



Food and Drug Administration
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Silver Spring, MD 20993-0002

Vital Images, Inc.
% Mr Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343-4414

April 6, 2015

Re: K150738
Trade/Device Name: VitreaView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 18, 2015
Received: March 20, 2015

Dear Mr. Shah:

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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150738

Device Name

VitreaView

Indications for Use (Describe)

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 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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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510(k) 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:	Modifications to a legally marketed device which are not qualified for a Special 510(k) notification
Submitter:	Vital Images, Inc. 5850 Opus Parkway Suite 300 Minnetonka, MN, 55343-4414
Establishment Registration:	2134213
Contact Person:	Parthiv Shah Sr. Regulatory Affairs Specialist Phone : 952-487-9574 Fax: 952-487-9510 E-mail: pshah@vitalimages.com
510(k) Type:	Traditional
Summary Date:	March 30, 2015
Device Trade Name:	VitreaView Software
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 Devices:

Predicate Device(s)	Manufacturer	FDA 510(k) number
VitreView	Vital Images, Inc.	K122136
VITALConnect	Vital Images, Inc.	K071362

Device Description:

VitreView is a cross-browser, cross-platform, zero-footprint universal medical image viewer solution capable of displaying both DICOM and non-DICOM medical images for diagnosis, review, communication, and reporting.

VitreView 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. It supports the physician in medical image viewing and treatment planning.

VitreView offers medical professionals a universal viewer for accessing multi-dimensional 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 zero footprint/zero download nature of VitreView. VitreView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases.

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

Intended Use / Indications for Use:

VitreView 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 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 VitreView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.

Intended for Disease / Condition / Patient Population:

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

Software Changes (from the last 510(k) clearance K122136):

Key changes:

- Query on demand searches archives in real-time directly from the source without the need for an index
- Color and Greyscale Softcopy Presentation State (CSPS and GSPS)
- Easy study navigation and study sharing via email, including bookmarking
- View DICOM key image objects that have been saved with a study
- Comparative review allows users to view multiple studies and to track and quantify changes
- Markup tools allow you to create measurements and add annotations, with indication if off-screen
- Window/Level sets specific window-level, grayscale-inverted, a user preset or stored-DICOM
- Volume rendering presets allow you to change the appearance of the 3D view
- Enhanced notifications for study changes and study processing
- Linking is available across modalities and can be applied to duplicated series. A default set of linking options are remembered by modality and applied to linked series, including: navigation, window/level and zoom per modality.
- Auto-Cine enables users of cine to quickly see the dynamic view of studies most often viewed in cine mode
- Provides diagnostic quality image review to medical professionals

Other minor enhancements:

- Annotation Indicator
- Markup Scrollbar Indicator for easy access to key slices
- Bookmarks automatically save when users log out
- Query retrieve progress indicator
- Text annotation is available with the Arrow tool
- Arrow tool is available from the Ruler toolbar
- Ability to review the report and move through the VitreaView studies
- Calibration handling for projection modalities
- Windows 8.1 support
- Internet Explorer 11 support
- Windows 8 support
- Internet Explorer 10 support
- Administrators can remove changed or deleted studies from the VitreaView Study List by authorized permissions
- The updated URL encryption method provides additional security for patient health information (PHI)
- Support for automatic LDAP group mapping
- Structured reports can be created from metadata during the initial study load
- The patient demographics display within the viewport has been refined to show more information when the browser is resized
- Custom actions are available to define specific search behavior
- Improved selection of the viewport layout
- MINT storage can be optimized to minimize overhead
- Improved access to related images and documents
- The status of Pending has been added to Administration Change Sets
- Ability to redirect the user to another URL

- Ability to use a custom logout hook
- Carousel swipe navigation
- Ability to disable pixel measurements
- Ability to disable logout

Substantial Equivalence Comparison:

- **Regulatory Comparison**

Characteristic	Modified VitreaView Software (Submission Subject)	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	ViTALConnect (K071362) (Predicate Device-2)	Noted Differences
Classification Name	Picture Archiving and Communications System	Picture Archiving and Communications System	Picture Archiving and Communications System	None
Regulatory Number	892.2050	892.2050	892.2050	None
Product Code	LLZ	LLZ	LLZ	None
Classification	Class II	Class II	Class II	None
Review Panel	Radiology	Radiology	Radiology	None
Decision Date	Under Review	September 7, 2012	May 30, 2007	Both predicates are cleared

