DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 21, 2017

Vital Images, Inc.
% Fei Li
Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

Re: K163232
Trade/Device Name: Vitrea View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 14, 2017
Received: June 15, 2017

Dear Fei Li:

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,

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)*
K163232

Device Name
Vitrea View

Indications for Use *(Describe)*
Vitrea View software is a medical image viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy medical images (including mammography and digital breast tomosynthesis), reports, and other patient-related information. This data is hosted within disparate archives and repositories for diagnosis, review, communication, and reporting of DICOM and non-DICOM data.

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

Vitrea View software is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.

When accessing Vitrea View software from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.

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 Vitrea View software which we believe is substantially equivalent to the FDA cleared VitreaView (K150738).
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Fei Li Regulatory Affairs Specialist Phone : 952-487-9539 Fax: 952-487-9510 E-mail: fli@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:	November 16, 2016
Device Trade Name:	Vitrea View
Device Common Name/ Regulatory Description:	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
VitreaView	Vital Images, Inc. 5850 Opus Parkway, Suite 300, Minnetonka, Minnesota 55343 U.S.A.	K150738

Reference Device(s):

Reference Device	Manufacturer	FDA 510(k) Number
McKesson Radiology	McKesson Medical Imaging Company 5995 Winward Parkway Alpharetta, GA 30005	K140909
Phillips Intellispace Radiology system	Philips Healthcare Informatics, Inc. 4100 E 3rd Ave Ste 101 Foster City, CA 94404	K111804

Device Description:

The Vitrea View software is a web-based, cross-platform, zero-footprint enterprise image viewer solution capable of displaying both DICOM and non-DICOM medical images. The Vitrea View software enables clinicians and other medical professionals to access patients' medical images with integrations into a variety of medical record systems, such as Electronic Health Record (EHR), Electronic Medical Record (EMR), Health Information Exchange (HIE), Personal Health Record (PHR), and image exchange systems. The Vitrea View software is a communication tool, which supports the physician in the treatment and planning process by delivering access to images at the point of care.

The Vitrea View software offers medical professionals an enterprise viewer for accessing imaging data in context with reports from enterprise patient health information databases, fosters collaboration, and provides workflows and interfaces appropriate for referring physicians and clinicians. IT departments will not have to incur time to install client systems, due to the web-based zero-footprint nature of the Vitrea View software. The Vitrea View software offers scalability to add new users as demand grows, and may be deployed in a virtualized environment.
Some of the general features include:

- Fast time-to-first-image
- Contextual launch integration with single-sign-on
- Easy study navigation and search capability
- Supports multi-modality vendor-neutral DICOM images
- Supports non-DICOM images
- Images display at full diagnostic quality (with appropriate hardware)
- Basic 2D review tools (zoom, pan, measure)
- Basic 3D and MPR viewing
- Radiology key images
- Comparative side-by-side review, regardless of image types
- Collaboration tools
- Leverages traditional DICOM as well as next-generation DICOMweb image transfer protocols
- Enables federated access to across multiple data sources across multiple sites
- Web-based zero-footprint architecture
- Secure Access on various Windows® and Mac computers through standard internet browsers
- Secure Access on various iOS®, Android™, and Windows® tablet devices through the device's Internet browser

- Secure Access on various iOS and Android smartphones through the device's Internet browser

Intended Use / Indications for Use:

Vitrea View software is a medical image viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy medical images (including mammography and digital breast tomosynthesis), reports, and other patient-related information. This data is hosted within disparate archives and repositories for diagnosis, review, communication, and reporting of DICOM and non-DICOM data.

Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used.

Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance.

Vitrea View software is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.

When accessing Vitrea View software from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.

Intended for Disease / Condition / Patient Population:

Vitrea View software is a medical image viewer software. Therefore, specific information on the intended disease, condition, and patient population is not applicable.

Key Changes from the last 510(k) clearance K150738

Key Changes include:

- Support for diagnostic viewing of mammographic images and digital breast tomography images
- Enhancements in the administration and support of the product
- Ability to allow clinicians to collaborate on images, information, and artifacts related to the imaging studies using the Vitrea View software
- User Centric enhancements
- Performance Improvements
- Licensing enhancements
- Better integration with EMRs by supporting more targeted searchers within the launch and history search APIs
- Ability to record information of users who accessed the Vitrea View software and which studies they viewed
- Add support for Breast Tomography SOP class
- Support for SQL Server 2014
- Improvements in connectivity to archives including PACS, VNA and DICOMWeb
- View the UDI for Vitrea View identification

Substantial Equivalence Comparison:

Regulatory Comparison:

Characteristic	Subject Device	Predicate Device	Comparison
	Vitrea View	VitreaView (K150738)	
Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications System	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	TBD	April 6, 2015	Predicate device is cleared

