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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

This assigned 510(k) number is: K083293

1. **Submitter's Identification**:

Viatronix Inc.
25 Health Sciences Drive
Suite 203/204
Stony Brook, NY 11790
Establishment Registration number – 2438935

Contact: Dongqing Chen Ph.D, Lead Scientist, Tel: (631) 444-9634

Date Summary prepared:

July 28, 2008

2. **Name of the Device**:

a) Device trade name: Viatronix V3D-Cardiac, revision 1.0
b) Device common name: Medical image processing software system
c) Classification name: 90JAK – Image Processing System

3. **Predicate Device Information**:

Predicate Device: GE. Medical System, CardIQ Xpress, revision 6.12.3, 510(k) #K041267 and #K013422

4. **Device Description**:

The Viatronix V3D-Cardiac is a software device for evaluating scanned images of heart. It is designed to aid the physician in analyzing the heart anatomy and detecting anomaly based on images from a CT scan. The heart anatomy includes coronary arteries, cardiac chambers, aorta root, cardiac valve, myocardium, and other parts of the heart. The goal is to simplify the physician's work as much as possible by providing fully or semi-automated tools for segmenting and measuring coronary artery and left ventricle and displaying reformatted images for visualizing complicated heart anatomy. It is an additional image processing option specific to heart imaging procedure added to our V3D visualization system product line, which pre-market clearance was granted by the FDA vide K002780, K013146, K020658, K022789, K032483, K033361, and K040126. It is a general software module, designed for use as a part of our V3D visualization system core technology. The V3D visualization system consists of V3D processor

and V3D viewer in multiple computer configuration or V3D processor and V3D viewer in a stand alone one computer configuration. Upon receipt of contrast enhanced, multi-slice CT scan images of human heart in a DICOM format, the V3D processor converts the DICOM image data into an internally recognized volume data format using our core software technology. If there are more than one phase images available, the V3D-processor shall automatically extract each phase image into a separate volume and label the phase percentage information based on the header information from DICOM images. The V3D-Cardiac is an organ specific V3D viewer application. The V3D-Cardiac provides interactive orthogonal and multi-planar reformatted 2D and 3D images. User can evaluate those images for normality or malformation in specified part of heart obtained from scanned CT images.

5. **Indications for Use**:

The Viatronix V3D-Cardiac is intended to be used for the display and 2D/3D visualization of medical image data derived from CT of the human heart. The goal of this non-invasive, image analysis software package is to assist physician in diagnosing of cardiovascular disease to include, coronary artery, function of the left ventricle, mayocardium, and follow-up for stent/graft placement, bypasses and plaque imaging. The image post-processing tools are applied real time on-line by the physician's interactive demand. There is no image processing stage required prior to the start of the using of the V3D-Cardiac. The V3D-Cardiac provides a set of fully or semi-automated tools, including, heart segmentation, initial coronary vessel tree segmentation, selected vessel segmentation, vessel cross-sectional quantification measurement, left ventricle volume measurement, and left ventricle volume functional parameter computation. The V3D-Cardiac will also provide automated setting and display of conventional cardiac imaging planes based on a single user input: selection of the center of the aorta valve. The automatic 2D/3D view correlation is available for vessel analysis. User can virtually fly thru the vessel lumen. Manual tools for adjusting and correcting left ventricle region initial segmentation results are provided. The V3D-Cardiac is intended for use by radiologist, clinicians and referring physicians to acquire, process, render, measure, evaluate, archive, print and distribute DICOM 3.0 compliant coronary artery, left ventricle and other heart anatomy images, utilizing PC hardware.

6 (a) **Summary of Differences in Predicate Device**:

Both V3D-Cardiac and the predicate device operate on DICOM images derived from CT scanner.

The V3D-Cardiac provides initial coronary artery tree segmentation automatically. After that, user allows selecting vessel segment by single mouse click at the distal end of the vessel segment. The selection of vessel triggers the final vessel segmentation. The initial artery tree segmentation results intends for vessel anatomy reference only rather than accurate vessel investigation. The predicate device does not provide automatically coronary artery tree segmentation. It provides GUI for semi-automatic extraction of coronary vessels.

Both the predicate device and V3D-Cardiac provide semi-automatic tools for left ventricle volume region extraction. The predicate device allows only for end diastolic and end systolic phases for volume analysis. The V3D-Cardiac allows volume measurement for all loaded phases.

6 (b) **Discussion of Similarities and Differences**:

The Viatronix V3D-Cardiac module utilizes the similar technological characteristics as the predicate device. Both devices are software products that augment an existing 2D/3D DICOM visualization system and are used for post-processing cardiac CT angiography studies.

Both devices permit the physician to select and segment coronary artery structure. Both devices allow the physician to analysis the coronary artery, cardiac chambers, cardiac valves, and myocardium via multi-planar reformatted images. Both devices also provide planar reformatted images along the vessel. The V3D-Cardiac allows color coded the left ventricle region in 2D views for verifying the segmentation accuracy. The predicate device displays contour around ventricle region for the same purpose. The ejection fraction are the essential indicator in both devices for estimating risk of poorer left ventricle function.