- **Intended Use / Indications for Use Comparison with the Predicate Device-1**

Characteristic	Modified VitreaView Software (Submission Subject)	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Noted Differences
Intended Use / Indications for Use	VitreView is a medical image viewing and information distribution application that provides access, through the internet and within the enterprise to multi-modality softcopy	VitreView is a medical image viewing and information distribution application that provides access, through the Internet and within the enterprise, to multi-modality softcopy	The only changes in the Intended Use statements are as below: <ul style="list-style-type: none"> • The following line from the Intended Use statement of already cleared VitreaView

Characteristic	Modified VitreaView Software (Submission Subject)	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Noted Differences
	<p>medical images, reports, and other patient-related information. This data is hosted within disparate archives and repositories <u>for diagnosis</u>, review, communication, and reporting of DICOM and non-DICOM data.</p> <p>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.</p> <p>Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations.</p> <p>When accessing VitreaView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.</p>	<p>medical images, reports and other patient-related information, that may be hosted within disparate archives and repositories for review, communication and reporting of DICOM and non-DICOM data. <u>VitreaView is not intended for primary diagnosis</u>. When accessed from a mobile tablet, VitreaView is for informational purposes only and not intended for diagnostic use.</p> <p>Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance.</p> <p>Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.</p>	<p>510(k) – K122136 has been removed:</p> <p>“VitreaView is not intended for primary diagnosis”</p> <ul style="list-style-type: none"> The following word has been added the in the updated Intended Use statement: “for diagnosis”
Modality Support	Multi-modality	Multi-modality	None

• **Intended Use / Indications for Use Comparison with the Predicate Device-2**

Characteristic	Modified VitreaView Software (Submission Subject)	ViTALConnect (K071362) (Predicate Device-2)	Noted Differences
Intended Use / Indications for Use	<p>VitreView 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 <u>for diagnosis</u>, review, communication, and reporting of DICOM and non-DICOM data.</p> <p>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.</p> <p>Lossy compressed mammography images and digitized film screen images must not be reviewed for primary image interpretations.</p> <p>When accessing VitreaView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.</p>	<p>ViTALConnect, Version 4.1 is a medical <u>diagnostic software</u> system intended to process, analyze, review, and distribute multi-dimensional digital images acquired from a variety of imaging devices including: CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>ViTALConnect is not meant for primary Image Interpretation In mammography.</p>	<p>None</p> <p>Both software products provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices.</p>

Characteristic	Modified VitreaView Software (Submission Subject)	ViTALConnect (K071362) (Predicate Device-2)	Noted Differences
Modality Support	Multi-modality	Multi-modality	None

• **Device Description Comparison with the Predicate Device-1**

Characteristic	Modified VitreaView Software (Submission Subject)	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Noted Differences
Device Description	<p>VitreView is a cross-browser, cross-platform, zero-footprint universal medical image viewer solution capable of displaying both DICOM and non-DICOM medical images for diagnosis, review, communication, and reporting.</p> <p>VitreView 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. It supports the physician in medical image viewing</p>	<p>VitreView is a cross-browser, cross-platform, zero-footprint universal medical image viewer solution capable of displaying both DICOM and non-DICOM medical images.</p> <p>VitreView 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. It supports the physician in medical image viewing and treatment planning.</p>	<p>The only change in the Device Description statements is as below:</p> <ul style="list-style-type: none"> The support for diagnostic quality medical image review has been added into the subject device.

Characteristic	Modified VitreaView Software (Submission Subject)	510(k) Cleared VitreView Software (K122136) (Predicate Device-1)	Noted Differences
	<p>and treatment planning.</p> <p>VitreView offers medical professionals a universal viewer for accessing multi-dimensional 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 zero footprint/ zero-download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases.</p> <p>When accessing VitreaView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.</p>	<p>VitreView offers medical professionals a universal 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 zero footprint, zero-download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases.</p> <p>When accessed the VitreaView software from a mobile device, the image viewed on the VitreaView software is for informational purposes only and not intended for diagnostic use.</p>	

