.
8 West Third Street, Suite M9
WINSTON SALEM NC 27101

Re: K082526
Trade/Device Name: Cardio Vue Quantitative Analysis and Reporting™/Image System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 18, 2008
Received: December 19, 2008

Dear Mr. Huber:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number: K082526

Device Name: CardioVue Quantitative Analysis and Reporting ™ / Image Processing System

Indications for use:

CardioVue Quantitative Analysis ™ is an integrated software component of the CardioVue (K060840) medical image management device that analyzes DICOM-compliant cardiovascular images acquired from MRI scanners and produces reports. CardioVue Quantitative Analysis™ assists qualified cardiologist, radiologist or other licensed professional healthcare practitioners in making their diagnosis by performing functional and blood flow analysis and in reporting their patient study findings. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-the-counter Use _____ (21 CFR 907 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082526