DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 3, 2016

Vital Images, Inc.
% Mr. Vince Swenson
Senior Director of Quality and Regulatory
5850 Opus Parkway, Suite 300
MINNETONKA MN 55343

Re: K161157
Trade/Device Name: Vitrea® CT Dual Energy Image View
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 29, 2016
Received: September 30, 2016

Dear Mr. Swenson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161157

Device Name
Vitrea® CT Dual Energy Image View

Indications for Use *(Describe)*
The CT Dual Energy Image View application accepts CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The material composition of body regions may be determined using the energy dependence of the attenuation coefficients of different materials. This approach enables images to be generated at multiple energies within the available spectrum to visualize and analyze information about anatomical and pathological structures.

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:	To obtain 510k clearance for Vital's software application Vitrea® CT Dual Energy Image View which is substantially equivalent to the cleared K132813 Dual Energy System Package manufactured by Toshiba Medical Systems Corporation.	
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414	
Establishment Registration:	2134213	
Contact Person:	Vince Swenson Sr. Dir. of Quality and Regulatory Affairs Phone: 952-487-9548 Fax: 952-487-9510 vswenson@vitalimages.com	
510(k) Type:	Traditional	
Summary Date:	September 29, 2016	
Device Trade Name:	Vitrea® CT Dual Energy Image View	
	Subject Device	**Predicate Device**
	Vitrea® CT Dual Energy Image View	**K132813 Dual Energy System Package**
Classification Name	Computed Tomography X-ray System.	Computed Tomography X-ray System.
Regulatory Number	892.1750	892.1750
Product Code	JAK	JAK
Classification	Class II	Class II
Review Panel	Radiology	Radiology
Decision Date	Under Review	February 6, 2014

Predicate Device(s):

Predicate Device	Manufacturer	FDA 510(k) Number
Dual Energy System Package	Toshiba Medical Systems Corporation 2441 Michelle Drive, Tustin, CA 92780	K132813

General Description of Dual Energy Technology:

Standard computed tomography (CT) scanners use normal X-rays to make cross-sectional pictures or images of the body. A dual energy CT scanner is a technology that uses both a normal X-ray and also a second less powerful X-ray to make the CT images. This can facilitate making some abnormalities in the body more clear on the images taken. Iodine for example, is a commonly used substance in X-ray contrast agents, and using a dual energy CT can facilitate improved images of blood vessels which might allow the radiologist to obtain more accurate information about a patient's condition. Dual Energy images can be obtained using a single examination instead of two separate examinations.

In addition, dual energy CT allows for the decomposition of materials and thus the differentiation of materials with high atomic numbers such as iodine. An iodine map image data set using dual energy methodology can display the distribution of iodine and thus differentiate regions of vascularity within the organ post scanned. The iodine enhancement map is usually a color overlay over an anatomical image to emphasize the differences in vascularity and to allow anatomical localization.

Device Description:

The Vitrea® CT Dual Energy Image View is a post-processing software application which functions on the Vitrea® Platform, cleared by K150258.This application allows you to load and combine two CT images, acquired from a Toshiba CT scanner with a Dual Energy protocol, of the same anatomical location; one obtained with low kV tube voltage and one obtained with high kV tube voltage. Vitrea® computes a Blended and an Enhanced image with adjustable virtual energy levels, a Virtual Non-Contrast (VNC) image, an Iodine Map overlaid on one of the original or derived images, a CT graph, and a best Contrast-to-Noise Ratio (CNR) image. For the Raw Data Analysis workflow, Vitrea® calculates a Monochromatic image.

The software supports Toshiba dual-energy studies containing image-based and projection-based reconstruction techniques.

- Image-based reconstructed data consists of a standard image reconstruction of the two scans. Use the Dual Energy Image Domain (Two Volumes) workflow for these datasets.
- Projection-based reconstructed data consists of special material image reconstruction where the two scans are combined to create two sets of images where a predefined material is defined, typically Iodine/Water and/or Calcium/Water. Use the Dual Energy Raw Data Analysis (Four or Six Volumes) workflow for these datasets.

