



Food and Drug Administration
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Vital Images, Inc.
% Mr. Parthiv Shah
Sr. Regulatory Affairs Specialist
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

June 3, 2015

Re: K151115
Trade/Device Name: MR Core Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 24, 2015
Received: April 27, 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)

K151115

Device Name

MR Core software

Indications for Use (Describe)

MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners.

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

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)

Purpose of Submission: Modifications to a legally marketed device (K040305) which are not qualified for a Special 510(k) notification

Submitter: Vital Images, Inc.
5850 Opus Parkway
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Minnetonka, MN, 55343-4414

Establishment Registration: 2134213

Contact Person: Parthiv Shah
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510(k) Type: Traditional

Summary Date: June 1, 2015

Device Trade Name: MR Core Software

Device Common Name: Radiological Image Processing Software

Device Classification Name: System, Image Processing, Radiological

Regulatory Description: Picture Archiving and Communications System

Regulation Number: 21 CFR 892.2050

Product Code: LLZ

Regulatory Classification: Class II

Device Panel: Radiology

Predicate Device:

Predicate Device	Manufacturer	FDA 510(k) number
Softread Software (Legally Marketed Device)	Vital Images, Inc.	K040305

Reference Device:

Reference Device	Manufacturer	FDA 510(k) number
Myrian (Legally Marketed Device)	Intrasense	K091001

Device Description:

MR Core allows intuitive navigation, quantification, and manipulation of medical images obtained from MRI scanners. This application enables clinicians to compare multiple series of the same patient, side-by-side, and switch to other integrated applications to further examine the data. It provides rich clinical tools to review images for efficient and effective patient care.

Key features:

General Viewing:

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

Access to Advanced Applications and Workflows:

- In-application access to advanced analysis applications
- Evidence creation and sharing across workflows

General Image Display, Manipulation, and Analysis Tools:

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

- Invert
- Rotate (Clockwise, counter-clockwise)
- Arrow
- Adjust Registration
- Window level/width selection and user configurable preset
- Auto window level/width setting
- Text/Arrow annotation (Label)
- Measurement of distance (Ruler), Angle, Cobb Angle, Ellipse ROI, and Freehand ROI

Specialized MR Tools:

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

Intended Use / Indications for Use:

MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners. The option also enables clinicians to compare multiple series for the same patient, side-by-side, and switch to other integrated applications to further examine the data.

Changes from the last 510(k) clearance K040305:

No.	Change(s)	Rationale for Changes
1	<p><u>Change-1: User Interface</u> Completely re-designed User Interface (UI) screen</p>	To utilize enhancements in the software technology for better look and user experience.
2	<p><u>Change-2: Stitching of MR data</u> Added a new feature of “stitching” that combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	To combine separately acquired images into a single view for easier interpretation.
3	<p><u>Change-3: Restricted Modality Support</u> MR Core only allows the examination and manipulation of a series of medical images obtained from MRI scanners.</p>	The current version of MR Core only supports MR modality.

No.	Change(s)	Rationale for Changes
4	Change-4: Restricted Features MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” (divide a single study into multiple stacks) features.	The current version of MR Core does not support “ <i>Image Filtering</i> ” and “ <i>Image Set Splitting</i> ” features.

Intended for Disease / Condition / Patient Population:

MR Core is a medical image viewer software device. Therefore, particular information regarding the disease, condition, and patient population are not applicable.

Substantial Equivalence Comparison:

- **Regulatory Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Device Type / Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Common Name	Radiological Image Processing Software	Radiological Image Processing Software	Same
Regulation / Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	LLZ	LLZ	Same
Classification	Class II	Class II	Same
Review Panel	Radiology	Radiology	Same

• **Intended Use Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Indications for Use	<p>Softread, is an option within the Vitrea 2 system and is intended to allow the examination and manipulation of a series of 2D images in a variety of modalities, including CT, MR, CR/DR/DX, SC, US, NM, PET, XA, and RF, etc.</p> <p>The option also enables clinicians to compare multiple series' for the same patient, side-by-side, and to switch to Vitrea to further examine the data in a 3D volume.</p>	<p>MR Core is an option within Vitrea® that allows the examination and manipulation of a series of medical images obtained from MRI scanners.</p> <p>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.</p>	<p>Same</p> <p>Note: The Intended Use statement of the modified software is a subset (i.e. only for MR datasets) of already cleared Intended Use of the legally marketed device.</p>

• **Technology Comparison with the Predicate Device**

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Image Communication Standard: DICOM	Yes	Yes	Same
2D Image Review	Yes	Yes	Same
2D Comparative Review	Yes	Yes	Same
Multi-Planner Reformatting	Yes	Yes	Same
Maximum and Minimum Intensity Projection (MIP/MinIP)	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
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
Report Generation	Yes	Yes	Same
Cine Image Display	Yes	Yes	Same
Multi-frame Display	Yes	Yes	Same
Color Image Display	Yes	Yes	Same
Simultaneous Multiple Studies Review	Yes	Yes	Same
Cross-reference Lines Support	Yes	Yes	Same
Display of Selected Images, Series, or Entire Study	Yes	Yes	Same
Comparison of Multiple Series or Studies	Yes	Yes	Same
Scroll Image	Yes	Yes	Same
Zoom Image	Yes	Yes	Same
Pan Image	Yes	Yes	Same
Focus Image	Yes	Yes	Same
Rotate Image	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
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
Window Level/Width Selection and User Configurable Preset	Yes	Yes	Same
Auto Window Level/Width Setting	Yes	Yes	Same
Measurement of Distance	Yes	Yes	Same
Measurement of Angle	Yes	Yes	Same
Measurement of Cobb Angle	Yes	Yes	Same
Identification and Display of Ellipse Regions of Interest (ROIs)	Yes	Yes	Same
Identification and Display of Freehand Regions of Interest (ROIs)	Yes	Yes	Same
Automatic Registration	Yes	Yes	Same
Adjust Registration	Yes	Yes	Same