• **Device Description Comparison with the Predicate Device-2**

Characteristic	Modified VitreaView Software (Submission Subject)	ViTALConnect (K071362) (Predicate Device-2)	Noted Differences
Device Description	<p>VitreView is a cross-browser, cross-platform, zero-footprint universal medical image viewer solution capable of displaying both DICOM and non-DICOM medical images <u>for diagnosis</u>, review, communication, and reporting.</p> <p>VitreView 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. It supports the physician in medical image viewing and treatment planning.</p> <p>VitreView offers medical professionals a universal viewer for accessing multi-dimensional imaging data in context with reports from enterprise patient health information databases, fosters collaboration,</p>	<p>The ViTALConnect system is a <u>medical diagnostic</u> device that allows the processing, review, analysis, communication and media interchange of multi-dimensional digital images acquired from a variety of imaging devices.</p> <p>The ViTALConnect system provides multi-dimensional visualization of digital images to aid clinicians in their analysis of anatomy and pathology. The ViTALConnect system user interface follows typical clinical workflow patterns to process, review, and analyze digital images.</p>	<p>None</p> <p>Both software products provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices.</p>

Characteristic	Modified VitreaView Software (Submission Subject)	ViTALConnect (K071362) (Predicate Device-2)	Noted Differences
	<p>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 zero footprint/ zero-download nature of VitreaView. VitreaView offers scalability to add new users as demand grows, may be deployed in a virtualized environment, and is designed to be integrated with enterprise patient health information databases.</p> <p>When accessing VitreaView from a mobile device, images viewed are for informational purposes only and not intended for diagnostic use.</p>		

• **Technological Characteristics Similarity with the Predicate Device-1**

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
Annotation and Measurement Tools	<ul style="list-style-type: none"> • Line • Angle • Ruler • Arrow 	Same	Same
User Installation Requirements	<ul style="list-style-type: none"> • Runs within browser using HTML and JavaScript only • No installation is required on user's machine 	Same	Same
Data Type Supported	<ul style="list-style-type: none"> • DICOM • Non-DICOM 	Same	Same
Image View/ Manipulation	<ul style="list-style-type: none"> • Image Zoom • Pan • Window Level • Auto Window Level • Reset • Scout Lines • Image Rotate • Image Flip • Magnify • Image Invert • Image Cine 	Same	Same
Data Encryption	<ul style="list-style-type: none"> • HTTPS • SSL 	Same	Same
Patient Demographic Display	Capable of displaying patient demographic information	Same	Same
Linking	Co-planar linking: <ul style="list-style-type: none"> • Autolink • Manual 	Same	Same

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
User and Password Control	Users can be managed via an internal database, active directory, or parent application	Same	Same
Data Security	Stored on server	Same	Same
Audit Trail	Audit trail logged	Same	Same
User Management	Database structure allows mapping users to groups internally or mapping external groups (AD, parent application) to internal groups and role	Same	Same
Transmission Modes	Via the web with Internet browsers	Same	Same
File Type Used	<ul style="list-style-type: none"> • JPEG for Lossy data • PNG for Lossless data 	Same	Same
MPR Viewing	This viewing feature enables the display of reformatted CT and MR images into axial, coronal and sagittal orientations.	Same	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	Same	Same

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	parameters of the 3D views to highlight features.		
Active Target Tool	This viewing feature provides a facility to view a single target location within multiple images.	Same	Same
Crosshair Navigation and Synchronization:	This viewing feature provides a facility to synchronize and scroll through multiple views at the same time.	Same	Same
Ability to clone images side by side	Ability to clone images side by side.	Same	Same
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.	Same	Same
Ability to select locale and language settings on the login screen	Ability to select locale and language settings on the login screen.	Same	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.	Same	Same
Help Tips	Proactive help tips appear for 10-15 seconds to educate users on certain functionality that may	Same	Same

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	not be obvious to a new user.		
Support for TIF Files	VitreaView can display TIF files.	Same	Same
Tablet support for information purpose only (Not for diagnostic use)	<p>This viewing feature provides access of VitreaView software on various iOS and Android tablet devices through the default internet browser. Key features are:</p> <ul style="list-style-type: none"> • 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 	Same	Same

• **Technological Characteristics Similarity with the Predicate Device-2**

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	ViTALConnect (K071362) (Predicate Device-2)	Explanation of Differences
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	Same	Same

• **Technological Characteristics Differences with the Predicate Device-1**

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
General Enhancements	<ul style="list-style-type: none"> • Color Softcopy Presentation State (CSPS) • Greyscale Softcopy Presentation State (GSPS) • Query on Demand provides real-time access to an archive, without indexing • Annotation Indicator • Ability to provide a bookmark 		These enhancements do not affect the intended use or alter the fundamental scientific technology of already cleared VitreaView.