NOTE: It is important that a description of the material is contained in the DICOM Image Comments tag (0020, 4000) for each dataset at the time of the scan. For Iodine/Water projection-based reconstruction, the Iodine material image should be labeled "I/H20," and the corresponding Water material image should be labeled "H20/I." For the Calcium/Water projection-based reconstruction, the Calcium material image should be labeled "Ca/H20," and the corresponding Water material image should be labeled "H20/Ca."

NOTE: The dual-energy datasets must be coincident with the same frame of reference UID.

NOTE: Available with Toshiba datasets only.

Intended Use / Indications for Use:

The CT Dual Energy Image View application accepts CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The material composition of body regions may be determined using the energy dependence of the attenuation coefficients of different materials. This approach enables images to be generated at multiple energies within the available spectrum to visualize and analyze information about anatomical and pathological structures.

Intended for Disease / Condition / Patient Population:

The CT Dual Energy Image View is a viewing option that allows users to combine different energy scans for the purpose of creating derived images. Specific information of intended for disease, condition, and patient population is not applicable as Dual Energy Image View can be used on variant diseases and conditions.

Substantial Equivalence Comparison:

Intended Use Comparison with Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea® CT Dual Energy Image View	**K132813 Dual Energy System Package**	
Indications for Use	The CT Dual Energy Image View application accepts CT images acquired using different tube voltages and/or tube currents of the same anatomical location. The material composition of body regions may be determined using the energy dependence of the attenuation coefficients of different materials. This approach enables images to be generated at multiple energies within the available spectrum to visualize and analyze information about anatomical and pathological structures.	The Dual Energy System allows the system to acquire two CT images of the same anatomical location using distinct tube voltages and/or tube currents during two tube rotations. The x-ray dose will be the sum of the dose of each tube rotation at its respective tube voltage and current. Information regarding the material composition of various organs, tissues, and contrast materials may be gained from the differences in x-ray attenuation between these distinct energies. This information may also be used to reconstruct images at multiple energies within the available spectrum, and to reconstruct basis images that allow the visualization and analysis of anatomical and pathological materials. The visualization of the differentiation between uric acid and others is provided with the Dual Energy system. When used by a qualified physician, a potential application is to determine the course of treatment.	Similar The subject device does not have the capacity to evaluate uric acid.

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea® CT Dual Energy Image View	**K132813 Dual Energy System Package**	
Intended Users	Trained radiologists, clinicians or technologists.	Radiologic technologists or other medical personnel who are qualified to operate X-ray CT scanners	Similar
Modality Support	CT /CTA	CT /CTA	Same

Device Description Comparison with Predicate Device:

Subject Device	Predicate Device	Comparison
Vitrea® CT Dual Energy Image View	**K132813 Dual Energy System Package**	
CT Dual Energy Image View software allows you to load and combine two Toshiba CT volumes, one obtained with low kV tube voltage and one obtained with high kV tube voltage. Vitrea computes a Blended and an Enhanced image with adjustable virtual energy levels, a virtual non-contrast (VNC) image, an Iodine map overlaid on one of the original or derived images, a CT graph, and a best contrast-to-noise ratio (CNR) image. For the Raw Data Analysis workflow, Vitrea calculates a monochromatic image. The software supports Toshiba dual-energy studies containing image- and projection- based reconstruction techniques. • Image-based reconstructed data consists of a standard image reconstruction of the two scans. Use the Dual Energy Image Domain (Two Volumes) workflow for these datasets. • Projection-based reconstructed data consists of special material image reconstruction where the two scans are combined to create two sets of images where a predefined material is defined, typically Iodine/Water and/or	Dual Energy System Package, CSDP-001A, consists of three software packages intended to be used on Toshiba CT systems which allows for the acquisition of two CT images of the same anatomical location using different tube voltages and/or tube currents during two tube rotations. CSDP-001A/1 (Dual Energy System) allows the same region to be scanned at two different tube voltages and tube currents and permits the CT values and ratio in the selected region to be measured based on the two image data sets obtained, providing information that is useful for identifying materials. CSDP-001A/2 (Dual Energy Raw Data Analysis) allows monochromatic images to be generated and permits images in which contrast enhancement is visualized to be generated based on the datasets acquired by scanning the same positions with different tube voltages, making it possible to perform analysis. CSDP-001A/3 (Dual Energy Composition Analysis) reads data acquired by scanning the same	Similar The subject device is a post-processing software application and only has a subset of capabilities of the predicate device. The subject device is able to display iodine maps and monochromatic images. However, it does not evaluate uric acid studies or have CT scanner capabilities.

