510(k) Summary

This 510(k) summary is submitted in accordance with the requirements by section 807.92.(c)

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Establishment Registration: 2134213

NOV 2 2012

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510(k) Type: Traditional 510(k)

Summary Date: October 5,2012

Device Name
Trade Name: VitreaAdvanced
Common Name: Picture Archiving and Communications System
Classification Name: System, Image Processing, Radiological (21 C.F.R. 892.2050,LLZ)

Predicate Devices:

Subject Functions	Predicate Devices		
	Manufacturer	Trade Name	510(k) Number
Advanced Image Post-processing	Vital Images, Inc.,	Vitrea®, Version 4.0	K071331
Vitrea® CT Body Perfusion	Toshiba America Medical System, Inc.,	CSBP-001A Body Perfusion System	K090504
Vitrea® CT Liver Analysis	MeVis - Center for Medical Diagnostic Systems and Visualization GmbH	MeVis LiverAnalyser / LiverViewer Software	K051528
	MEDIAN Technologies	LMS-Liver	K071241
Vitrea® CT Brain Perfusion	Vital Images, Inc	Vitrea® 4DCT	K072821
	Siemens Medical Solutions, Inc.	syngo® Volume Perfusion-CT Neuro	K073238

Device Description:

VitreaAdvanced is a package of noninvasive post-processing software applications for the Vitrea®
software platform. The system is a software only medical device to be installed on common IT
hardware. VitreaAdvanced leverages existing Vitrea® functionality for the processing, review, analysis,
communication, and media interchange of multi-dimensional digital images acquired from a variety of
imaging devices. It provides multi-dimensional visualization of digital images to aid medical
professionals in their analysis of anatomy and pathology. VitreaAdvanced can be used with a variety of
cleared Vitrea® based software applications. VitreaAdvanced uses the Vitrea® system user interface to
follow typical clinical workflow patterns and process, review, and analyze digital images, including:
- Receive DICOM image data from a variety of sources
- Display images using dedicated protocols adapted to exam types
- Select images for closer examination from collection of 2D, 3D or 4D views
- Interactively manipulate an image in real-time to visualize anatomy and pathology
- Annotate, tag, measure, and record selected views
- Output selected views to compatible devices and publishing tools (e.g. printers, DICOM
  devices, etc.)

In addition, VitreaAdvanced includes three Vitrea® applications:

Vitrea® CT Body Perfusion is noninvasive post-processing software that has been designed to assess
dynamic (time lapsed collections) CT volume scans and provide data related to the volume sets. It
displays blood flow parametric maps for single-input and dual-input workflows.

Vitrea® CT Liver Analysis is noninvasive post-processing software that displays CT image data. It
processes image data to segment liver structures and evaluate resection surfaces as well as volumes.
Vitrea® CT Liver Analysis provides automatic registration and composite views of multiple series,
optimized screen layouts and measurement tools. It also generates standardized reports for WHO and
RECIST protocols and for percentage change tumor response values.

Vitrea® CT Brain Perfusion is noninvasive post-processing software that calculates cerebral blood flow
(CBF), cerebral blood volume (CBV), local bolus timing (i.e., delay of tissue response, time to peak),
and mean transit time (MTT) from dynamic CT image data. It displays time density curves, perfusion
characteristics in parametric and summary maps, as well as regions of interest and mirrored regions.

Intended Use / Indications for Use:

VitreaAdvanced is a medical diagnostic system for the processing, review, analysis, communication and
media interchange of multi-dimensional digital images acquired from a variety of imaging devices.
VitreaAdvanced is not meant for primary image interpretation in mammography. It can be used with a
variety of cleared Vitrea® based software applications. In addition, VitreaAdvanced includes three
Vitrea® applications:

> **Vitrea® CT Body Perfusion** is a noninvasive post-processing application designed to evaluate
> perfusion of organs and tumors. The software can calculate perfusion characteristics from
> dynamic CT image data acquired after the injection of contrast media. The software also allows
> the separate calculation of the arterial and venous components of perfusion in organs. It
> supports evaluation of regions of interest and the visual inspection of time density curves. When
> used by a trained and qualified physician a potential application is to differentiate blood flow
> between normal and diseased tissue. Determination of the change of perfusion parameters
> during the course of treatment may be helpful in therapy monitoring.

