



FEB 14 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

Cardiovascular Imaging Solutions Ltd.  
c/o Mr. Carl Thomas, Consultant  
OTech, Inc.  
1600 Manchester Way  
CORINTH TX 76210

Re: K073194  
Trade/Device Name: CMRtools™ and plug-ins VentricularTools™  
& Thalassemia Tools™  
Regulation Number: 21 CFR §892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: November 12, 2007  
Received: November 13, 2007

Dear Mr. Thomas:

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.

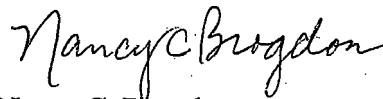
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(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 Biometric's (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,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number:

Device Name:

CMRtools™ and plug-ins VentricularTools™ & ThalassaemiaTools™

Indications for Use:

CMRtools™ and plug-ins VentricularTools™ & ThalassaemiaTools™ is a software device used for viewing and analyzing cardiovascular magnetic resonance images. It allows high performance image manipulation, 3D visualization, and advanced image processing on a standard PC without dedicated hardware. All software plug-ins have comprehensive quantification facilities with full analysis session recording for providing comprehensive audit trails. It contains an image viewer for importing DICOM images, browsing through patient datasets, viewing cine images and performing region-of-interest analysis.

Plug-ins are used for specialist cardiac assessment including VentricularTools for left ventricular assessment and ThalassaemiaTools for T2\* image quantification. It is important that CMRtools is only used to view and analyze human cardiac and or liver images acquired with a cardiovascular magnetic resonance scanner. CMRtools must not be used to view or analyze images acquired with any other type of imaging device.

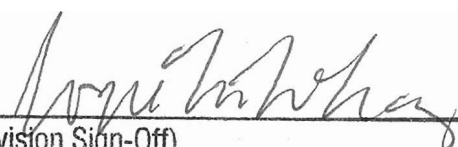
The software must not be used to view or analyze images of any part of the body except the heart and or liver or the vascular system. Furthermore, the software must not be used to view or analyze images acquired from animals.

Only DICOM images will be used for presentation, display and diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  AND/OR Over-The-Counter Use   
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

  
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(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number 15073194