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	<p>when sharing a study</p> <ul style="list-style-type: none"> • Markup Scrollbar Indicator for easy access to key slices • Share studies via email • Bookmarks automatically save when users log out • Query retrieve progress indicator • Text annotation is available with the Arrow tool • Arrow tool is available from the Ruler toolbar • Ability to review the report and move through the VitreaView studies • Simple Auto-Cine automatically plays the cine at the expected rate 		

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	<ul style="list-style-type: none"> • Calibration handling for projection modalities • Windows 8.1 support • Internet Explorer 11 support • Windows 8 support • Internet Explorer 10 support • Administrators can remove changed or deleted studies from the VitreaView Study List by authorized permissions • The updated URL encryption method provides additional security for patient health information (PHI) • Support for automatic LDAP group mapping 		

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	<ul style="list-style-type: none"> • Structured reports can be created from metadata during the initial study load • The patient demographics display within the viewport has been refined to show more information when the browser is resized • Custom actions are available to define specific search behavior • Improved selection of the viewport layout • MINT storage can be optimized to minimize overhead • Improved access to related images and documents 		

Modified VitreaView Software (Submission Subject) Technological Characteristic	Description	510(k) Cleared VitreaView Software (K122136) (Predicate Device-1)	Explanation of Differences
	<ul style="list-style-type: none"> • The status of Pending has been added to Administration Change Sets • Ability to redirect the user to another URL • Ability to use a custom logout hook • Carousel swipe navigation • Ability to disable pixel measurements • Ability to disable logout 		
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		This feature is substantially equivalent to the Predicate Device-2.

- **Technological Characteristics Differences with the Predicate Device-2**

None, as both software provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices.

Summary of Non-Clinical Tests:

The changes to the VitreaView software were 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 enhancements of the VitreaView 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 enhancements 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:

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 VitreaView software, experienced radiologists evaluated that the resulting image was of diagnostic quality. The radiologists evaluated acceptability of datasets on

brightness, sharpness, artifacts, and overall diagnostic quality. In all cases the radiologists found the display to be of diagnostic quality.

Summary of Clinical Tests:

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

Cyber and Information Security:

VitreView follows security best practices, including those outlined by OWASP and HIPAA, to limit the risk of unauthorized access to the system or data. In summary, the following HIPAA security standards have been implemented:

- HIPAA §164.312 User Identification
- HIPAA §164.312 Automatic logoff
- HIPAA §164.312 Audit
- HIPAA §164.312 Data integrity
- HIPAA §164.312 Authentication

Security is enforced at multiple layers within the system:

- **Transport Layer Security**

The most common form of security found in web applications is TLS, or SSL (secure sockets layer). All communication over SSL is encrypted. VitreaView has been designed to allow and encourage operation with SSL turned on “full time” for all components.

- **Authentication & Authorization**

VitreView provides Active Directory integration via Kerberos for Single Sign On, an internal database for user passwords, and an integration layer to authenticate users against a 3rd party system, such as a PACS.

Once a user is authenticated, the system determines actions the user is authorized to perform. Access to a given action may be guarded by one or more permissions. Roles are defined to aggregate a set of permissions, and roles are assigned to one or more groups.

- **Access Control**

Access Control is concerned with governing what data a user may perform their permitted operations upon. Access Control is site-configurable through installation of a custom script that is executed each time a study is launched.

- **Audit**

VitreView includes an audit subsystem that tracks user operations along with source IP address, time of day, specific operation performed, etc.

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 VitreaView software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2011) (Recognition Number 12-238)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	03/16/2012
ISO 14971:2007 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	03/16/2012
IEC 62304:2006 (Recognition Number 13-32)	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes (Software / Informatics)	2006	08/20/2012

Substantial Equivalence Analysis Conclusion:

Vital Images believes that VitreaView software has a substantially equivalent intended use, indications for use, and technological characteristics as the predicate devices. Any minor differences noted have been explained and do not raise any new questions of safety or effectiveness as the predicate devices. The implemented design controls, risk management, and performed testing demonstrate the VitreaView software device is as safe and effective as both predicate devices. Based on the comparison data and test data Vital Images believes the subject device should be found substantially equivalent to the predicate devices.