K111373

AUG 2 3 2011

510(K) SUMMARY

circle
CARDIOVASCULAR
IMAGING

Submitter's Name	Circle Cardiovascular Imaging Inc.
Address	Suite 12, 3535 Research Road NW, Calgary, AB, Canada T2L 2K8
Establishment Registration Number	3007301305
Date of Summary	May 12, 2011
Telephone Number **Fax Number**	1 403 338 1870 1 403 338 1895
Email	shirantha@circlecvi.com
Contact Person	Shirantha Samarappuli
Name of the Device	ct[42] Cardiac Computed Tomography (CT) Software
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	ct[42] is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables; • Importing Cardiac CT Images in DICOM format • Supporting clinical diagnostics by qualitative analysis of the cardiac CT images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases, 3D reconstruction of images including multi-planner reconstructions of the

images.

- Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac CT 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 CT images.
- Supporting clinical diagnostics by quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. ct^{42} is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the ct^{42} is not restricted, however the image acquisition by a cardiac CT scanner may limit the use of the device for certain sectors of the general public.

ct^{42} shall not be used to view or analyze images of any part of the body except the cardiac CT images acquired from a cardiovascular CT scanner.

Device Description

ct^{42} is a dedicated software application for evaluating cardiovascular images in a DICOM Standard format. The software can be used as a stand-alone product that can be integrated into a hospital or private practice environment. ct^{42} has a graphical user interface which allows users to qualitatively and quantitatively analyze cardiac CT images for volume/mass, and calcium scoring. It provides a comprehensive set of tools for the analysis of Cardiovascular Computed Tomography (CT) images.

510(k) SUMMARY, continued

Indications for Use Comparison

DEVICE	INDICATIONS FOR USE
ct[42]	ct[42] is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables; • Importing Cardiac CT Images in DICOM format • Supporting clinical diagnostics by qualitative analysis of the cardiac CT images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases, 3D reconstruction of images including multi-planner reconstructions of the images. • Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac CT 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 CT images. • Supporting clinical diagnostics by quantitative measurements of calcified plaques in the coronary arteries (calcium scoring), specifically Agatston and volume and mass calcium scores It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. ct[42] is a software application that can be used as a stand-alone product or in a networked environment. The target population for the ct[42] is not restricted, however the image acquisition by a cardiac CT scanner may limit the use of the device for certain sectors of the general public. ct[42] shall not be used to view or analyze images of any part of the body except the cardiac CT images acquired from a cardiovascular CT scanner.

DEVICE	INDICATIONS FOR USE
K083446 Cardiac Function Analysis Calcium Scoring	The Cardiac Function Analysis software option for use with Ziostation is intended for noninvasive post-processing of DICOM compliant cardiac CT images to semi-automatically calculate and display various functional parameters, such as left ventricular ejection fraction, end diastolic volume, end systolic volume, stroke volume, cardiac output, cardiac index, wall thickness, wall thickness ratio and regional wall motion display. These measurements can be used to assist the clinician in a cardiac evaluation. The Calcium Scoring software option for use with Ziostation is a non-invasive post processing software tool that can be used with CT images to evaluate calcified plaques in the coronary arteries, which may be a risk factor for coronary artery disease.

Device Comparison Table

Feature	Ziosoft – Cardiac Function Analysis & Calcium Scoring	ct[42]	Remarks
510k #	K083446	TBD	
Device Class	II	II	
Device Classification	LLZ	LLZ	
Regulation Name	Picture Archiving and communications systems	Picture Archiving and communications systems	
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	
Post processes ECG gated – Cardiac CT images	YES	YES	
Image viewer functionality	YES	YES	
Left ventricular ejection fraction	YES	YES	
End diastolic volume	YES	YES	
End systolic volume	YES	YES	
Stroke volume	YES	YES	
Cardiac output	YES	YES	
Cardiac Index	YES	YES	
Wall thickness	YES	YES	
Wall thickness ratio	YES	YES	
Wall movement	YES	YES	
Volume Curve	YES	YES	
Calcium Scoring	YES	YES	
Evaluates calcified plaque in the coronary arteries,	YES	YES	
Agatston calcium score	YES	YES	
Volume calcium score	YES	YES	
Calcium mass/density calculations	YES	YES	Ziosoft calculate density and ct[42] calculate mass
DICOM complaint	YES	YES	

510(k) SUMMARY, continued

Description and Conclusion of Testing

Testing:
ct^{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 ct^{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.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Shirantha Samarappuli, Ph.D.
Vice President-Regulatory Affairs and Quality Assurance
Circle Cardiovascular Imaging
12, 3535 Research Road NW
Calgary, AB, T2L 2K8
CANADA

AUG 2 3 2011

Re: K111373
Trade/Device Name: ct^{42} Cardiac Computed Tomography (CT) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 10, 2011
Received: August 12, 2011

Dear Dr. 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111373

Device: ct[42] Cardiac Computed Tomography (CT) Software

Indications for Use:

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Prescription Use ___X___ (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)~~ OIVD

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111373