Indications for Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea View	VitreaView (K150738)	
Indications for Use	Vitrea View software is a medical image viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy medical images (including mammography and digital breast tomosynthesis), reports, and other patient-related information. This data is hosted within disparate archives and repositories for diagnosis, review, communication, and reporting of DICOM and non-DICOM data. Lossy compressed mammography	VitreaView is a medical image viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy medical images, reports, and other patient-related information. This data is hosted within disparate archives and repositories for diagnosis, review, communication, and reporting of DICOM and non-DICOM data. Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control	Similar Added support for Vitrea View to be used for diagnostic viewing of mammographic images and digital breast tomography images

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea View	VitreaView (K150738)	
	images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA or displays accepted by the appropriate regulatory agency for the country in which it is used. Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance. Vitrea View software is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists. When accessing Vitrea View software from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.	requirements for their use and maintenance. Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. When accessing VitreaView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.	
Intended Users	Qualified healthcare professionals including, but not restricted to,	Qualified healthcare professionals including, but not restricted to,	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea View	**VitreaView (K150738)**	
	radiologists, non-radiology specialists, physicians and technologists.	radiologists, non-radiology specialists, physicians and technologists.	
Patient Population	Vitrea View software is a medical image viewer software. Therefore, specific information on the intended disease, condition, and patient population is not applicable.	VitreaView is a medical image viewer software. Therefore, specific information on the intended disease, condition, and patient population is not applicable.	Same
Modality Support	Multi-modality	Multi-modality	Same

Similarities in Technology with the Predicate Device:

Criteria	Description	Subject Device	Predicate Device	Comparison
		Vitrea View	VitreaView (K150738)	
Annotation and Measurement Tools	• Line • Angle • Ruler • Arrow	Yes	Yes	Same
User Installation Requirements	• Runs within browser using HTML and JavaScript only • No installation is required on user's machine	Yes	Yes	Same
Data Type Supported	• DICOM • Non-DICOM	Yes	Yes	Same
Image View/ Manipulation	• Image Zoom • Pan • Window Level • Auto Window • Level • Reset • Scout Lines • Image Rotate • Image Flip • Magnify • Image Invert • Image Cine	Yes	Yes	Same
Data Encryption	• HTTPS • SSL	Yes	Yes	Same
Patient Demographic Display	Capable of displaying patient demographic information	Yes	Yes	Same
Linking	Co-planar linking: • Autolink • Manual	Yes	Yes	Same
User and Password Control	Users can be managed via an internal database, active directory, or parent application	Yes	Yes	Same
Data Security	Stored on server	Yes	Yes	Same
Audit Trail	Audit trail logged	Yes	Yes	Same

Criteria	Description	Subject Device	Predicate Device	Comparison
		Vitrea View	VitreaView (K150738)	
User Management	Database structure allows mapping users to groups internally or mapping external groups (AD, parent application) to internal groups and role	Yes	Yes	Same
Transmission Modes	Via the web with Internet browsers	Yes	Yes	Same
File Type Used	• JPEG for Lossy data • PNG for Lossless data	Yes	Yes	Same
MPR Viewing	This viewing feature enables the display of reformatted CT and MR images into axial, coronal and sagittal orientations.	Yes	Yes	Same
3D Volume Rendered Viewing	This viewing feature enables the display of 3D perspective views of CT and MR image sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features.	Yes	Yes	Same
Active Target Tool	This viewing feature provides a facility to view a single target location within multiple images.	Yes	Yes	Same
Crosshair Navigation and Synchronization:	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	Yes	Yes	Same
Ability to clone images side by side	Ability to clone images side by side.	Yes	Yes	Same

Criteria	Description	Subject Device	Predicate Device	Comparison
		Vitrea View	VitreaView (K150738)	
Ability to close an image by clicking an "X" in the upper-left portion of the viewport	Ability to close an image by clicking an "X" in the upper-left portion of the viewport.	Yes	Yes	Same
Ability to select locale and language settings on the login screen	Ability to select locale and language settings on the login screen.	Yes	Yes	Same
Ability to customize the columns in the study directory by selecting the dropdown arrow on the right side of each column.	Ability to customize the columns in the study directory by selecting the dropdown arrow on the right side of each column.	Yes	Yes	Same
Help Tips	Proactive help tips appear for 10-15 seconds to educate users on certain functionality that may not be obvious to a new user.	Yes	Yes	Same
Support for TIF Files	Vitrea View can display TIF files.	Yes	Yes	Same

