DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Vital Images, Inc.
% Mr. Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

December 4, 2014

Re: K143079
Trade/Device Name: Endovascular Stent Planning Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 24, 2014
Received: October 27, 2014

Dear Mr. Shah:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143079

Device Name
Endovascular Stent Planning Software

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c)

Purpose of Submission:	Vital Images, Inc. hereby submits this special 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared Endovascular Stent Planning software (K091498).
Submitter:	Vital Images, Inc. 5850 Opus Parkway Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Parthiv Shah Sr. Regulatory Affairs Specialist Phone : 952–487–9574 Fax: 952–487–9510 E-mail: pshah@vitalimages.com
510(k) Type:	Special
Summary Date:	October 24, 2014
Device Trade Name:	Endovascular Stent Planning Software
Device Common Name:	Radiological Image Processing Software
Device Classification Name:	System, Image Processing, Radiological
Regulatory Description:	Picture Archiving and Communications System
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Device:

Predicate Device	Manufacturer	FDA 510(k) number
Endovascular Stent Planning (Legally Marketed Device)	Vital Images, Inc.	K091498

Device Description:

The Endovascular Stent Planning software 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 endovascular stent planning application module enables visualization and measurements of the aortic vessel for evaluation, treatment and follow up for aortic vascular disorders that may require a stent procedure. The software performs automated 3D segmentation of the aorta and initializes stent measurements based on a template provided by the stent manufacturers. The physicians 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, in a fast and efficient manner.

The software provides imaging information as an assist to the physician. The software does not provide diagnostic information or determine recommended medical care. In summary, the software provides:

- Automated segmentation of the aortic vessel, including thrombus with centerline and contour editing tools
- Stent-graft templates for abdominal and thoracic aortic aneurysms
- User-guided workflow with automated identification of anatomical landmarks and automated initialization of endovascular measurements (diameters, lengths, angles, volumes) based on the stent template selection, with easy centerline and contour editing tools
- Auto-populated reporting worksheet with selected stent template measurements
- Key measurements that helps medical professionals to identify location of fenestrations to support fenestrated stent planning by adding the clock angle tool and the clock angle overlay functionality
- Create new, add/or modify, stent planning templates with the Custom Device Template Editor
- Data tables export results to CSV
- Multi-study support for longitudinal comparison
- 3D measurement overview for streamlined communication of results
- Volume measurements for pre and post aneurysmal size measurement
- Workflows for pre-treatment (stent, surgery) planning and post-treatment follow up, including a side-by-side comparative review layout and longitudinal measurements

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. 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.

Rationale for Adding Clock Angle Tool in the Software
Typically, a vascular surgeon or interventional cardiologist is responsible for all necessary stent planning procedures, which includes identifying necessary anatomical measurements from patient's CT scan data for proper size stent selection including fenestrated stents, which is required for patients whose aneurysm begins close to the renal arteries (i.e. an inadequate length of suitable aorta for the standard stent.) The surgeon/ cardiologist prefer to have a "Clock Angle" tool in the software that can provide additional measurements required to fill order sheet for ordering fenestrated stent.

The clock angle tool provides a special set of measurements required on fenestrated stent sizing worksheet. The Clock Angle tool provides a time relative to a noon marker. This provides information for designating vessel locations relative to a common frame of reference.

Generally, the responsible surgeon/cardiologist and manufacturer will re-verify software provided measurements by other standardized methods before finalizing fenestrated stent sizing for a patient.

Intended for Disease / Condition / Patient Population:
The Endovascular Stent Planning Software application is intended for assisting medical professionals in the analysis, treatment and follow-up of aortic vascular disorders that may require a stent procedure.

Substantial Equivalence Comparison:

- **Regulatory Comparison**

Criteria	**Legally Marketed Device** **Endovascular Stent Planning Software (K091498)**	**Modified Subject Device**	**Comparison**
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

- **Intended Use Comparison**

Criteria	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
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.	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.	Same

Criteria	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
	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.	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.	

