DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 16, 2016

Vital Images, Inc.
% Ms. Alexis Erazo
Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343-4414

Re: K160150
Trade/Device Name: Vitrea CT Colon Analysis
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 20, 2016
Received: January 21, 2016

Dear Ms. Erazo:

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

Robert Ochs, Ph.D.
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)*
K160150

Device Name
Vitrea CT Colon Analysis

Indications for Use *(Describe)*
The separately-licensed CT Colonography option is intended for closely examining the lumen of the colon using features such as auto-segmentation, axial imaging, multi-planar reformatting, fly-through, simultaneous display of prone and supine images, and transparent wall view.

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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510K Summary

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

Basis for the Submission:	Vital Images, Inc. hereby submits this Traditional 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared K052632 **VITREA2** Version 3.8 (CT Colonography Application).
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Alexis Erazo Regulatory Affairs Specialist Phone : 952–487–9774 Fax: 952–487–9510 E-mail: aerazo@vitalimages.com
510(k) Type:	Traditional
Summary Date:	January 20, 2016
Device Trade Name:	Vitrea® CT Colon Analysis
Device Common Name/ Regulatory Description:	Radiological Image Processing Software
Device Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Device(s):

Predicate Device	Manufacturer	FDA 510(k) Number
VITREA2, Version 3.8 Medical Image Processing System (CT Colonography)	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343	K052632

Reference Device(s):

Reference Device	Manufacturer	FDA 510(k) Number
syngo.CT Colonography	Siemens Medical Solutions USA, Inc. 51 Valley Stream Parkway Malvern, PA 19355	K140920

Device Description:

Vitrea® CT Colon Analysis software generates 2D and 3D images of the colon to allow close examination of the lumen of the colon, thereby increasing the speed and ease of locating and analyzing suspected polyps, masses and lesions. Vitrea® CT Colon Analysis software has the following features:

- Auto-segmentation of the colon
- Segmentation editing
- Axial imaging, multi-planar reformatting and 3D views
- Manual and automatic endoluminal fly-through of the colon
- Eye-based navigation for performing fly-through and target-based navigation for examining POI and Reverse View mode
- MPR eye placement to adjust view direction down lumen
- Transparent wall view of the colon with a field-of-view cone to act as a reference during fly-through
- Dual Volume Viewer window format for side-by-side comparison of prone and supine studies
- Ability to mark points in the colon with arrows; arrow are hidden from view when you fly too close
- SPACE BAR to step through images containing arrows
- Prone/supine registration
- Polyp Probe tool to select and characterize polyps
- Polyp assessment using the C-RADS guidelines
- Fly-through image batches and digital movies
- Special report template that contains an anatomically-labeled diagram of the colon for easier documentation of findings, as well as a C-RADS report template
- Fly-through keyboard shortcuts
- Automatic fluid/stool tagging and subtraction

Vitrea® CT Colon Analysis software deploys from the Vitrea® Platform, cleared under K150258, Vitrea®, Version 7.0 Medical Image Processing Software. The software provides imaging information as an assistance to the physician. The software does not provide diagnosis or determine the recommended medical care.

Intended Use / Indications for Use:

The separately-licensed CT Colonography option is intended for closely examining the lumen of the colon using features such as auto-segmentation, axial imaging, multi-planar reformatting, fly-through, simultaneous display of prone and supine images, and transparent wall view.

Intended for Disease / Condition / Patient Population:

The software provides trained Radiologists, Clinicians or Technologist with a robust dedicated suite of software tools to aid in the creation of evidence to support these physicians with their screening and assessment of adult patients with suspected colon pathologies (i.e. suspicious polyps, masses, and lesions).