Criteria	Description	Subject Device	Predicate Device	Comparison
		Vitrea View	VitreaView (K150738)	
Tablet support for information purpose only (Not for diagnostic use)	This viewing feature provides access of Vitrea View software on various iOS and Android tablet devices through the default internet browser. Key features are: • Two-finger pinch to zoom and pan • Touch and drag to scroll • Double-tap to access Gesture menu • Tap Carousel thumbnail, then tap Image Pane to swap images • Ambient Lighting Check	Yes	Yes	Same
Diagnostic quality medical image review	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices	Yes	Yes	Same

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea View	VitreaView (K150738)	
Feature: Support for diagnostic viewing of mammographic images and digital breast tomography images	Yes	No	Expanded the Indications for Use to include the ability to allow viewing of multi-modality images (including mammography and digital breast tomosynthesis) for review and diagnosis when used in conjunction with monitors cleared by the FDA, and viewed by appropriately qualified personnel.
General Enhancements: (see below for detailed information)			The majority of these general modifications are enhancements to pre-existing functionality or features within the already cleared VitreaView (K150738). Any new functionality does not alter the fundamental technology and does not affect the safety/ effectiveness or the intended use for viewing multi-modality images.
• Enhancements in the administration and support of the product	Yes	No	
• Ability to allow clinicians to collaborate on images, information, and artifacts related to the imaging studies using the Vitrea View software	Yes	No	
• User Centric enhancements	Yes	No	
• Performance Improvements	Yes	No	
• Licensing enhancements	Yes	No	
• Better integration with EMRs by supporting more targeted searchers within the launch and history search APIs	Yes	No	
• Ability to record information of users who accessed the Vitrea View software and which studies they viewed	Yes	No	
• Support for SQL Server 2014	Yes	No	

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea View	VitreaView (K150738)	
• Improvements in connectivity to archives including PACS, VNA and DICOMWeb	Yes	No	
• View the UDI for Vitrea View identification	Yes	No	
• Add support for Breast Tomography SOP class	Yes	No	

Similarities in Technology with the Reference Device

Criteria	Subject Device	Reference Device	Reference Device	Comparison
	Vitrea View	McKesson Radiology (K140909) (Mammography)	Phillips Intellispace Radiology system (K111804) (Digital Breast Tomosynthesis)	
Feature: Support for diagnostic viewing of mammographic images	Yes	Yes	N/A	Same
Feature: Support for diagnostic viewing of digital breast tomography images	Yes	N/A	Yes	Same
Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications System	Picture Archiving and Communications System	Same
Regulatory Number	892.2050	892.2050	892.2050	Same
Product Code	LLZ	LLZ	LLZ	Same
Classification	Class II	Class II	Class II	Same
Review Panel	Radiology	Radiology	Radiology	Same
Decision Date	TBD	July 2, 2014	July 28, 2011	Reference devices are cleared
Indications for Use	Vitrea View software is a medical image	McKesson Radiology™ is medical image and	IntelliSpace PACS 4.x is an image management	Similar

Criteria	Subject Device	Reference Device	Reference Device	Comparison
	Vitrea View	McKesson Radiology (K140909) (Mammography)	Phillips Intellispace Radiology system (K111804) (Digital Breast Tomosynthesis)	
	viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy medical images (including mammography and digital breast tomosynthesis), reports, and other patient-related information. This data is hosted within disparate archives and repositories for diagnosis, review, communication, and reporting of DICOM and non-DICOM data. Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared display that meets technical specifications reviewed and accepted by FDA	information management software that is intended to receive, transmit, store, archive, retrieve, manage, display, print and process digital medical images, digital medical video and associated patient and medical information. McKesson Radiology includes a suite of standalone, web-enabled software components, and is intended for installation and use with off-the-shelf hardware that meets or exceeds minimum specifications. McKesson Radiology Station™ is the primary software component used for processing and presentation of medical images on display devices with network access to McKesson Radiology. McKesson Radiology Station is intended to	system intended to be used by trained professionals, including but not limited to physicians, nurses and medical technicians. The system is a software package used with general purpose computing hardware to acquire, store, distribute, process and display images and associated data throughout a clinical environment. The software performs digital image processing, measurement, communication and storage. Lossy compressed mammographic images and digitized screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor	

Criteria	Subject Device	Reference Device	Reference Device	Comparison
	Vitrea View	**McKesson Radiology (K140909) (Mammography)**	**Phillips Intellispace Radiology system (K111804) (Digital Breast Tomosynthesis)**	
	or displays accepted by the appropriate regulatory agency for the country in which it is used. Display monitors used for reading medical images for diagnostic purposes must comply with the applicable regulatory approvals and quality control requirements for their use and maintenance. Vitrea View software is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists. When accessing Vitrea View software from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.	process and display lossless and non-lossless compressed medical images provided from DICOM conformant modalities such as X-Ray Radiography (including digital mammography), X-Ray Computed Tomography, Magnetic Resonance Imaging, Ultrasound, and Nuclear Medicine, as well as medical images obtained from other DICOM-compliant modalities. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display.	that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.	

