K091498
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2. 510(K) SUMMARY AS REQUIRED BY 21 CFR 807.92

JUN - 5 2009

510(k) Number: K

Date Prepared: May 5, 2009

SUBMITTER INFORMATION	
Submitter: Vital Images, Inc. Street Address: 5850 Opus Parkway Suite 300 Minnetonka, MN 55343-4414 Establishment registration: 2134213	Contact Person Darin Busch Manager, Regulatory Affairs Phone: Phone: (952) 487-9680 Fax: (952) 487-9510 Email: dbusch@vitalimages.com

DEVICE INFORMATION	
Trade Name	Endovascular Stent Planning Software
Common Name	Radiological Image Processing Software
Classification Name	System, Image Processing, Radiological
Regulation /Product Code	21 CFR 892.2050
Product Code	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

The Endovascular Stent Planning Software is substantially equivalent to the following predicate devices.

Predicate Device	**Manufacturer**	**FDA 510(k)**
Vitrea®, Version 4.0 Medical Image Processing Software	Vital Images, Inc	K071331
Vitrea2, version 2.1	Vital Images, Inc	K002519
Preview® Treatment Planning Software	MEDICAL MEDIA SYSTEMS, INC	K040852
GE AVA II/Vessel Xpress (AVA II/Vessel Xpress)	GE HealthCare Waukesha, WI	K060779

2.1. Device Description

The Endovascular Stent Planning Software, an application module for the Vitrea software, enables visualization and measurements of the aortic vessel for evaluation, treatment and follow up for aortic vascular disorders that may require a stent procedure. It has the following features:

- Automated segmentation of the aortic vessel, including thrombus
- Custom and manufacturer-recommended stent-graft worksheets and report templates for stent sizing
- Automatic initialization of endovascular measurements (diameters, lengths, angles, volumes) based on the stent template selection, with easy centerline and contour editing tools
- Workflows for pre-treatment (stent, surgery) planning and post-treatment follow up, including a side-by-side comparative review layout

2.2. Intended Use/Indications for Use

Vitrea® is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography. In addition, Vitrea has the following additional indication:

The Endovascular Stent Planning Software application is intended for use with CT (computed tomography) images to assist medical professionals in the analysis, treatment and follow-up of aortic vascular disorders that may require a stent procedure. The software provides 3D segmentation of the aorta and initializes stent measurements based on a template provided by the stent manufacturers. The user can review the 2D and 3D images, verify and correct the results of the segmentation and initialization, and generate a report with the stent measurements.

2.3. Summary of Testing

The software was designed, developed and tested according to written procedures. Software testing was completed to insure the Endovascular Stent Planning Software features function according to the requirements and interact without impact to existing functionality. The test results support a determination of substantial equivalence.

2.4. Conclusions

Vitrea Endovascular Stent Planning software has similar intended use as the predicate devices and essentially identical technological characteristics. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device. The Vitrea Endovascular Stent Planning Software application performs as intended, and presents with no unacceptable risks to the intended patient population or end user. Vitrea Endovascular Stent Planning Software is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2009

Vital Images, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

Re: K091498
Trade/Device Name: Vitrea® Endovascular Stent Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 19, 2009
Received: May 20, 2009

Dear Mr. Job:

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 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 Center for Devices and Radiological Health's (CDRH's) 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 892.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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. **INDICATIONS FOR USE STATEMENT** .

Indications for Use

510(k) Number (if known): K091498

Device Name: Vitrea® Endovascular Stent Planning Software

Indications for Use:

Vitrea® is a medical diagnostic system that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices. Vitrea is not meant for primary image interpretation in mammography. Vitrea has the following additional indication:

The Endovascular Stent Planning Software application is intended for use with CT (computed tomography) images to assist medical professionals in the analysis, treatment and follow-up of aortic vascular disorders that may require a stent procedure. The software provides 3D segmentation of the aorta and initializes stent measurements based on a template provided by the stent manufacturers. The user can review the 2D and 3D images, verify and correct the results of the segmentation and initialization, and generate a report with the stent measurements.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 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 K091498