Subject Device	Predicate Device	Comparison
Vitrea® CT Dual Energy Image View	**K132813 Dual Energy System Package**	
Calcium/Water. Use the Dual Energy Raw Data Analysis (Four or Six Volumes) workflow for these datasets.	positions with different tube voltages and extracts suspected uric acids from the acquired images.	

Similarities in Technology with Predicate Device:

Criteria	Description of Feature	Subject Device	Predicate K132813	Comparison
Modality				
CT	Computed Tomography	Yes	Yes	Same
Data Loading				
DICOM	Digital Imaging and Communications in Medicine	Yes	Yes	Same
Function(s)				
Iodine Map/ Iodine Map Generation	Description: A color scale of iodine regions generated using the high kV and low kV scans. The map is overlaid on one of the original or derived volumes. Purpose: Iodine map images indicate whether or not the contrast-enhanced regions are present. Iodine Mapping is intended to visualize the presence of contrast enhancement, more specifically, the uptake of iodine. Input Data: Low and High kVp acquisition data.	Yes	Yes	Same

Criteria	Description of Feature	Subject Device	Predicate K132813	Comparison
Virtual-Non-Contrast	Description: An estimation of a comparable image if no contrast agent was administered. The image is generated by replacing the iodine HU enhancement with an estimation of the original soft tissue texture. Purpose: Virtual-Non-Contrast images attempt to estimate a comparable image as if no contrast agent was administered. Input Data: Low and High kVp acquisition data.	Yes	Yes	Same
Monochromatic	Description: Image created by combining the material pair volumes to simulate the appearance of a single energy level. The image initially displays at a virtual energy level of 66 keV. The virtual energy level is adjustable. Purpose: Monochromatic images simulate the appearance of a single energy level. Input Data: Material reconstruction of Low and High kVp acquisition data.	Yes	Yes	Same
Best CNR	Description: An image that displays the best contrast-to-noise ratio of all energy levels. Purpose: Best CNR images are used to minimize the trade-off between contrast and noise. Input Data: Low and High kVp data.	Yes	Yes	Same
Display Blended Image	Description: Image created by combining the high kV and low kV images to simulate the appearance of a single energy scan.	Yes	Yes	Same

Criteria	Description of Feature	Subject Device	Predicate K132813	Comparison
	The image initially displays at a virtual energy level of 120 kVp. The virtual energy level is adjustable. Purpose: Blended images are intended to simulate the appearance of a single-energy scan at a user-specified kVp value Input Data: Low and High kVp acquisition data.			
Display Enhanced Image	Description: Image created using a weighted averaging for the estimated contrast-enhanced regions relative to the Blended image. The image initially displays at a virtual energy level of 120 kVp. The virtual energy level is adjustable. Purpose: Enhance the previously blended images which simulate the appearance of a single-energy scan at a user-specified kVp value Input Data: Low and High kVp acquisition data.	Yes	Yes	Same
Material composition of body regions	Description: The software exploits the energy dependence of the attenuation coefficients of different materials to perform a decomposition into basis materials. This fundamental technique is used to generate the iodine map and virtual non-contrast (VNC) images. Purpose: A graph of Hounsfield unit attenuation vs. energy level is provided within a user-defined region of interest (ROI). The shape characteristics of the energy response curve can provide additional information about the material composition within the ROI. Input Data:	Yes	Yes	Same

Criteria	Description of Feature	Subject Device	Predicate K132813	Comparison
	Low and High kVp data.			

