DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 22, 2014

Circle Cardiovascular Imaging Inc
% Shirantha Samarappuli
VP- Regulatory Affairs and Quality Assurance
815 8th Avenue SW Suit 250
CALGARY, CA T2P 3P2
CANADA

Re: K141480
Trade/Device Name: cvi42
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: August 01, 2014
Received: August 04, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141480

Device Name
cvi42

Indications for Use *(Describe)*
Cvi42 vascular analysis add-on is an image analysis software package add-on for evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplaner reconstruction (MPR), thin/think maximum intensity projection (MIP) thin and think, inverted MIP thin and think, volume rendering technique (VRT), curved planner reformation, processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images), the software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions.

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cvi42 is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the cvi42 is not restricted.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name Circle Cardiovascular Imaging Inc.

Address Suite 250, 815 8th Avenue SW, Calgary, AB, Canada T2P 3P2

Establishment Registration Number 3007301305

Date of Summary May 29, 2014

Telephone Number 1 403 338 1870
Fax Number 1 403 338 1895

Email shirantha@circlecvi.com

Contact Person Shirantha Samarappuli

Name of the Device cvi42

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
cvi42 vascular analysis add-on is an image analysis software package add-on for evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplaner reconstruction (MPR), thin/think maximum intensity projection (MIP) thin and think, inverted MIP thin and think, volume rendering technique (VRT), curved planner reformation, processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images), the software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions.

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cvi42 is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the cvi42 is not restricted, however the image acquisition by a cardiac CT or MR scanner may limit the use of the device for certain sectors of the general public.

Device Description

cvi42 vascular add-on is 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. cvi42 has a graphical user interface which allows users to qualitatively and quantitatively analyze cardiac CT & MR images.

Indications for Use

DEVICE	INDICATIONS FOR USE
cvi42	cvi42 vascular analysis add-on is an image analysis software package add-on for evaluating CT and MR images of blood vessels. Combining digital image processing and visualization tools such as multiplaner reconstruction (MPR), thin/think maximum intensity projection (MIP) thin and think, inverted MIP thin and think, volume rendering technique (VRT), curved planner reformation, processing tools such as bone removal (based on both single energy and dual energy) table removal and evaluation tools (vessel centerline calculation, lumen calculation, stenosis calculation) and reporting tools (lesion location, lesion characteristics) and key images), the software package is designed to support the physician in conforming the presence or absence of physician identified lesion in blood vessels and evaluation, documentation and follow up of any such lesions. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular CT or MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cvi42 is a software application that can be used as a stand-alone product or in a networked environment. The target population for the cvi42 is not restricted, however the image acquisition by a cardiac CT or MR scanner may limit the use of the device for certain sectors of the general public.

DEVICE	INDICATIONS FOR USE
iNtuition K121916	To receive, store, transmit, post-process, display and allow manipulation of reports and medical images from acquisition devices, including optical or other non-DICOM format images, DICOM images with modality type XA, US, CR, DR, SPECT, NM and MG, and images from volumetric medical scanning devices such as EST, CT, PET or MRI. To provide access to images derived data and derived images via client-server software, web browser and mobile technology. Visualization in 2D, 3D and 4D are supported for single or multiple datasets, or combinations thereof. Tools are provided to define and edit paths through structures such as centerlines, which may be used to analyze cross-sections of structures, or to provide flythrough visualizations rendered along such a centerline. Segmentation of regions of interest and quantitative analysis tools are provided, for images of vasculature, pathology and morphology, including distance, angle, volume, histogram, ratios thereof, and tracking of quantities over time. A database is provided to track and compare results using published comparison techniques such as RECIST and WHO. Calcium scoring for quantification of atherosclerotic plaque is supported. Support is provided for digital image processing to derive metadata or new images from input image sets, for internal use or for forwarding to other devices using the DICOM protocol. Image processing tools are provided to extract metadata to derive parametric images from combinations of multiple input images, such as temporal phases, or images co-located in space but acquired with different imaging parameters, such as different MR pulse sequences, or different CT image parameters (e.g. dual energy). iNtuition is designed for use by healthcare professionals and is intended to assist the physician in diagnosis, who is responsible for making all final patient management decisions. Interpretation of mammographic images or digitized film screen images is supported only when the software is used without compression and with an FDA-Approved monitor that offers at least 5Mpixel resolution and meets other technical specifications reviewed and accepted by the FDA.

Device Comparison Table

Feature	**iNtuition**	**cvi42**	**Remarks**
510k #	K121916	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	
Receive, store, transmit, post process, display and allow manipulation of medical MR and CT images	YES	YES	
Client server functionality	YES	YES	
Visualization in 2D, 3D and 4D of single or multiple datasets	YES	YES	
Define and edit paths through structures such as centerlines	YES	YES	
Analysis of cross references of structures	YES	YES	
Fly-through visualization	YES	YES	
Segmentation of regions of interest	YES	YES	
Quantitative analysis including distance, angle, volume, histogram, and tracking quantities over time.	YES	YES	
Derive metadata or new images from input image sets	YES	YES	
Creating/forwarding DICOM images	YES	YES	
DICOM complaint	YES	YES	

Description and Conclusion of Testing
cvi42 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 cvi42 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.