



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Shirantha Samarappuli
Director-Regulatory Affairs & Quality Assurance
Circle Cardiovascular Imaging, Inc.
Suite 130, 31 Street NW
Calgary, Alberta, T2L 2K7
CANADA

NOV 20 2008

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.

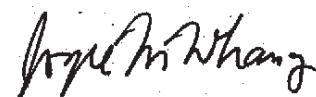
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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" (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 (if known): K082628

Device: cmr⁴² Cardiac Magnetic Resonance Imaging Software

Indications for Use:

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;

- 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.

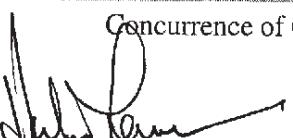
Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(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

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