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
Image subtraction of two MR series/datasets	Yes	Yes	Same
Study and Series Linking	Yes	Yes	Same
Ability to launching into Vitrea platform for any advanced applications	Yes	Yes	Same

- Technology Comparison with the Reference Device

Criteria	Reference Device	Subject Device	Comparison
	Myrian (K091001)	MR Core Software	
<p>Feature: Stitching</p> <p>Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	Yes	Yes	<p>Same</p> <p>Note: The added “Stitching” feature is similar to the feature on the already cleared Intrastense, MYRIAN (“Reference device”)’s “Image Alignment” feature by K091001.</p> <p>Therefore, the added feature does not raise different questions of safety and effectiveness.</p>

• Differences in Technology with the Predicate Device

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
<p>Feature: Stitching</p> <p>Stitching feature combines MR images covering distinct contiguous, or slightly overlapping, regions of the human body anatomy into one or multiple images.</p>	No	Yes	<p>The added feature does not affect the intended use or fundamental scientific technology of already cleared Softread software (K040305).</p> <p>Note: The added “Stitching” feature is similar to the feature on the already cleared Intrasure, MYRIAN (“Reference device”)’s “Image Alignment” feature by K091001. Therefore, the added feature does not raise different questions of safety and effectiveness.</p>
<p>Restricted Modality Support</p> <p>The current version of MR Core only supports MR modality.</p>	Multi-modality	MR	<p>The support for additional modalities is available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise different questions of safety and effectiveness of the subject device.</p>
<p>Restricted Features</p> <p>The current version of MR Core does not support “Image Filtering” and “Image Set Splitting” features.</p>	<ul style="list-style-type: none"> • Image Filtering • Image Set Splitting 	None	<p>These additional features are available in the predicate device but not in the subject device.</p> <p>Therefore, they do not raise different questions of safety</p>

Criteria	Predicate Device	Subject Device	Comparison
	Softread Software (K040305)	MR Core Software	
			and effectiveness of the subject device.

- **Substantial Equivalence Analysis**

The enhancements in the software do not affect the intended use or alter the fundamental scientific technology of legally marketed Softread software (K040305). The modified Softread software (known as MR Core) has the same indications for use, principle of operation, and performs similar technological functions as the already cleared Softread software (K040305) (Predicate Device). The added “Stitching” feature is similar to the already cleared Intrasure, Myrian software (K091001) (Reference Device). The modifications are not consequential from the standpoint of device operation, safety, effectiveness or intended use.

Any minor differences noted have been explained and do not raise different questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and the performed verification and validation tests demonstrate the safety and efficacy of the device is equivalent to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device.

Summary of Non-Clinical Tests:

The changes to the Softread software were designed, developed and tested according to written procedures that included applying risk management. Software testing was completed to ensure the new features operate according to their requirements.

Testing included verification, validation, and evaluation on previously acquired medical images. The following quality assurance measures were applied to the development:

- Risk Management
- Requirements reviews
- Code designs
- Code reviews
- Design reviews
- Verification of the software – that included performance and safety testing
- Validation of the software – that included simulated usability testing by independent experienced medical professionals.

Risk Management:

Each risk pertaining to this feature 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 “Remote”. All risks for this feature were collectively reviewed to determine if the benefits outweigh the risk. Based on the post market information contained in our Clinical Evaluation Report, injury or death is very rare for our product and products similar to ours. Because of this history and 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 MR Core software, experienced medical professionals evaluated the application. All validators confirmed that the MR Core software fulfills its intended uses.

Summary of Clinical Tests:

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

Cyber and Information Security:

- **Confidentiality**
The Vitrea platform (K150258) relies on built in Windows Login security to limit access to the system. The Vitrea platform can only be installed and configured by an administrator of the Windows machine.
- **Integrity**
The Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances.
- **Availability**
The Vitrea platform is always available to the logged on user as long as the Windows machine itself is properly maintained.
- **Accountability**
The Vitrea platform includes an audit capability that tracks authenticated and authorized user operations along with information on what data was accessed. Vitrea audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:

The FDA has not established mandatory performance standards and no special controls exist for this device. General software verification and validation tests were conducted to confirm proper function of the device's features.

The MR Core 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

Conclusion:

Vital Images believes that the MR Core software application has the same intended use and indications and similar principle of operation, and technological characteristics as the predicate and reference devices. Any minor differences noted have been explained and do not raise different questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and performed tests demonstrate the safety and efficacy of the device in comparison to the predicate device. Based on the comparison data and test data, Vital Images believes the subject device should be found substantially equivalent to the predicate device. The MR Core software device is as safe and effective as the predicate device.