K103761

FEB 1 1 2011

5 510(k) Summary

Submitter: The Medipattern Corporation
3080 Yonge Street, Suite 4070
Toronto, Ontario, Canada M4N 3N1

Contact Person: Erin Walsh
Regulatory and Quality Manager

Date Prepared: December 22, 2010

Trade name: Visualize:Vascular

Classification Name: Archiving and Communications Workstation
(21 CFR 892.2050)

Product Code: LLZ

Panel: Radiology

Predicate Devices:
1. Philips QLab; cleared under K021966 and K040227
2. TomTec Echo-View; cleared under K022824 and K040546

Device Description: Visualize:Vascular™ 1.0 is a software application designed to assist in visualization, analysis and reporting of ultrasound vascular images. All images acquired for use with Visualize must be obtained using the data acquisition protocol found in the Visualize:Vascular User Guide.

Visualize:Vascular displays cine clips in stack mode, which can be viewed going forward and in reverse. When the user selects a region(s) of interest within the cine clips, Visualize provides a 3D volume reconstruction and surface rendering of the segmented information. The user can manipulate and annotate the 3D reconstructed images. Visualize can also map the cine colour flow information provided by the ultrasound system onto the 3D rendered data. Visualize provides an automated method to measure the narrowest and widest sections of segmented areas.

Visualize:Vascular displays 2D sagittal ultrasound images and provides a manual tool for measurements to be recorded on these 2D images.

The software application automatically generates reports from user inputs annotated during the image analysis process. The user may select the images, measurements and clinical findings to display in the report. All fields may be modified by the user at any time during the analysis and prior to archiving.

An output may be viewed and sent to standard film or paper printers or sent electronically to an intranet web server or other DICOM device. The software may retrieve archived reports from a web server or other DICOM device.

The Visualize software is a Windows 7, DICOM-compatible platform that may be installed on a standalone PC, PACS, imaging system or embedded in software applications cleared for use in medical imaging. The Medipattern software is designed to be compatible with any of the DICOM-compliant medical devices distributed by various OEM ultrasound equipment manufacturers.

Intended Use:

Visualize:Vascular is a software application package. It is designed to view and quantify image data acquired on commercially available ultrasound products. Regions of interest can be segmented, measured and annotated. The results can be displayed in 2D or 3D. The system automatically generates reports of user inputs.

Comparative Analysis:

Visualize:Vascular has been demonstrated to be as safe and effective as the predicate devices for their intended use.

Functional/Safety Testing:

Visualize:Vascular has successfully undergone functional testing. This product has been shown to be equivalent to the predicate devices.

Conclusion:

Visualize:Vascular is substantially equivalent to the predicate devices.

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

Ms. Erin Walsh
Regulatory and Quality Manager
The Medipattern Corporation
3080 Yonge Street, Suite 4070
Toranto, Ontario, M4N 3N1
CANADA

FEB 1 1 2011

Re: K103761
Trade/Device Name: Visualize: Vascular™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: LLZ
Dated: December 22, 2010
Received: December 23, 2010

Dear Ms. Walsh:

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 Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known):

Device Name: Visualize:Vascular™

Indications for Use:

Visualize:Vascular is a software application package. It is designed to view and quantify image data acquired on commercially available ultrasound products. Regions of interest can be segmented, measured and annotated. The results can be displayed in 2D or 3D. The system automatically generates reports of user inputs.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF 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 K103761