Differences in Technology with the Predicate Device:

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea® CT Dual Energy Image View	K132813 Dual Energy System Package	
Differentiation between Uric Acid and other materials	No	Yes	The subject device contains a subset of the Dual Energy System Package features which does not include these features. Vital is not making any claims for these features.
Dose	N/A	Yes	
Kidney Stone Characterization	No	Yes	
Uric Acid Characterization	No	Yes	
Acquisition of Images	N/A	Yes	

Currently, the Vitrea Dual Energy Image View application does not have the capability to differentiate between Uric Acid and other materials, it does not perform Kidney Stone Characterization and/or Uric Acid Characterization. As Vitrea Dual Energy image View is a post-processing software application and not a scanner, dosage and acquisition of images is not an applicable function. Furthermore, the acquisition of images is based on the scanner parameters, which are determined by the manufactures' protocol. The manufacturers' protocols would determine parameters such as scan extent, slice thickness, scan field of view, and the low and high kVp values.

Summary of Non-Clinical Tests:

The Vitrea® CT Dual Energy Image View software was designed, developed, and tested according to written procedures that included risk management. Software testing was completed to ensure the new features operate according to defined requirements.

The following design control measures were applied to the development of the Vitrea® CT Dual Energy Image View 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 phantom testing and 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:

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.

Internal Validation (Phantom Testing):

The software validation team provided internal validation of Vitrea® CT Dual Energy Image View. Internal validation included internal user acceptance testing using various phantoms. Testing included side-by-side visual comparisons of dual energy algorithm outputs with Toshiba Display Console as the predicate device using phantom data. Details are included in Algorithm Verification and Validation.

External Validation:

During external validation, three experienced clinical experts evaluated the Vitrea CT Dual Energy Image View based on the following features: Iodine maps, Virtual non-contrast, monochromatic images, Best CNR, Blended images and Enhanced images at different energy levels. Two Radiological Technologists were provided a series of questions to obtain their feedback regarding performance and usability of each feature. In addition, a clinical radiologist evaluated multiple test cases comparing the Vitrea CT Dual Energy Image View to the Toshiba Dual Energy System Package (Predicate K132813). The radiologist was asked to rate the quality and performance of each feature to establish equivalence to the predicate device. All external validation testing passed with each expert confirming the Vitrea® CT Dual Energy Image View software fulfils the intended use and meets the needs of the user. Details of the external validation are included in the performance bench testing section.

Summary of Clinical Tests:

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

Cyber and Information Security:

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

Integrity
The Vitrea® platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. New DICOM produced by Vitrea® is identified as such with the appropriate manufacturer tags per the DICOM standard.

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

Accountability
The Vitrea® platform includes an audit capability that enables accountability by tracking authenticated and authorized user operations along with information accessed. Vitrea® audit logs are time stamped, enabling correlation with Windows system logging to track information accessed by a user.

Performance Standards:

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

The Vitrea® software complies with the following voluntary recognized consensus standards:

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

Substantial Equivalence Analysis Conclusion:

Vital Images believes that the Vitrea® CT Dual Energy Image View software is substantially equivalent to the legally marketed Dual Energy System Package (K132813) based on a comparison of its features and its performance. The Vitrea® CT Dual Energy Image View accepts CT images acquired using different tube voltages and/or tube currents of the same anatomical location as does the Dual Energy System Package. Both predicate and subject devices are able to provide users with Monochromatic views and Iodine Maps to allow for evaluation of images produced by low and high kV tube voltage.

In addition, the verification and validation testing performed by Vital Images demonstrated the subject device is as safe and effective as the predicate device and does not raise different questions of safety and efficacy than the predicate device.

In conclusion, Vital Images believes the Vitrea® CT Dual Energy Image View software application has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed Dual Energy System Package (K132813).

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 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.