Criteria	Subject Device	Reference Device	Reference Device	Comparison
	Vitrea View	McKesson Radiology (K140909) (Mammography)	Phillips Intellispace Radiology system (K111804) (Digital Breast Tomosynthesis)	
		McKesson Radiology is indicated for use by qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.		

Summary of Non-Clinical Tests:

The Vitrea View software was designed, developed, and tested according to IEC 62304:2006 standard for Medical Device Software - Software Life Cycle Processes. Vital Images' internal Agile Development Processes is summarized in the Vital Images' Agile Product Development Process (SOP-301.150).

The following design control measures were applied to the development of the Vitrea View 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 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 "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 risks were reduced as low as possible

- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- The overall residual risk for the project is deemed acceptable

Verification 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 Vitrea View software functions according to its requirements. Performance testing for the Vitrea View software included internal verification and external validation.

External validation was done to:

a) Establish the substantial equivalence between the Vitrea View software with the McKesson Radiology system ((K140909) reference device) to modify the current Vitrea View software indications to include viewing of diagnostic mammography images.
b) Establish the substantial equivalence between the Vitrea View software with the Phillips Intellispace Radiology system ((K111804) reference device) to modify the current Vitrea View software indications to include viewing of diagnostic digital breast tomography images.

a) Mammography Image Quality Validation

The validation was a multi-reader, multi-case test with four experienced radiologists reviewing Digital Mammography X-Ray Image Storage SOP class studies. The validation used the already cleared McKesson Radiology system (K140909) in association with WIDE PN21IQS monitors (K052312), side by side with the Vitrea View software displayed on Barco Coronis Fusion 10MP monitors (K133984).

Fifty studies were chosen randomly from existing patient studies obtained over a two-day time-frame at the designated Breast Imaging center. The radiologists were asked to rate the image quality equivalence of the Vitrea View software on a scale of 1 to 3 compared to the McKesson system for:

1. Visualization of the adipose and fibroglandular tissue
2. Visualization of the breast tissue and underlying pectoralis muscle
3. Image contrast for differentiation of subtle tissue density differences
4. Sharpness, assessment of the edges of fine linear structures, tissue borders and benign calcifications
5. Tissue visibility at the skin line
6. Artifacts due to image processing, detector failure and other external factors to the breast
7. Overall clinical image quality

The radiologists found all of the images displayed met the clinical equivalence for diagnostic quality when displayed using the Vitrea View software as compared to the same studies displayed using the McKesson system.

b) Digital Breast Tomosynthesis Image Quality Validation

The validation was a multi-reader, multi-case test with three experienced radiologists reviewing Digital Breast Tomosynthesis Image Storage SOP class studies. The validation used the already cleared Phillips Intellispace Radiology system (K111804) in association with Barco Nio 5MP MDCG-5221 monitors (K133984), side by side with the Vitrea View software displayed on Barco Mammo Tomosynthesis 5 MegaPixel MDMG-5221 monitors (K161229).

Fifty studies were chosen randomly from existing patient studies obtained at the designated Breast Imaging center. The radiologists were asked to rate the image quality equivalence of the Vitrea View software on a scale of 1 to 3 compared to the Phillips Intellispace Radiology system for:

1. Visualization of the adipose and fibroglandular tissue
2. Visualization of the breast tissue and underlying pectoralis muscle
3. Image contrast for differentiation of subtle tissue density differences
4. Sharpness, assessment of the edges of fine linear structures, tissue borders and benign calcifications
5. Tissue visibility at the skin line
6. Artifacts due to image processing, detector failure and other external factors to the breast
7. Overall clinical image quality

The radiologists found all of the images displayed met the clinical equivalence for diagnostic quality when displayed using Vitrea View as compared to the same studies using the sites existing Phillips Radiology system.

Overall, the testing performed on the Vitrea View software confirmed the software functions according to its requirements, conforms to the intended use and is safe and effective.

Summary of Clinical Tests:

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

Cyber and Information Security

Vitrea View 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 View 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 View software has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed, predicate device VitreaView (K150738). The added feature to allow for viewing of mammography for review and diagnosis is substantially equivalent to the feature in the reference device, McKesson Radiology, which was cleared by the FDA under K140909. Additionally, the feature to allow for viewing of digital breast tomosynthesis for review and diagnosis is substantially equivalent to the Phillips Intellispace Radiology system, which was cleared by the FDA under K111804.

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 support for diagnostic viewing of mammographic images and digital breast tomography images in the Vitrea View 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.