510(k) Summary (REVISED) - K082628 cmr$^{42}$ Cardiac MR Software Application

Submitter's Name: Circle Cardiovascular Imaging Inc.

Address: Suite 130, 3553 31 Street NW, Calgary, AB, Canada T2L 2K7

Establishment Registration Number: Not available

Date of Summary: November 05, 2008

Telephone Number: 1 403 775 1857
 Fax Number: 1 403 270 2384

Email: shirantha@circlecvii.com

Contact Person: Shirantha Samarappuli

Name of the Device: cmr$^{42}$

Common or Usual Name: Image Processing System

Classification Name: Classification Name: Picture Archiving and Communications System
 Device Class: II
 Product Code: LLZ
 Regulation Number: 21 CFR 892.2050

Indications for Use

cmr$^{42}$ is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

It enables:

- Importing Cardiac MR Images in DICOM format
- Supporting clinical diagnostics by qualitative analysis of the cardiac MR images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases.
- Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR images, specifically distance, area, volume and mass
- Supporting clinical diagnostics by using area and volume measurements for measuring LV function and...
derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR images.

- Flow quantifications based on velocity encodes images

It shall 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. cmr42 is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the cmr42 is not restricted, however, the image acquisition by a cardiac magnetic resonance scanner may limit the use of the device for certain sectors of the general public.

cmr42 shall not be used to view or analyze images of any part of the body except the cardiac magnetic resonance images acquired from a cardiovascular magnetic resonance scanner.

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**Identification of the Legally Marketed Device (Predicate Device)**

**MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS)**
Classification Name: System, Nuclear Magnetic Resonance Imaging
Device Class: II
Product Code: LNH
Regulation Number: 21 CFR 892.1000
510k #: K994283

**MRI-Flow Analytical Software (FLOW)**
Classification Name: System, Nuclear Magnetic Resonance Imaging
Device Class: II
Product Code: LNH
Regulation Number: 21 CFR 892.1000
510K #: K994282

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**Device Description**

cmr42 is a dedicated software application for evaluating cardiovascular images in a DICOM Standard format. The software

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can be used as a stand-alone product that can be integrated into a hospital or private practice environment. cmr$^2$ has a graphical user interface which allows users to qualitatively and quantitatively analyze cardiac images for volume/mass, and flow quantification. It provides a comprehensive set of tools for the analysis of Cardiovascular Magnetic Resonance (CMR) images.
510(k) SUMMARY, continued

Indications for Use Comparison

<table>
<thead>
<tr>
<th>DEVICE</th>
<th>INDICATIONS FOR USE</th>
</tr>
</thead>
</table>
| cmr42 CARDIAC MR SOFTWARE K082628 | cmr42 is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables:  
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# DEVICE INDICATIONS FOR USE

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</tr>
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<tbody>
<tr>
<td>MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS) K994283</td>
<td>MASS, including its option, has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac MR data sets. The software enables the display of images for use by trained medical personnel. Intended purposes are: 1. Supporting clinical diagnoses about the status of the global and regional function and anatomy of the cardiac chambers; 2. Supporting the subsequent clinical decision making processes; 3. Supporting the use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of interventions;</td>
</tr>
<tr>
<td>MRI-FLOW ANALYTICAL SOFTWARE K994282</td>
<td>Flow has been developed for the objective and reproducible analysis of velocity-encoded cine MR imaging studies of arterial vessels and heart valves. Intended purposes are: 1. Supporting clinical diagnoses about the status of the function of the cardiac chambers; 2. Supporting clinical diagnoses about the status of the flow velocity and volume flow through cardiac and peripheral vessels, both under basal and increased flow conditions; 3. Supporting subsequent clinical decision making purposes; 4. Supporting the use in clinical research trials, directed at studying changes in function of the heart chambers and in the flow through cardiac and peripheral vessels as a result of interventions;</td>
</tr>
</tbody>
</table>
### 510(k) SUMMARY, continued

#### Device Comparison Table

<table>
<thead>
<tr>
<th>Feature</th>
<th>Submission (cmr42) Cardiac MR Software K082628</th>
<th>Predicate MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS) K994283</th>
<th>Predicate MRI-Flow Analytical Software K994282</th>
</tr>
</thead>
<tbody>
<tr>
<td>Images from all MRI scanner vendors supported</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Workstation operating system</td>
<td>MacOS, Microsoft Windows</td>
<td>Microsoft Windows, Unix, Linux</td>
<td>Microsoft Windows, Unix, Linux</td>
</tr>
<tr>
<td>Import and display magnetic resonance images</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>DICOM compliant networking</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Images can be displayed by study and series</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Store images</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Quantitative assessment of cardiac function</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Task specific modules with corresponding tool sets</td>
<td>X</td>
<td></td>
<td></td>
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<tr>
<td>Analysis of velocity-encoded images</td>
<td>X</td>
<td></td>
<td>X</td>
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<tr>
<td>Dynamic display of ventricular contractions</td>
<td>X</td>
<td>X</td>
<td></td>
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<tr>
<td>Reports containing visualization of images and quantitative parameters</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Analyzes long and short-axis views of the heart for quantitative assessment of cardiac function</td>
<td>X</td>
<td>X</td>
<td></td>
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</tbody>
</table>
510(k) SUMMARY, continued

**Testing:**

cmr\(^42\) have 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 software development process as described in the company’s product development process.

**Conclusion:**

The successful non-clinical testing demonstrates the safety and effectiveness of the cmr\(^42\) when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.
Mr. Shirantha Samarappuli  
Director-Regulatory Affairs & Quality Assurance  
Circle Cardiovascular Imaging, Inc.  
Suite 130, 31 Street NW  
Calgary, Alberta, T2L 2K7  
CANADA  

Re: K082628  
Trade/Device Name: cmr42 Cardiac Magnetic Resonance Imaging Software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: November 11, 2008  
Received: November 12, 2008  

Dear Mr. Samarappuli:  

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" (21 CFR 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 (if known): K082628

Device: cmr$^{42}$ Cardiac Magnetic Resonance Imaging Software

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Prescription Use $\times$ AND/OR Over-The-Counter Use

(Please do not write below this line-continue on another page of needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082628