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

July 13, 2016

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

Re: K161419
Trade/Device Name: Multi Modality Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 20, 2016
Received: May 23, 2016

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)*
K161419

Device Name
Multi Modality Viewer

Indications for Use *(Describe)*
Multi Modality Viewer is a software application within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI and CT scanners.
The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

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 obtain 510(k) clearance for the Multi Modality Viewer software which is substantially equivalent to the FDA cleared MR Core Software (K151115).
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Katie Ryan, M.S. Regulatory Affairs Specialist Phone : 952–487–9793 Fax: 952–487–9510 E-mail: kryan@vitalimages.com
510(k) Type:	Traditional
Summary Date:	May 20, 2016
Device Trade Name:	Multi Modality Viewer
Device Common Name/ Regulatory Description:	Radiological Image Processing Software, Picture Archiving and Communications System
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
MR Core Software	Vital Images, Inc.	K151115

Reference Device(s):

Reference Device	Manufacturer	FDA 510(k) Number
Softread Software (Vitrea® 2, Version 3.5 Medical Image Processing Software)	Vital Images, Inc.	K040305

Device Description:

Multi Modality Viewer is a software application which functions on the Vitrea Platform, cleared by K150258. This application allows intuitive navigation, quantification, and manipulation of medical images obtained from MRI and CT scanners. This application enables clinicians to compare multiple series of the same patient, side-by-side, and switch to other integrated applications to further examine the data.

It provides clinical tools to review images to help qualified physicians provide efficient and effective patient care.

Key features:

General Viewing:

- Linked 2D, MPR and 4D viewers for single and multi-study comparison
- Creation of retrievable evidence and snapshots
- User defined flexible display protocols

Access to Advanced Applications and Workflows:

- In application access to MR Stitching application
- Evidence creation and sharing across workflows

General Image Display, Manipulation, and Analysis Tools:

- Maximum and Minimum Intensity Projection (MIP/MinIP)
- Identification and Display of Regions of Interest (ROIs)
- CINE image display
- Multi-frame display
- Color image display
- Simultaneous multiple studies review
- Cross-reference lines support
- Display of selected images, series, or entire study
- Comparison of multiple series or studies
- Scroll
- Pan
- Zoom
- Focus
- Flip (Vertically, horizontally)
- Invert
- Rotate (Clockwise, counter-clockwise)
- Arrow

- Adjust Registration
- Auto window level/width setting
- Text/Arrow annotation (Label)
- Measurement of distance (Ruler), Angle, Cobb Angle, Ellipse ROI, and Freehand ROI

Specialized Tools:

- Image subtraction of two series/datasets
- Access to semi-automated image stitching
- Study and series linking
- Register two different series or groups that do not share a frame of reference to link them spatially

Intended Use / Indications for Use:

Multi Modality Viewer is a software application within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI and CT scanners.

The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

Intended for Disease / Condition / Patient Population:

Multi Modality Viewer is medical image viewer software. Therefore, particular information of intended for disease, condition, and patient population is not applicable.

Substantial Equivalence Comparison:

Regulatory Comparison:

Characteristic	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**MR Core Software (K151115)**	
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	June 3, 2015	Predicate device is cleared

Indications for Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**MR Core Software (K151115)**	
Indications for Use	Multi Modality Viewer is a software application within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI and CT scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.	MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further exam the data.	Similar Added support for the ability to examine and manipulate medical images obtained from CT scanners was not part of the predicate device's indications for use.
Intended Users	Radiologists, Clinicians or Technologists	Radiologists, Clinicians or Technologists	Same
Patient Population	Multi Modality Viewer is medical image viewer software. Therefore, particular information of intended for disease, condition, and patient population is not applicable.	MR Core Software is medical image viewer software. Therefore, particular information of intended for disease, condition, and patient population is not applicable.	Same
Modality Support	CT and MRI	MRI	Similar Added support for the ability to examine and manipulate medical images obtained from CT scanners was not part of the predicate device's indications for use.

Similarities in Technology with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	MR Core Software (K151115)	
Data Loading			
Image Communication Standard: DICOM	Yes	Yes	Same
Data Viewing Support			
2D Image Review	Yes	Yes	Same
2D Comparative Review	Yes	Yes	Same
Features and Capabilities			
Multi-Planner Reformatting	Yes	Yes	Same
Maximum and Minimum Intensity Projection (MIP/MinIP)	Yes	Yes	Same
Image Editing, Setting, Saving	Yes	Yes	Same
Annotation & Tagging Tools (Label)	Yes	Yes	Same
Display Options (e.g. thickness)	Yes	Yes	Same
Quantitative Measurements	Yes	Yes	Same
Snapshot	Yes	Yes	Same
Cine Image Display	Yes	Yes	Same
Multi-frame Display	Yes	Yes	Same
Color Image Display	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	MR Core Software (K151115)	
Simultaneous Multiple Studies Review	Yes	Yes	Same
Cross-reference Lines Support	Yes	Yes	Same
Display of Selected Images, Series, or Entire Study	Yes	Yes	Same
Comparison of Multiple Series or Studies	Yes	Yes	Same
Scroll Image	Yes	Yes	Same
Zoom Image	Yes	Yes	Same
Pan Image	Yes	Yes	Same
Focus Image	Yes	Yes	Same
Rotate Image	Yes	Yes	Same
Flip Image - Vertical	Yes	Yes	Same
Flip Image - Horizontal	Yes	Yes	Same
Rotate Image - Clockwise	Yes	Yes	Same
Rotate Image - Counter-clockwise	Yes	Yes	Same
Invert Image	Yes	Yes	Same
Arrow	Yes	Yes	Same
Auto Window Level/Width Setting	Yes	Yes	Same
Measurement of Distance	Yes	Yes	Same
Measurement of Angle	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	MR Core Software (K151115)	
Measurement of Cobb Angle	Yes	Yes	Same
Identification and Display of Ellipse Regions of Interest (ROIs)	Yes	Yes	Same
Identification and Display of Freehand Regions of Interest (ROIs)	Yes	Yes	Same
Manual Registration	Yes	Yes	Same
Image subtraction of two series/datasets	Yes	Yes	Same
Study and Series Linking	Yes	Yes	Same
Semi-automated image stitching	Yes	Yes	Same
Time Intensity Analysis	Yes	Yes	Same
Batch Save of MPR reformats	Yes	Yes	Same

