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

January 26, 2017

Vital Images, Inc.
% Ms. Susan Atwood
Principal Quality Engineer
5850 Opus Parkway, Suite 300
MINNETONKA ME 55343

Re: K163574
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: December 16, 2016
Received: December 19, 2016

Dear Ms. Atwood:

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)*

K163574

Device Name
Multi Modality Viewer

Indications for Use *(Describe)*

Multi Modality Viewer is an option within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI, CT, CR, DX, RG, RF, XA, PET, and PET/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 Multi Modality Viewer (previous version) Software (K161419).
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Susan Atwood Principal Quality Engineer Phone: 952-487-9759 Fax: 952–487–9510 E-mail: satwood@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:	Traditional
Summary Date:	December 16, 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
Multi Modality Viewer Software	Vital Images, Inc.	K161419

Reference Device(s):

Reference Device	Manufacturer	FDA 510(k) Number
Mirada RT (marketed as Mirada XD)	MIRADA MEDICAL LTD. Mill Street Innovation House Oxford, Oxfordshire, GB Ox2 0JX	K102687
VitalConnect	Vital Images, Inc. 5850 Opus Parkway, Suite 300, Minnetonka, Minnesota 55343 U.S.A.	K071362

Device Description:

Multi Modality Viewer is a medical image viewer software application, available on the Vitrea software platform cleared by K150258. The application allows qualified clinicians, including physicians, radiologists and technologists, to display, navigate, manipulate and quantify medical images obtained from MRI, CT, CR, DX, RG, RF, XA, PET, and PET/CT modalities.

The Multi-Modality Viewer provides an overview of the study, facilitates side-by-side comparison including priors, allows clinicians to record evidence and return to previous evidence, and provides easy access to other Vitrea applications for further analysis.

Existing Features:

General image display:

- Display of images, volumes, and time sequences from MRI and CT modalities
- Display of derived modality images and secondary capture (SC) images
- 2D image display, MPR display, cine and 4D cine display for appropriate modalities
- Maximum, minimum, or average intensity projection for MPR with adjustable thickness
- Display of high-resolution (1024 matrix) CT images

Image cross-reference and comparison:

- Single MPR plane, 3-plane orthogonal MPR, and oblique MPR display
- Linked scrolling of MPR images and 2D images in the same plane
- Linked pan, zoom, and matched presentation of images in the same plane
- Cross-reference lines and MPR cross-hairs to indicate orthogonal planes
- Focus tool to pinpoint the same location in all series
- Automatic linking of series with the same frame of reference
- Manually set reference point for linking separately acquired series

Hanging and viewing adjustments

- Ability to load only one study or including all priors
- User-defined, flexible hanging layouts
- Automatic initial hanging, manual hanging using drag & drop thumbnails
- Scroll, pan, zoom, W/L, W/L presets, fit to view, reset
- Image flip, rotate clockwise/counterclockwise, invert
- Demographics more, less, on/off, reference lines on/off, linking on/off

Measurement, annotation, and snapshots:

- Ruler, angle, and Cobb angle measurement
- Ellipse ROI and freehand ROI with pixel value statistics
- HU measurement for CT
- Time-Intensity Analysis ROI
- Arrow and text annotation
- Manual snapshots. Auto snapshot on measurement or annotation
- Ability to restore the presentation state of a snapshot

Derived series and specialized tools:

- MPR batch series generation
- Direct access to MRI Stitching application
- Access to all other applications on Vitrea system

New Features Since the Last 510(k) Clearance K161419:

General image display:

- Display of images and time sequences from projection modalities (CR, DX, RG, RF, and XA)
- Display of PET images in grayscale or with a color map
- Display of PET/CT images acquired with the same frame of reference
- Fused display of PET/CT images acquired with the same frame of reference
- Rotating MIP display of PET hotspots

Image cross-reference and comparison:

- Linking of PET hotspots in MIP and MPR views

Measurement, annotation, and snapshots:

- SUV measurement for PET

Derived series and specialized tools:

- Image subtraction of two compatible series

Intended Use / Indications for Use:

Multi Modality Viewer is an option within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI, CT, CR, DX, RG, RF, XA, PET, and PET/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 on the intended for disease, condition, and patient population is not applicable.

Substantial Equivalence Comparison:

Regulatory Comparison:

Characteristic	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**Multi Modality Viewer (K161419)**	
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	May 20, 2016	Predicate device is cleared

Indications for Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**Multi Modality Viewer (K161419)**	
Indications for Use	Multi Modality Viewer is an option within Vitrea that allows the examination and manipulation of a series of medical images obtained from MRI, CT, CR, DX, RG, RF, XA, PET, and PET/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.	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.	Similar Added support for the ability to examine and manipulate medical images obtained from CR, DX, RG, RF, XA, PET and PET/CT modalities which was not part of the predicate device's indications for use.
Intended Users	Physicians, Radiologists, Clinicians or Technologists	Physicians, Radiologists, Clinicians or Technologists	Same
Patient Population	Multi Modality Viewer is medical image viewer software. Therefore, particular information on the intended disease, condition, and patient population is not applicable.	Multi Modality Viewer is medical image viewer software. Therefore, particular information on the intended disease, condition, and patient population is not applicable.	Same
Modality Support	MRI, CT, CR, DX, RG, RF, XA, PET and PET/CT	MRI and CT	Similar Added support for the ability to examine and manipulate medical images obtained from CR, DX, RG, RF, XA, PET and PET/CT modalities which 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	Multi Modality Viewer (K161419)	
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