Rationale for Additions and Enhancements to CT Colonography Software:

Vitrea users, require an intuitive, accurate, and efficient application to review, investigate, and problem solve their colonography exams in order to provide information for the referring clinicians. Many patients are unable to complete full evacuation of fecal material and residual liquids in the colon, which can obscure potential lesions and pathology. Vital customers have repeatedly requested to have functionality to electronically remove this residual material from the colon in order to fully evaluate the colon for any abnormalities. When viewing the colon in either 2D or 3D it is very important to see all aspects of the colon, so Vital is introducing "Bowel Cleansing" as a means to remove any residual materials that may inhibit a reader from fully visualizing all aspects of the colon interior. Vital customers will now be able to electronically remove any residual fecal material that has been tagged with a tagging agent.

Substantial Equivalence Comparison:

Regulatory Comparison:

Characteristic	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	892.2050	892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same
Decision Date	Under Review	December 15, 2005	Predicate and Reference devices are cleared

Indications for Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
Indications for Use	The separately-licensed CT Colonography option is intended for closely examining the lumen of the colon using features such as auto-segmentation, axial imaging, multi-planar reformatting, fly-through, simultaneous display of prone and supine images, and transparent wall view.	The separately-licensed CT Colonography option is intended for closely examining the lumen of the colon using features such as auto-segmentation, axial imaging, multi-planar reformatting, fly-through, simultaneous display of prone and supine images, and transparent wall view.	Same
Intended Users	Radiologists, Clinicians or Technologist	Radiologists, Clinicians or Technologist	Same
Patient Population	Adult patients with suspected colon pathologies	Patients with suspected colon pathologies	Similar

Similarities in Technology with Predicate Device:

Criteria/Feature	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632	
Modality			
CT	Yes	Yes	Same
Data Loading			
DICOM	Yes	Yes	Same
Ability to load one or two series of chest CT exam	Yes	Yes	Same
Data Viewing Support			
2D Imaging Real-time window level, zoom and pan	Yes	Yes	Same
3D Imaging Volume rendering with window-level, rotate, zoom an pan	Yes	Yes	Same
Features and Capabilities			
3D Measurements Manual contour volumes and diameter	Yes	Yes	Same
2D Measurements Ruler and ROI tools with statistics	Yes	Yes	Same
3D/Axial Review	Yes	Yes	Same
Dual Volume Viewer	Yes	Yes	Same
Endoluminal Fly-Through	Yes	Yes	Same

Criteria/Feature	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
Target-based navigation for examining a POI	Yes	Yes	Same
Eye-based navigation for performing fly-throughs	Yes	Yes	Same
Assisted navigation	Yes	Yes	Same
Reverse view mode	Yes	Yes	Same
Fly-through images batches and digital movies	Yes	Yes	Same
Viewer auto rotation to keep gravity	Yes	Yes	Same
MPR eye placement to adjust view direction down lumen	Yes	Yes	Same
Multi-planner reformatting Any user defined linear plane, MIP and average	Yes	Yes	Same
Auto-cine	Yes	Yes	Same
Save workflow Restorable state from user snapshots, including multiple volume sessions	Yes	Yes	Same
Printing Printing to standard windows printers	Yes	Yes	Same

Criteria/Feature	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
Ease of use • Visualization presets for typical image review procedures • Click-Drag-Click ruler interaction • When In fly Though, click on tissue rotates to look at the crosshair • "decoupled" eye and crosshair	Yes	Yes	Same
Viewers • Ability to not update MPRs while flying, only updates when you stop flying • Lock MPR Cine • Displays x, y, z, value for crosshair position to lower right of viewers	Yes	Yes	Same
Viewing capacities • MPR viewing of candidates • Endoluminal viewing of candidates with "obstructed	Yes	Yes	Same

Criteria/Feature	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
viewing" technology			
Hardware Requirements	Identical to the Vitrea® Platform	Identical to the Vitrea® Platform	Same
Software Requirements	Identical to the Vitrea® Platform	Identical to the Vitrea® Platform	Same
Performance Testing			
Nonclinical Testing *Safety and Performance Standards*	Yes. The subject device is designed to fulfill the requirements of the following standards DICOM, IEC 62304, and ISO 14971.	Yes. The CT Colonography software within VITREA2, Version 3.8 was designed to fulfill the requirements of the following standards DICOM, IEC 62304, and ISO 14971.	Same.
Software Verification and Validation	Yes. Vital has completed and provided Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005	Yes. The K052632 Submission contained Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005	Same. Please reference Attachments_035-043 for more details.
Clinical Testing	Yes. Clinical performance tests were conducted to demonstrate performance, safety, and effectiveness of the CT Colon Analysis Electronic Bowel Cleansing feature using datasets based on	Yes. Clinical performance tests were conducted to demonstrate performance, safety, and effectiveness of the CT Colonography software within VITREA2, Version 3.8.	Same. Please reference Attachment_036 VLC-08319 A Colon Electronic Bowel Cleansing Algorithm Verification and Validation and Attachment_039