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**MR Core Software (K151115)**	
Feature: Support for CT Modality Data	Yes	No	Multi Modality Viewer allows the examination and manipulation of medical images obtained from CT scanners in addition to MRI scanners. Note: The added CT Modality feature is similar to the feature available on Vital Image's Softread software ("Reference Device"), which was cleared by the FDA under K040305 (Vitrea 2, Version 3.5 Medical Image Processing Software). Therefore, this added feature does not raise different questions of safety and effectiveness.

Similarities in Technology with the Reference Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**Softread (K040305)**	
Modality			
Support for CT and MRI Modality Data	Yes	Yes	Same
Data Loading			
Image Communication Standard: DICOM	Yes	Yes	Same
Data Viewing Support			

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	Softread (K040305)	
2D Image Review	Yes	Yes	Same
2D Comparative Review	Yes	Yes	Same
Features and Capabilities			
Multi-Planner Reformatting	Yes	Yes	Same
Maximum and Minimum Intensity Projection	Yes	Yes	Same
Image Editing, Setting, Saving	Yes	Yes	Same
Annotation & Tagging Tools (Label)	Yes	Yes	Same
Display Options (e.g. thickness)	Yes	Yes	Same
Quantitative Measurements	Yes	Yes	Same
Snapshot	Yes	Yes	Same
Cine Image Display	Yes	Yes	Same
Multi-frame Display	Yes	Yes	Same
Color Image Display	Yes	Yes	Same
Simultaneous Multiple Studies Review	Yes	Yes	Same
Cross-reference Lines Support	Yes	Yes	Same
Display of Selected Images, Series, or Entire Study	Yes	Yes	Same
Comparison of Multiple Series or Studies	Yes	Yes	Same
Scroll Image	Yes	Yes	Same
Zoom Image	Yes	Yes	Same

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	Softread (K040305)	
Pan Image	Yes	Yes	Same
Focus Image	Yes	Yes	Same
Rotate Image	Yes	Yes	Same
Flip Image - Vertical	Yes	Yes	Same
Flip Image - Horizontal	Yes	Yes	Same
Rotate Image - Clockwise	Yes	Yes	Same
Rotate Image - Counter-clockwise	Yes	Yes	Same
Invert Image	Yes	Yes	Same
Arrow	Yes	Yes	Same
Auto Window Level/Width Setting	Yes	Yes	Same
Measurement of Distance	Yes	Yes	Same
Measurement of Angle	Yes	Yes	Same
Measurement of Cobb Angle	Yes	Yes	Same
Identification and Display of Ellipse Regions of Interest (ROIs)	Yes	Yes	Same
Identification and Display of Freehand Regions of Interest (ROIs)	Yes	Yes	Same
Manual Registration	Yes	Yes	Same
Image subtraction of two series/datasets	Yes	Yes	Same
Study and Series Linking	Yes	Yes	Same

Summary of Non-Clinical Tests:

The Multi Modality Viewer 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 Multi Modality Viewer 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 simulated usability testing by experienced professionals.

Risk Management:

Each risk pertaining to these features have 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 at least "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:

- All Occurrence Factors for Hazards were mitigated as low as possible
- Of the unresolved defects remaining in the released application, each has been carefully evaluated and it has been determined that the software can be used safely and effectively.
- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together.

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 the Multi Modality Viewer software, experienced medical professionals evaluated the application. All validators confirmed that the Multi Modality Viewer software fulfills its intended use.

Summary of Clinical Tests:

The subject of this 510(k) notification, Multi Modality Viewer 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 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:

Multi Modality Viewer is a software application within Vitrea that allows for the examination and manipulation of a series of medical images obtained from MRI and CT scanners. Vital Images believes the Multi Modality Viewer software application has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed, predicate device MR Core Software (K151115). In addition, the CT Modality feature is similar to the feature in the reference device, Softread, which was cleared by the FDA under K040305 (Vitrea 2, Version 3.5 Medical Image Processing Software).

Furthermore, the verification and validation testing performed demonstrate the subject device is as safe and effective as the predicate and reference devices and does not raise any different questions of safety and effectiveness. Therefore, Vital believes the addition of the CT Modality feature in the Multi Modality Viewer software does not alter the fundamental scientific technology, safety or intended use of the device.

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.