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	Multi Modality Viewer (K161419)	
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
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

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	**Multi Modality Viewer (K161419)**	
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
Semi-automated Image Stitching	Yes	Yes	Same
Time Intensity Analysis	Yes	Yes	Same
Batch Save of MPR Reformats	Yes	Yes	Same
Examination and manipulation of a series of medical images obtained from MRI and CT datasets	Yes	Yes	Same

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	Multi Modality Viewer (K161419)	
Feature: Support for PET and PET/CT Modality Data	Yes	No	Multi Modality Viewer allows the examination and manipulation of medical images obtained from PET and PET/CT scanners in addition to MRI and CT scanners. Note: The added PET and PET/CT modalities are similar to the features available on the Mirada XD software ("Reference Device"), which was cleared by the FDA under K102687. Therefore, this added feature does not raise different questions of safety and effectiveness.
Feature: Support for CR, DX, RG, RF, and XA Modality Data	Yes	No	Multi Modality Viewer allows the examination and manipulation of medical images obtained from CR, DX, RG, RF, and XA modalities in addition to MRI and CT scanners. Note: The added CR, DX, RG, RF, and XA modalities are similar to the features available on the VitalConnect 4.1 software ("Reference Device"), which was cleared by the FDA

Criteria	Subject Device	Predicate Device	Comparison
	Multi Modality Viewer	Multi Modality Viewer (K161419)	
			under K071362. Therefore, this added feature does not raise different questions of safety and effectiveness.

Similarities in Technology with the Reference Device

Criteria	Subject Device	Reference Device	Comparison
	Multi Modality Viewer	Mirada XD (K102687)	
Modality			
Support for PET and PET/CT Modality Data	Yes	Yes	Same
Support for following measurements: • Becqerel per milliliter (BQML) • SUV body weight (SUVbw) • SUV body surface area (SUVbsa) • SUV lean body mass (SUVlbm)	Yes	Yes	Same
PET/CT Fusion View	Yes	Yes	Same
PET/CT Fusion Blending	Yes	Yes	Same
Window/width Functionality for PET & CT Images	Yes	Yes	Same
PET & CT window/width Presets	Yes	Yes	Same
Zoom Image	Yes	Yes	Same

Criteria	Subject Device	Reference Device	Comparison
	Multi Modality Viewer	Mirada XD (K102687)	
Scroll Image	Yes	Yes	Same
Pan Image	Yes	Yes	Same
Focus Tool (triangulate)	Yes	Yes	Same
Ruler Measurement Tool	Yes	Yes	Same
Ellipse ROI	Yes	Yes	Same
Fixed ROI	Yes	Yes	Same
Label	Yes	Yes	Same
Arrow	Yes	Yes	Same
Reset Image	Yes	Yes	Same
Snapshots	Yes	Yes	Same
View Current and Prior Scans	Yes	Yes	Same
CT & PET MPR Display & Manipulation	Yes	Yes	Same
PET MIP Display & Manipulation	Yes	Yes	Same
CT & PET 2D Views	Yes	Yes	Same
PET Color Overlay	Yes	Yes	Same
Update/correct Parameters (height, weight, dose)	Yes	Yes	Same

Similarities in Technology with the Reference Device

Criteria	Subject Device	Reference Device	Comparison
	Multi Modality Viewer	VitalConnect (K071362)	
Modality			
Support for CR, DX, RF, RG, and XA Modality Data	Yes	Yes	Same

Software Development Environment Description:

The Multi Modality Viewer software was designed, developed, and tested according to IEC 62304:2004 standard for Medical Device Software: Software Life Cycle Processes.

The following design control measures were applied to the development of the Multi Modality Viewer software:

- Risk Management
- Software 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 associated with the Multi Modality Viewer 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 at least "Improbable." Because of the risk control measures, it is believed that the risk for the Multi Modality Viewer software as a whole, is extremely low.

During the final risk management 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 and Validation:

The software was designed, developed, tested, verified, and validated according to written procedures. Verification confirmed that the feature functions according to its requirements.

Software testing was completed to ensure the Multi Modality Viewer software functions according to its requirements and operates on the Vitrea software platform without degrading the existing functionality of the Vitrea software platform. Performance testing for the Multi Modality Viewer software included internal verification and external validation. The Multi Modality Viewer software has achieved all product release criteria.

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 software platform (K150258) relies on built in Windows Login security to limit access to the system. The Vitrea software platform can only be installed and configured by an administrator of the Windows machine.

Integrity

The Vitrea software 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 software platform is always available to the logged on user as long as the Windows machine itself is properly maintained.

Accountability

The Vitrea software platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea software platform 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 Multi Modality Viewer 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 Multi Modality Viewer software has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed, predicate device Multi Modality Viewer (K161419). The added features to allow for the examination and manipulation images obtained from PET and PET/CT scanners is similar to the features in the reference device, Mirada RT which was cleared by the FDA under K102687. Additionally, the ability to view and manipulate images obtained from CR, DX, RG, RG and XA scanners is similar to the feature in the reference device, VitalConnect, which was cleared by the FDA under K071362.

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 examination and manipulation of a series of medical images obtained from CR, DX, RG, RF, XA, PET, and PET/CT scanners 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.