NOV - 5 2003

EXHIBIT #1
4 pages

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.

The assigned 510(k) number is: K033361

1. **Submitter's Identification:**

Viatronix Inc.
25 East Loop Road
Suite 203/ 204
Stony Brook, NY 11790
Establishment Registration number- 2438935

Contact: Frank Dachille Ph.D, Associate Director of R&D, Tel# 631-444-6759

Date Summary Prepared:

October 6, 2003

2. **Name of the Device:**

a) Device trade name: Viatronix V3D Vascular, revision 1.0
b) Device common name: Medical Image processing software system
c) Classification name: 90LLZ- Image Processing system

3. **Predicate Device Information:**

Predicate Device #1: G.E. Medical –Smart Vessel Analysis Option,510(k) # K993792.
Predicate Device #2: Vital Images Vitrea 2, Version 2.1, 510(k) # K002519.

4. **Device Description:**

The V-3D Vascular is a software device for evaluating scanned images of selected vessels. The V3D Vascular module is designed to aid the physician in analyzing the vascular system based on images from a CT or MR scan or X-Ray angiography. The vessels include the coronary arteries, the carotid arteries, the peripheral arteries, the aorta, arteries of the brain, and any opacified veins. The goal is to automate routine inspection of the vessels as much as possible. It is an additional image processing option added to our V-3D visualization system for which pre-market clearance was granted by the FDA

vide K#002780, dated November 17, 2000. It is a general software module, designed for use as a part of our V-3D visualization system core technology. The system consists of a V-3D processor and a V-3D viewer in two computer configuration or V-3D processor and V3D viewer in a stand alone one computer configuration. Upon receipt of a multi-slice CT or MR scan image for any selected vessel in a DICOM format, the V-3D processor converts the DICOM image data into an internally recognized volume data format using our core software. technology. The V-3D viewer provides interactive orthogonal and multiplanar reformatted 2D and 3D images from the V-3D processor and user can evaluate these images for any abnormality or malformation in specified vessels obtained from scanned images using the following methods:

a) The V3D Vascular shall initially segment out all the possible vessels of interest in the dataset.

b) The V3D Vascular shall provide a selection view that allows selection of the vessels that the user wishes to visualize. Any vessels not desired or not actually vessels will then be hidden from view unless the user goes back to the view to re-select.

When examining a vessel the module shall be used to aid in the following ways:

c) The V3D Vascular shall be used to aid the physician in the determination and localization of stenosis in the vessels.

d) The V3D Vascular shall be used to help determine the type of plaque in the vessels.

e) The V3D Vascular shall be used to determine the presence or absence of a bulge or an aneurysmal sac in the wall of the vessel.

f) The V3D Vascular shall be used to determine the presence or absence of a dissection. A dissection is a break in the interior lining of the vessel – the intima – that leads to pooled fluid between the intima and media that form the wall of the vessel.

The intended user can use the software device to acquire, process, render, evaluate, archive, print and distribute DICOM 3.0 compliant images of any vessel, utilizing PC hardware.

5. **Indications for Use:**

The Viatronix V3D Vascular is intended to be used for the display and 2D/3D visualization of medical image data derived from CT, MRI scans or 3D X-Ray angiography of the selected human vessels, e.g., the coronary arteries, the carotid arteries, the peripheral arteries, the aorta, arteries of the brain, and any opacified veins. The goal of this device is to automate routine inspection of human vessels to detect stenosis, plaque, bulge, aneurismal sac and dissection in the vessel. It also supports the interactive segmentation of any vessel by hiding certain parts of the data set from display for critical evaluation of selected part(s) of vessel. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, measure, evaluate, archive, print and distribute DICOM 3.0 compliant vessel image studies, utilizing PC hardware.

6 (a) Summary of Differences in Predicate Device

The data source of the various devices differs in some regards. All devices operate on 3D angiography data derived from a CT scanner (CTA), MR scanner (MRA), or X-ray scanner with 3D reconstruction capability (XA). Predicate device #1 operates on 3D angiography data from various sources and Predicate device #2 operates on angiography

data from CT and MR scanners exclusively. The Viatronix V3D Vascular software operates on data from all three modalities.