Criteria/Feature	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
	real patient data and phantoms.		VLC-08836 A Vitrea CT Colon EBC Verification and Validation Summary for more details.

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea® CT Colon Analysis Software	**VITREA2, Version 3.8 Medical Image Processing System (CT Colonography) K052632**	
Electronic Bowel Cleansing	Yes	No	Predicate device does not contain the automatic fluid/stool tagging and subtraction feature. The added feature does not affect the intended use, indications for use, or fundamental scientific technology of the already cleared CT Colonography K052632.

Similarities in Technology with the Reference Device:

The Electronic Bowel Cleansing enhancement features, subject of this 510(k) Submission, are highlighted in yellow color.

Feature/Criteria	Subject Device	Reference Device	Comparison
	Vitrea® CT Colon Analysis Software	**syngo.CT Colonography (K140920)**	
Modality			
CT	Yes	Yes	Same

Feature/Criteria	Subject Device Vitrea® CT Colon Analysis Software	Reference Device syngo.CT Colonography (K140920)	Comparison
Data Loading			
DICOM	Yes	Yes	Same
Data Viewing Support			
2D Imaging	Yes	Yes	Same
3D Imaging	Yes	Yes	Same
Features and Capabilities			
Flythrough View	Yes	Yes Panoramic Endoluminal View	Same
Stool Tagging	Yes	Yes	Same
Filet View	Yes	Yes Virtual Dissection	Same
Cube View	Yes	Yes. Polyp Lens	Same
Electronic Bowl Cleansing	Yes	Yes Stool Subtraction	Same
Paging	Yes	Yes Navigation through the CT Volume Data Sets	Same
Semi-Automatic Measurements	Yes	Yes	Same
Movie Reporting	Yes	Yes	Same
Volume Rendering	Yes	Yes Volume Rendering Technique (VRT)	Same
Size measurements of polyps	Yes	Yes	Same
Segmentation in Global View	Yes	Yes	Same

Feature/Criteria	Subject Device Vitrea® CT Colon Analysis Software	Reference Device syngo.CT Colonography (K140920)	Comparison
Flythrough Cut Plane	Yes	Yes Polyp Enhanced Viewing (PEV)	Same
Multiplanar Reconstruction (MPR)	Yes	Yes	Same
Flythrough	Yes	Yes Virtual Flight	Same
Performance Testing			
Nonclinical Testing *Safety and Performance Standards*	Yes. The subject device is designed to fulfill the requirements of the following standards DICOM, IEC 62304, and ISO 14971.	Yes. The syngo.CT Colonography was designed to fulfill the requirements of the following standards DICOM, IEC 62304, and ISO 14971.	Same.
Software Verification and Validation	Yes. Vital has completed and provided Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005	Yes. The K140920 Submission contained Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005	Same. Please reference Attachments_035-043 for more details.
Clinical Testing	Yes. Clinical performance tests were conducted to demonstrate performance, safety, and effectiveness of the CT Colon Analysis Electronic Bowel Cleansing feature using datasets based on	Yes. Clinical performance tests were conducted to demonstrate performance, safety, and effectiveness of syngo.CT Colonography. Testing was provided to cover a variety of clinical situations that would be seen in daily	Similar. Please reference Attachment_036 VLC-08319 A Colon Electronic Bowel Cleansing Algorithm Verification and Validation and

Feature/Criteria	Subject Device	Reference Device	Comparison
	Vitrea® CT Colon Analysis Software	syngo.CT Colonography (K140920)	
	real patient data and phantoms.	clinical use of the subject device.	Attachment_039 VLC-08836 A Vitrea CT Colon EBC Verification and Validation Summary for more details.

