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

October 5, 2017

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

Re: K172855
Trade/Device Name: Vitrea Advanced Visualization, Version 7.6
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 19, 2017
Received: September 20, 2017

Dear Ms. Ryan:

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.

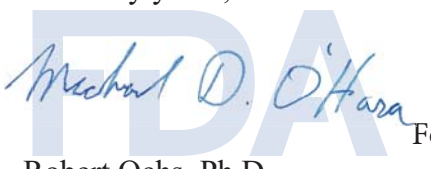
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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)*
K172855

Device Name
Vitrea Advanced Visualization, Version 7.6

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.

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 special 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared Vitrea Advanced Visualization software (K150258)
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Katie Ryan Sr. Regulatory Affairs Specialist Phone: 952-487-9793 Fax: 952-487-9510 E-mail: kryan@vitalimages.com **Alternate Contact Person:** Vince Swenson Sr. Director of Quality and Regulatory Phone: 952-487-9548 Fax: 952-487-9510 E-mail: vswenson@vitalimages.com
510(k) Type:	Special
Summary Date:	October 4, 2017
Device Trade Name:	Vitrea Advanced Visualization, Version 7.6
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
Vitrea®, Version 7.0 Medical Image Processing Software	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343	K150258

Device Description:

The Vitrea Advanced Visualization software 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.
The Vitrea Advanced Visualization system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The Vitrea Advanced Visualization user interface follows typical clinical workflow patterns to process, review, and analyze digital images, including:

- Retrieve image data over the network via DICOM
- Display of images in dedicated protocols which are automatically adapted based on exam type
- Select images for closer examination from a gallery of 2D or 3D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, measure, and record selected views
- Output selected views to standard film or paper printers, or post a report to an intranet web server or export views to another DICOM device
- Retrieve reports that are archived on a Web server

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.

Intended for Disease / Condition / Patient Population:

Vitrea Advanced Visualization 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. Therefore, intended disease, conditions, or patient population information is not applicable.

Key Changes from last 510k clearance K150258

The following list contains the key changes since the last 510k. These changes were made to improve user experience, performance and regulatory compliance:

- Improvements to the Study List and data launching workflows
- Enhancements to export and save to media workflows
- Reporting enhancements for printing
- Support for STL file generation and exporting (output anatomical model is not for diagnostic use)
- Improved efficiency and performance of data handling
- Licensing enhancements
- High resolution monitor support

- System Health and Performance monitoring tool
- Enhancements to PACS integrations and workflows
- Support for upgrades
- Display of the UDI for Vitrea Advanced Visualization
- Addition of Vitrea Extend and Vitrea Enterprise deployments

Substantial Equivalence Comparison:

Regulatory Comparison:

Characteristic	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	Vitrea Software Version 7.0 (K150258)	
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	March 5, 2015	Predicate device is cleared

Indications for Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	Vitrea Software Version 7.0 (K150258)	
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 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.	Same
Intended Users	Qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists,	Qualified healthcare professionals including, but not restricted to, radiologists, non-radiology	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
	physicians and technologists.	specialists, physicians and technologists.	

Similarities in Technology with Predicate Device:

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
General Features:			
Selection and loading a patient study **Component**: AppShell / Vitrea Client and Study List	**Yes**	**Yes**	**Same**
Selection of protocol and preset for patient study **Component:** Gallery Window	**Yes**	**Yes**	**Same**
Visualization and analysis of patient study **Component:** Viewer Window	**Yes**	**Yes**	**Same**
Allows access to the visual, analysis, and batch pages **Component:** Viewer Window	**Yes**	**Yes**	**Same**
Segment, trim, sculpt, perform measurements, and change display settings **Component:** Viewer Window	**Yes**	**Yes**	**Same**
Record images, batches of images, and movies for physician reporting **Component:** Viewer Window	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
Creation of a report for the patient study) data publishing and archiving **Component:** Report Window	**Yes**	**Yes**	**Same**
Review of report for any patient study **Component**: Report Window	**Yes**	**Yes**	**Same**
Help on Vitrea software **Component**: Help Window	**Yes**	**Yes**	**Same**
DICOM Compliance and Data Management	**Yes**	**Yes**	**Same**
Data Security and HIPAA Compliance	**Yes**	**Yes**	**Same**
Multi-vendor scanner compatibility	**Yes**	**Yes**	**Same**
Integrated 2D and 3D visualization measurements	**Yes**	**Yes**	**Same**
Interactive navigation in 3D	**Yes**	**Yes**	**Same**
Large data set capability, including the ability to render multi-detector computed tomography (MDCT) data	**Yes**	**Yes**	**Same**
Multiple User Workstation Deployment	**Yes**	**Yes**	**Same**
Multi-modality Support	**Yes**	**Yes**	**Same**
Vitrea Advanced Visualization Basic Clinical Toolset:			
Retrieve image data over the network	**Yes**	**Yes**	**Same**
Display images that are automatically adapted to exam type via dedicated protocols	**Yes**	**Yes**	**Same**
Select images for closer examination from a gallery of up to six 2D or 3D views	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
Interactively manipulate an image in real-time to visualize anatomy and pathology	**Yes**	**Yes**	**Same**
Annotate, tag, measure, and record selected views	**Yes**	**Yes**	**Same**
Output selected views to standard film or paper printers, or post a report to an Intranet	**Yes**	**Yes**	**Same**
Study List:			
Automatic reading and display of demographic and scanner information including Patient, ID, Date, Time, Series, Modality, Exam Type, Thickness/Spacing, and the number of images in the series	**Yes**	**Yes**	**Same**
Each patient entry can include multiple series of image data	**Yes**	**Yes**	**Same**
Fully sortable listing of all studies present on the system to optimize data searching and selection for users, along with user-specific filters	**Yes**	**Yes**	**Same**
Preview of an image of the selected series to ensure its applicability	**Yes**	**Yes**	**Same**
Customization of the layout of study list to each user's personal preference	**Yes**	**Yes**	**Same**
Series thumbnail display indicating available series	**Yes**	**Yes**	**Same**
Display of selected images, series, or entire study and loading of multiple series or studies for simultaneous analysis and review	**Yes**	**Yes**	**Same**
Direct launch into 2D or 3D workflow for a study or series	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	Vitrea Software Version 7.0 (K150258)	
Display image findings and reports in the Evidence Manager	**Yes**	**Yes**	**Same**
Retrieve reports that are archived on a Web server	**Yes**	**Yes**	**Same**
Gallery Window:			
Unique clinical protocols based on anatomy, workflow, and image type	**Yes**	**Yes**	**Same**
Automatic pre-selection of clinical protocol of images to exam type, as indicated in the DICOM header fields	**Yes**	**Yes**	**Same**
Easy selection of independent 2D and 3D views of selected image data for review, optimized and rendered based on the clinical protocol	**Yes**	**Yes**	**Same**
Ability to return to the Gallery window at any time to select other views, or to select alternative protocols	**Yes**	**Yes**	**Same**
Customized presets that can be created in the Viewer window for display and selection in the Gallery window (one custom preset for each view available for any of the protocols)	**Yes**	**Yes**	**Same**
Viewer Window:			
A choice of four 2D review and four 3D display formats, as well as a 2D "All Exams" comparative viewer that allows the user to display up to nine series on the screen at once	**Yes**	**Yes**	**Same**
Pick tabs in both 2D comparative and 2D montage formats, allowing the user to change the orientation of the image views and the order of the series displayed in comparative viewing	**Yes**	**Yes**	**Same**
Simultaneous view of 3D volume-rendered projections and correlated	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
multi-planar reformatted projections (MPRs)			
Orthogonal, Oblique, Double Oblique, and Curved MPRs	**Yes**	**Yes**	**Same**
Cross-reference lines (Crosshairs) to identify and correlate point of interest in all 2D and 3D views	**Yes**	**Yes**	**Same**
Ability to navigate, scroll, pan, cine, zoom, rotate, flip, invert interactively that lets the user select, edit, measure, annotate, and record the optimum 2D and 3D views for diagnosis and reporting	**Yes**	**Yes**	**Same**
Navigation through or around the 3D view selected (Fly-around, Fly-through, Point-of-interest)	**Yes**	**Yes**	**Same**
Adjustment of window/level on screen interactively	**Yes**	**Yes**	**Same**
Adjustment of a broad range of imaging controls and displays such as rendering (Normal, Min/Max Intensity Projections), brightness, contrast, shading, transparency, and color	**Yes**	**Yes**	**Same**
Image segmentation using any of several segmentation methods (trimming, freehand/box sculpting, semi-automated vessel inclusion/bone removal based on threshold and connectivity)	**Yes**	**Yes**	**Same**
Variable size slab reformat and rendering	**Yes**	**Yes**	**Same**
Annotation of the images with embedded 3D arrows and text	**Yes**	**Yes**	**Same**
Distance measurements using ruler and area and volume measurements using ellipse or freehand ROI	**Yes**	**Yes**	**Same**
Keyboard shortcuts for many functions	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
Creation of custom visualization presets to appear in the Gallery Tab	**Yes**	**Yes**	**Same**
Recording of selected views (snapshots) for report generation and to allow return to the same view at a later time to continue the work done previously; ability to record a multi-volume snapshot for cases when multiple series or volumes have been loaded simultaneously	**Yes**	**Yes**	**Same**
Batch creation functionality that allows 2D, 3D, or 3D fly through batched images or movies to print or be sent to the report page	**Yes**	**Yes**	**Same**
Report Application:			
Report configuration in various reporting displays	**Yes**	**Yes**	**Same**
Report header that includes user configurable information such as Institution Name, Patient ID, Patient Name, Referring Physician, Reading Physician, Exam Type, Modality, Scan Date, and Scan Time	**Yes**	**Yes**	**Same**
Inclusion or deletion of patient and hospital information for filming purposes	**Yes**	**Yes**	**Same**
Slide Tray containing snapshots, batches, and movies saved in the Viewer window	**Yes**	**Yes**	**Same**
Movie preview	**Yes**	**Yes**	**Same**
Electronic posting of reports to a Web server	**Yes**	**Yes**	**Same**