Predicate device #2 does not have the capability to select an entire vessel tree using a single seed point. The other systems are able to select a large, branching vascular structure having a near uniform intensity by some simple mechanism that selects voxels based on a single seed point. This feature simply allows for a faster selection of complicated vessel structures to save time. It does not change the measurement capabilities of any system.

The Viatronix V3D Vascular system does not provide angle and tortuosity measurements, while the two predicate devices have this capability to some extent. Many radiologists surveyed had no direct use for the angle and tortuosity measurements so it was deemed unimportant.

6 (b) Discussion of Similarities and Differences

The Viatronix V3D Vascular system utilizes the same technological characteristics as the predicate devices. All are software products that augment an existing 2D/3D DICOM visualization system and are used for post-processing vascular studies.

All permit the physician to select and segment a vascular structure in a 3D stack of 2D DICOM images. All allow the physician to analyze the vessel by looking at curved multiplanar reformatted images through the centerline of the vessel as well as double-oblique reformatted images along the vessel. These are the primary modes of diagnosis used in all three software systems because they allow the physician to view the vessel from all angles while cutting through the vessel in a cross-section.

All three provide 3D views of the vessels using 3D volume rendering (VR) or maximum intensity projection (MIP) for examination from the exterior of the vessel. Some of the devices do not provide tortuosity and angle measurements. All provide measurements of area and diameter along the vessel cross-sections as well as percent stenosis and length measurements along the centerline.

In summary, all three devices are similar in design, utility, and presentation. They all allow the physician to select vessels, qualitative judge the vessel shape, and to quantify the vessel sizes.

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

Scanned image datasets of various patients vessels with known abnormalities or status were used as input for testing of software functionalities in accordance with a test protocol. The V3D Vascular software module provided interactive orthogonal and multiplanar reformatted 2D and 3D images from datasets to detect and evaluate the known abnormalities or status of vessels. The Length, Area, Minimum Diameter and

Maximum Diameter measuring features provided in the software were used to evaluate and quantify any abnormality of vessels.
The V3D Vascular Module has been developed in a manner consistent with accepted standards for software development, including both unit and system integration testing protocols. Testing on phantom datasets has determined its level of accuracy, which correlates perfectly with pre-calculated values. The product has shown itself to be reliable, easy to use and capable of evaluating DICOM 3.0 compliant scanned images of any human vessels.
We conclude from these tests that V3D Vascular module is substantially equivalent to the predicate devices in its ability to evaluate any human vessels.

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

Tests and validations on Patients' various vessels were performed per protocol. Loaded Patients' scanned vessels images to the predicate device. Evaluated various vessels using the predicate device and recorded the results of evaluation and quantification of Length, Area, Minimum Diameter and Maximum Diameter of vessels under study..

Same scanned vessels images were loaded into the Viatronix V3D Vascular application. Evaluated all Patients' various vessels using V3D Vascular application, and recorded the results of evaluation and quantification of Length, Area, Minimum Diameter and Maximum Diameter.

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

In conclusion, it was established that the V3D Vascular application is substantially equivalent to the predicate devices.

9. **Conclusions:**

The Viatronix V3D Vascular has the same intended use and similar technological characteristics as the GE Medical Smart Vessel Analysis Option (K # 9993792) Vital Images Vitrea 2, Version 2.1 (K # 002519) . Moreover, tests and validations using Patients'Vessels Image data and non-clinical tests performed demonstrated that the Viatronix V3D Vascular application is substantially equivalent to the predicate devices in its ability to review, analyze, measure and evaluate CT/ MR scan and 3D X-Ray angiography images of various vessels to facilitate analysis and evaluation of abnormality or malformation in vessels by a trained physician. The Viatronix V3D Vascular application does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2003

Viatronix, Inc.
% Ms. Susan Gill
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K033361
Trade/Device Name: Viatronix V3D Vascular, Revision 1.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: October 20, 2003
Received: October 21, 2003

Dear Ms. Gill:

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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

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

Enclosure

Exhibit B

INDICATIONS FOR USE

510(k) Number (if known): K033361

Device Name: Viatronix V3D Vascular, revision 1.0

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** **OR** **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033361