Summary of Non-Clinical Tests:

The Vitrea® CT Colon Analysis software was designed, developed, and tested according to written procedures that included risk management. Software testing was completed to ensure the new features operate according to defined requirements.

The following design control measures were applied to the development of the Vitrea® CT Colon Analysis software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included phantom testing and simulated usability testing by experienced professionals.

Risk Management:

Each risk pertaining to the Electronic Bowel Cleansing 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. 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:

- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- All risks have been reduced as low as possible
- 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. Reference Attachment_013 Summary of Performed Verification Tests with results.

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 properly to conform to the intended use. Reference Attachment_015 Summary of Performed Validation Tests with results.

Internal Validation and Phantom Testing:

The software validation team provided internal validation of Vitrea® CT Colon Analysis software. Internal validation included internal user acceptance testing using real scans as well as synthetic phantoms. The validation criteria covered image quality, qualitative comparison of segmentation to previous releases, quantitative evaluation of polyp diameter accuracy using phantom datasets, and run time performance evaluation. Reference Attachment_014 Summary of Performed Phantom Tests with results.

External Validation:

During external validation of the CT Colon Analysis software, experienced users evaluated the auto-segmentation, axial imaging, multi-planar reformatting, fly-through viewing, simultaneous display of prone and supine images, and transparent wall view among other features. Each user felt that the Vitrea® CT Colon Analysis software meets the users' expectations and conforms to the intended use. Reference Attachment_015 Summary of Performed Validation Tests with results.

Summary of Clinical Tests:

The subject of this 510(k) notification, Vitrea® CT Colon Analysis software, did not require clinical studies to support safety and effectiveness of the software.

Cyber and Information Security:

Confidentiality

The Vitrea® platform (K150258) 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. New DICOM produced by Vitrea® is identified as such with the appropriate manufacturer tags per the DICOM standard.

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 Vitrea® CT Colon Analysis 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
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Substantial Equivalence Analysis Conclusion:

Vital Images believes that the Electronic Bowel Cleansing feature is only an enhancement to the predicate device, as the predicate (CT Colonography software cleared within K052632 VITREA2, Version 3.8) already contained the capability to identify and review visible polyps in different views. The basic workflow hasn't changed due to this enhancement. The predicate allowed the user to navigate through the colon and interrogate polyps in 2D and 3D viewers. This enhancement is an optional tool, which now allows the user to hide the tagged material to allow the user to see the polyps more clearly (the ones that were covered by tagged material). It is important to note that the tagged material will not be necessarily hidden in all viewers because the user has the capability to control when or if they want it hidden. The user can toggle tagged material on or off in 2D and 3D views so it is up to the user to have it hidden in both, hidden in 3D only or visible in both. The risk of incorrectly removing polyps when hiding tagged material in 3D (which was observed 0% of the time during our validation) has been mitigated because the polyps can still be seen in 2D. Therefore, Vital believes this enhancement does not alter the fundamental scientific technology, safety or intended use of the device.

Furthermore, the verification and validation testing performed demonstrated the modified device is as safe and effective as the predicate device and does not raise different questions of safety

and effectiveness than the predicate device (CT Colonography software within K052632 VITREA2, Version 3.8).

Vital Images believes the Vitrea® CT Colon Analysis software application has the same intended use, indications for use, principle of operation, and technological characteristics as the legally marketed predicate device K052632 VITREA2, Version 3.8 Medical Image Processing System (CT Colonography). The addition of the Electronic Bowel Cleansing feature is similar to the already cleared reference device Siemen's syngo.CT Colonography (K140920).

Any noted minor differences have been explained and do not raise any different questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and performed verification and validation tests demonstrate the safety and efficacy of the subject device. Based on the comparison information provided above, Vital Images believes the subject device should be found substantially equivalent to the predicate device.