- **Technology Comparison**

Feature	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
Vessel segmentation of the aortic vessel, including thrombus and centerline extraction	Yes	Yes	Same
Custom or manufacture stent graft specific worksheet templates	Yes	Yes	Same
Initialization of endovascular measurements	Yes	Yes	Same
Display of image side by side in 3D and MPR	Yes	Yes	Same
Manual centerline and contour editing tools	Yes	Yes	Same

Feature	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
Sequential viewing	Yes	Yes	Same
Diameter, Area, Lengths, Stenosis measurements	Yes	Yes	Same
Tortuosity, Angle, Volume measurements	Yes	Yes	Same
Intensity (HU) based color coding of vessel lumen and wall regions	Yes	Yes	Same
DICOM Modality	CT	CT	Same
Hardware Requirements	Identical to Vitrea platform	Identical to Vitrea platform	Same
Software Requirements	Identical to Vitrea platform	Identical to Vitrea platform	Same
Tool: Ruler It provides a length measurement between 2 points. Used commonly for diameters of vessels.	Yes	Yes	Same
Tool: Length It provides a length between 2 centerline points along the centerline.	Yes	Yes	Same

Feature	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
Tool: Angle It provides an angle in degrees derived from 3 points which create 2 line segments.	Yes	Yes	Same
Tool: Volume It provides a volume of a given region by adding all the voxels contained within the region of interest.	Yes	Yes	Same

- **Differences in Technology**

Feature	Legally Marketed Device Endovascular Stent Planning Software (K091498)	Modified Subject Device	Comparison
Tool: Clock Angle It provides a time relative to a noon marker. This is a way of designating vessel locations relative to a common frame of reference.	No	Yes	The added feature does not affect the intended use or fundamental scientific technology of already cleared Endovascular Stent Planning Software (K091498).

- **Substantial Equivalence Analysis**

  The addition of Clock Angle tool and related measurements do not affect the intended use or alter the fundamental scientific technology of legally marketed Endovascular Stent Planning software (K091498). The modified Endovascular Stent Planning software has the same indications for use, principle of operation, and performs the same technological functions as already cleared Endovascular Stent Planning software - K091498 (Predicate Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use.

  Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness when used as labeled. The implemented design mitigations,

labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.

Summary of Non-Clinical Tests:
The changes to the Endovascular Stent Planning software was designed developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new feature operates according to its requirements.

Testing included verification, validation, and evaluation on previously acquired medical images. The following quality assurance measures were applied to the development:

- Risk Management
- Requirements reviews
- Code designs
- Code reviews
- Design reviews
- Verification of the software – that included performance, phantom, and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals.

Risk Management:
Each risk pertaining to this feature has been individually assessed to determine if the benefits outweigh the risk. Every risk has been reduced as low as possible and has been evaluated to have a probability of occurrence of harm of "Improbable." All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Based on the post market information contained in our Clinical Evaluation Report, injury or death is very rare for our product and products similar to ours. Because of this history and because of the risk control measures included in this feature, it is believed that the risk for the feature as a whole is extremely low. Taking into account all risks against the benefits of this feature, it has been assessed that the benefits do outweigh the risks for this feature.

During the design review, the following conclusions were reached:

- All risks were reduced as low as possible
- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- The overall residual risk for the project is deemed acceptable

Verification:
The software verification team's primary goal was to assure that the software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As a part of creating the test cases, the verification team reviewed and monitored the Requirements Traceability Matrix ("RTM") to ensure coverage of the items within the RTM.

Validation:
The software validation team's primary goal was assuring the software conforms to user needs and intended use. The validation team conducted workflow testing that provided evidence that the system requirements and features were implemented, reviewed and met.

External Validation:
During external validation of enhanced Endovascular Stent Planning software, experienced medical professionals evaluated the application. Both validators confirmed that the Fenestrated Stent Planning using Endovascular Stent Planning software was safe and effective and met the intended use of assisting medical professionals in the analysis, treatment, and follow-up of aortic vascular disorders that may require a stent procedure.

Summary of Clinical Tests:
The subject of special 510(k) notification, Endovascular Stent Planning software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

- ***Confidentiality***
  The Vitrea platform (K071331) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.
- ***Integrity***
  The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. The Vitrea platform identifies the data it produces, marking and encoding the appropriate DICOM fields.
- ***Availability***
  The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.
- ***Accountability***
  The Vitrea platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:
The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The Endovascular Stent Planning software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012

Standard No.	Standards Organization	Standard Title	Version	Date
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Conclusion:
Vital Images believes that Endovascular Stent Planning software application has a substantially equivalent intended use, indications for use, principle of operation, and technological characteristics as the predicate device. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness as the predicate device. The implemented design mitigations, labeling, and performed tests demonstrate the safety and efficacy of the device in comparison to the predicate device. Based on the comparison data and test data Vital Images believes, the subject device should be found substantially equivalent to the predicate device. The Endovascular Stent Planning software device is as safe and effective as the predicate device.