K082607

DEC 0 5 2008

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR Part 807.92, Subpart E.

1. Identification of Submitter:

Submitter:	VPDiagnostics
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Phone:	206-428-6160
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Contact:	Michael Hartmann
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Summary Date:	June 19, 2008

2. Identification of Product:

Device Name:	MRI-PlaqueView
Device Common Name:	System, Image Processing, Radiological
Device Classification:	21 CFR 892.2050, Class II, LLZ
Manufacturer:	VPDiagnostics

3. Predicate Devices

MRI-PlaqueView provides viewing and post-acquisition image analysis of user-selected regions of interest on MR images. This software medical device is substantially equivalent to the following devices:

Model:	Vitrea Version 4.0 with SUREPlaque
Manufacturer:	Vital Images
510K Number:	K071331

Model:	QPlaque-MR
Manufacturer:	Medis
510K Number:	K073156

4. Device Description:

MRI-PlaqueView is an image analysis software toolbox that facilitates visualization and quantitative analysis of MR images of carotid arteries acquired on 1.5T or 3.0T scanners. MRI-PlaqueView provides a set of image review, delineation, registration, editing, visualization, and measurement tools. The MRI-PlaqueView user interface is designed to follow typical clinical workflow patterns to review, process, edit, validate, analyze, and visualize digital images and to present, distribute and save the findings.

The software application operates on a Windows XP platform that may be installed on a standalone PC, PACS or other medical imaging system. The software is designed to read MRI images from DICOM-compliant medical devices distributed by various OEM vendors.

The input to the system consists of one to six standard MRI series, which provide information through use of different MRI contrast weightings, such as T1, T2, Proton Density, and TOF weighted images

Once the user has selected a region of interest (ROI) for analysis, the MRI-PlaqueView tools will help to delineate the lumen and outer wall boundaries using either semi-automatic boundary detection or manual drawing/editing tools

The software provide the user an option to further analyze the multiple contrast weighted MRI data using either semi-automated algorithms or manual drawing/editing tools to segment and label the internal structure of the vessel wall, delineating calcified and soft plaque regions.

To facilitate the use of multiple contrast weighted data, the software displays the identified contours simultaneously on original images from all available series. Automated and user-controlled registration functions enable mapping of contours from one contrast weighting to another.

The quantitative measurements this software provides include volumes, thicknesses, maximal areas, and area ratios of the different regions outlined. The software also supports review and visualization of the data using standard rendering techniques, such as maximum intensity projections. The analysis results (both contours and quantitative measurements) can be saved in separate files to facilitate restoring previous works for subsequent sessions, and for reporting results.

5. Indications for Use

The MRI-PlaqueView software provides a set of post-processing tools to assist trained cardiologists and radiologists in the quantitative analysis of atherosclerotic carotid arteries from 1.5T or 3.0T magnetic resonance imaging (MRI) studies acquired with a combination of one or more contrast weightings such as T1, T2, Proton Density, and Time of Flight. Users of MRI-PlaqueView perform semi-automatic delineation of lumen and outer vessel wall boundaries. Users may also perform semi-automatic, user configurable segmentation or manual drawing for delineation of atherosclerotic plaque components within the vessel wall. Users may edit the results on the fly. The software enables length, thickness, and area and volume measurements of the vessel wall as well as quantification of user-indicated areas. MRI-PlaqueView further aids in the visualization of atherosclerotic arteries (for example, through maximum intensity projections) of MRI data and color-coded maps of segmented arteries. When interpreted by a trained physician, the output of this image analysis toolbox can be used to support the decision-making process in clinical practice or to support investigations in clinical research and trials.

6. Comparison with Predicate Devices

MRI-PlaqueView is substantially equivalent to several software applications that analyze and measure regions of interest in magnetic resonance or CT images. The predicate devices include

K071331- Vital Images Vitrea Version 4.0 with SUREPLAQUE (Appendix A)
K073156 -Medis QPlaque-MR) (Appendix B)

Vital Images Vitrea Version 4.0 has been classified under 21 CFR 892.2050 as a Class II medical device
Medis QPlaque-MR has been classified under 21 CFR 892.1000 as a Class II medical device.

Both of these devices provide automated and interactive analysis tools to delineate and make measurements of size (volume, area, thickness) of regions of interest (ROI) in magnetic resonance (Medis QPlaque MR) or CT images (Vital Images Vitrea) and provide visualization and reporting utilities for the results. Both of these devices specifically address ROI measurements in blood vessels and specifically address measurement of ROIs within atherosclerotic plaque for CT (Vital Images Vitrea) and magnetic resonance images (Medis QPlaque-MR) respectively. Both provide substantially equivalent indications for use and have been developed with substantially equivalent mathematical algorithms.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2008

Mr. Michael Hartmann
VP, Product and Business Development
VPDiagnostics, Inc.
819 Virgina St., Suite 2209
SEATTLE WA 98101

Re: K082607
Trade/Device Name: MRI-PlaqueView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 4, 2008
Received: September 8, 2008

Dear Mr. Hartmann:

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

4 **Indication(s) for Use Statement**

510(k) Number: To be assigned K082607

Device Name: MRI-PlaqueView

Indications for Use:

The MRI-PlaqueView software provides a set of post-processing tools to assist trained cardiologists and radiologists in the quantitative analysis of atherosclerotic carotid arteries from 1.5T or 3.0T magnetic resonance imaging (MRI) studies acquired with a combination of one or more contrast weightings such as T1, T2, Proton Density, and Time of Flight. Users of MRI-PlaqueView perform semi-automatic delineation of lumen and outer vessel wall boundaries. Users may also perform semi-automatic, user configurable segmentation or manual drawing for delineation of atherosclerotic plaque components within the vessel wall. Users may edit the results on the fly. The software enables length, thickness, area, and volume measurements of the vessel wall as well as quantification of user-indicated areas. MRI-PlaqueView further aids in the visualization of atherosclerotic arteries (for example, through maximum intensity projections) of MRI data and color-coded maps of segmented arteries. When interpreted by a trained physician, the output of this image analysis toolbox can be used to support the decision-making process in clinical practice or to support investigations in clinical research and trials.

Prescription Use ___✓___ 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082607