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	Vitrea Software Version 7.0 (K150258)	
Printing of the report on DICOM or Postscript® format printers, exporting to a DICOM image archive, posting on Vitrea software's web server, recording on a CD or a DVD, or exporting to a MS Word document with a defined template	**Yes**	**Yes**	**Same**
Evidence Manager:			
Allows the user to view published Image / batch finding reports and related digital movies	**Yes**	**Yes**	**Same**
Snapshot restoration	**Yes**	**Yes**	**Same**
Help Window:			
Provides on-line help manual, quick reference and index in HTML format or as PDF documents	**Yes**	**Yes**	**Same**
DICOM Data Management:			
DICOM conformance	**Yes**	**Yes**	**Same**
DICOM Storage as SCU & SCP (receive and push)	**Yes**	**Yes**	**Same**
DICOM query/retrieve SCU (pulling images from other DICOM devices)	**Yes**	**Yes**	**Same**
DICOM query/retrieve SCP (can serve images to other vendor workstations)	**Yes**	**Yes**	**Same**
DICOM Connection Management	**Yes**	**Yes**	**Same**
Save & Send images in DICOM	**Yes**	**Yes**	**Same**
Data Security and HIPAA Compliance:			

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea Advanced Visualization Version 7.6	**Vitrea Software Version 7.0 (K150258)**	
Software can de-identify patient data, removing patient name and information from the image	**Yes**	**Yes**	**Same**
Software controls workstation access and reporting security	**Yes**	**Yes**	**Same**
Authentication and access controls require users to enter a confidential password to view both patient studies and reports	**Yes**	**Yes**	**Same**
Secured access (NT or domain -Login)	**Yes**	**Yes**	**Same**
User group preference and access control	**Yes**	**Yes**	**Same**
Vitrea Advanced Visualization Components:			
CPU-Based Rendering Engine	**Yes**	**Yes**	**Same**
Vitrea Information Management System (VIMS)	**Yes**	**Yes**	**Same**
Medical Imaging Network Transport (MINT)	**Yes**	**Yes**	**Same**
Vitrea Services Platform (VSP)	**Yes**	**Yes**	**Same**

Summary of Non-Clinical Tests:

The changes to the Vitrea Advanced Visualization software were designed, developed, and tested according to written procedures that included risk management. Software verification 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 Advanced Visualization software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the software

Risk Management:

Each risk pertaining to the modifications to the Vitrea Advanced Visualization software 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 Post Market information and because of the risk control measures included in these modifications, it is believed that the risk for these modifications as a whole is extremely low. Considering 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 software product 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, requirements and risk mitigations. Verification testing confirmed the software functions according to its requirements and all risk mitigations are functioning properly.

Summary of Clinical Tests:

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

Cyber and Information Security:

The Vitrea Advanced Visualization software follows internal documentation which includes information based on the FDA Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Internal documentation covers the following:

1. Hazard analysis, mitigations, and design considerations pertaining to intentional and unintentional cybersecurity risks associated with your device, including:
    - A specific list of all cybersecurity risks that were considered in the design of your device;
    - A specific list and justification for all cybersecurity controls that were established for your device.
2. A traceability matrix that links your actual cybersecurity controls to the cybersecurity risks that were considered;
3. A summary describing the plan for providing validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its safety and effectiveness. The FDA typically will not need to review or approve medical device software changes made solely to strengthen cybersecurity.
4. A summary describing controls that are in place to assure that the medical device software will maintain its integrity (e.g. remain free of malware) from the point of origin to the point at which that device leaves the control of the manufacturer; and
5. Device instructions for use and product specifications related to recommended cybersecurity controls appropriate for the intended use environment (e.g. anti-virus software, use of firewall).

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 Advanced Visualization 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 the Vitrea Advanced Visualization software has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed, predicate device Vitrea (K150258).

Furthermore, the verification and validation testing performed demonstrates the subject device is as safe and effective as the predicate device and does not raise any different questions of safety and effectiveness. Therefore, Vital believes the enhancements in the Vitrea Advanced Visualization software do not alter the fundamental scientific technology, safety or intended use of the device.

Each change was evaluated for the impact to the safety and effectiveness of the software. It was concluded that the changes 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.