The V3D-Cardiac extracts vessel based on centerline of the contrast enhanced vessel lumen. The predicate device extracts vessel based on the human interaction via the "easy growing" tool. The vessel measurements are similar between both devices.

In summary, both devices are similar in design, utility, and presentation. They allow the physician to analyze the coronary artery, cardiac chambers, valves, and myocardium via reformatted 2D and 3D views. They allow physician selecting coronary artery, qualitative judge artery shape, and quantify the artery size. Both devices allow physician to measure left ventricle ejection fraction as essential indicator of risk of poorer left ventricle function.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows**:

Scanned images datasets of actual patients were selected retrospectively and used as input for testing of software functionalities in accordance with a test procedure document CAR0040 in Exhibit # 5. The V3D-Cardiac software module provided interactive orthogonal and multiplanar reformatted 2D and 3D images from DICOM images to detect and evaluate the abnormalities of heart. The area, diameter, and percentage of stenosis measurement features provided in the software were used to evaluate and quantify any abnormality of coronary arteries. The ejection fraction measurement features in the software were used to evaluate and quantify the risk of function of left ventricle.

The V3D-Cardiac module has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. The product has shown itself of reliable, easy to use and capable of evaluating DICOM 3.0 compliant scanned CT images of contrast enhanced human heart. Internal validation for vessel measurements had

been implemented on selected actual patient studies. The internal validation compared the measurement created from V3D-Cardiac against to that from V3D-Vascular, revision 2.0, 510k #k033361. (The V3D-Vascular is a module to assist physician reviewing and investigating vascular disease based on CT and MR angiography DICOM images).

We conclude from these tests that V3D-Cardiac module is substantially equivalent to the predicate devices in its ability to evaluate coronary arteries, left ventricle, myocardium, and other parts of human heart.

8. **Discussion of Clinical Tests\Evaluations Performed**:

Tests and validations on actual patient data were performed per established protocol. The selected patient DICOM images were loaded into the predicate devices. Evaluated coronary arteries results and ejection fraction of left ventricle using the predicate device were recorded. Same image series were loaded into the Viatronix V3D-Cardiac application and the results of evaluation and quantification of coronary arteries and ejection fraction for left ventricle were recorded.

Evaluation results of both predicate device and V3D-Cardiac were same and no significant differences were detected in the results of evaluation.

9. **Conclusions**:

The Viatronix V3D-Cardiac has the same intended use and similar technological characteristics as the GE Medical System CardIQ Xpress (FDA 510(k) #K041267, #K013422). Moreover, tests and validations using patient's heart images and non-clinical tests performed demonstrated that the Viatronix V3D-Cardiac application is substantially equivalent to the predicate devices in its ability to review, analyze, measure and evaluate CT scan images of human heart to facilitate analysis and evaluation of abnormality or malformation in vessels by a trained physician. The Viatronix V3D-Cardiac application does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2008

Viatronix, Inc.
% Mr. Jeff D. Rongero
Senior Project Engineer, Medical Business Unit
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709-3995

Re: K083293
Trade/Device Name: Viatronix V3D-Cardiac, revision 1.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: November 25, 2008
Received: November 26, 2008

Dear Mr. Rongero:

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

Exhibit B

V3D-Cardiac Indications for Use

510(k) Number (if known): K083293

Device Name: Viatronix V3D-Cardiac, revision 1.0

Indications For Use:

The Viatronix V3D-Cardiac is intended to be used for the display and 2D/3D visualization of medical image data derived from CT of the human heart. The goal of this non-invasive, image analysis software package is to assist physician in diagnosing of cardiovascular disease to include, coronary artery disease, functional problem of left ventricle, myocardium anomaly, other heart diseases, and follow-up for stent/graft placement, bypasses and plaque imaging. The image post-processing tools are applied real time on-line by the physician's interactive demand. There is no image processing stage required prior to the start of the using of the V3D-Cardiac. The Viatronix V3D-Cardiac provides a set of fully or semi-automated tools, including, rib cage removal, initial coronary vessel tree segmentation, selected vessel segmentation, vessel cross-sectional size measurements, and left ventricle volume functional parameter computation. The V3D-Cardiac will also provide automated setting and display of conventional cardiac imaging planes based on a single user input: selection of the center of the aorta valve. The automatic 2D/3D view correlation is available for vessel analysis views. User can virtually fly thru the vessel lumen in the endoluminal 3D view. Manual tools for adjusting location of center of mitral valve for left ventricle region segmentation are provided. The V3D-Cardiac is intended for use by radiologist, clinicians and referring physicians to acquire, process, render, measure, evaluate, archive, print and distribute DICOM 3.0 compliant coronary artery, left ventricle and other heart anatomy images, utilizing PC hardware.

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTIUNE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083293

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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