Vitrea® CT Liver Analysis is a noninvasive post-processing application designed to evaluate liver tumors and plan for liver surgery. It displays images for analysis and preoperative liver surgery planning, such as organ segmentation, tumor segmentation and intrahepatic vessels segmentation, as well as the approximation of vascular territories. It supports preoperative evaluation of specific surgery strategies by allowing the user to interactively define virtual resections splitting the liver. It also allows the user to evaluate safety-margins around lesions and to identify affected vascular branches and territories. Vitrea® CT Liver Analysis also provides automatic registration of multiple series and measurement tools for characterization and follow-up of the lesions. When used by a trained and qualified physician a potential application is to assist in the assessment of tumor response to therapy.

Vitrea® CT Brain Perfusion is a noninvasive post-processing application designed to evaluate areas of brain perfusion. The software can calculate cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e., delay of tissue response, time to peak), and mean transit time (MTT) from dynamic CT image data acquired after the injection of contrast media. The package also allows the calculation of regions of interest and mirrored regions, as well as the visual inspection of time density curves. Vitrea® CT Brain Perfusion supports the physician in visualizing the apparent blood perfusion in brain tissue affected by acute stroke. Areas of decreased perfusion, as is observed in acute cerebral infarcts, appear as areas of changed signal intensity (lower for both CBF and CBV and higher for time to peak and MTT).

Comparison with Predicate Devices:

VitreaAdvanced is a package of noninvasive post-processing software applications for the Vitrea® software platform. It leverages the basic functionality and technology of the existing 510(k) cleared Vitrea® software platform. VitreaAdvanced includes advance applications that extend the functionality of the platform for specific uses. The specific uses are substantially equivalent to the cleared uses of existing post-processing software applications available on other platforms. Also, the software applications use similar technology as existing post-processing software applications.

Vitrea® CT Body Perfusion:

Vitrea® CT Body Perfusion (Submission Subject)	Description	Toshiba CSBP-001A Body Perfusion System (K090504)	Explanation of Differences
Analysis Model	Maximum slope (Fick principal)	Includes	The subject and predicate both implement Maximum-slope. The predicate implements additional models: Compartment model and Patlak Plot.

Vitrea® CT Body Perfusion (Submission Subject)	Description	Toshiba CSBP-001A Body Perfusion System (K090504)	Explanation of Differences
Parameters	Blood flow	Includes	The subject and predicate both display blood flow parameters. The predicate includes additional parameters: Blood volume, MTT, HAF (PI), equivalent blood volume using the additional analysis models.
Functions	Single input, dual input, map display and ROI measurement	Same	None

Vitrea® CT Liver Analysis:

Vitrea® CT Liver Analysis (Submission Subject)	Description	MeVis Liver Analyser / LiverViewer Software (K051528)	Median LMS-Liver (K071241)	Explanation of Differences
Analysis Model	Rigid and deformable registration, Segmentation and region growing	Same	Same	None
Parameters	Basic measurements, volume, resection plane, RECIST, WHO and comparisons	Partial (volumes, resection planes and comparisons)	Partial (RECIST, WHO and comparisons)	MeVis provides basic measurements for volumes, resection planes and comparisons. LMS-Liver provides RECIST and WHO measurements and comparison.

Vitrea® CT Liver Analysis (Submission Subject)	Description	MeVis Liver Analyser / LiverViewer Software (K051528)	Median LMS-Liver (K071241)	Explanation of Differences
Functions	Segment: organs, tumors and intrahepatic vessels, Resection planning tool (defines vascular territories), multi-phase fusion and standardized reports	Partial (segmentation, resection planning and multi-phase fusion)	Partial (standardized reports)	MeVis provides segmentation, resection planning and multi-phase fusion. LMS-Liver provides standardized reports.

Vitrea® CT Liver Analysis:

Vitrea® CT Brain Perfusion (Submission Subject)	Description	Vitrea® 4DCT (K072821)	Siemens syngo® Volume Perfusion – CT Neuro (K073238)	Explanation of Differences
Analysis Model	Deconvolution	Same	Includes	syngo® Volume Perfusion-CT Neuro uses both deconvolution and maximum slope.
Parameters	Cerebral blood flow (CBF), cerebral blood volume (CBV), local bolus timing (i.e., delay of tissue response, time to peak), and mean transit time (MTT)	Same	Includes	syngo® Volume Perfusion-CT Neuro has all the parameters and vascular permeability

Vitrea® CT Brain Perfusion (Submission Subject)	Description	Vitrea® 4DCT (K072821)	Siemens syngo® Volume Perfusion – CT Neuro (K073238)	Explanation of Differences
Functions	Display regions of interest, mirrored regions, time density curves and perfusion characteristics in parametric and summary maps	Partial	Same	4DCT does not include summary maps (maps that combine parameters). syngo® Volume Perfusion- CT Neuro includes maps that combine parameters.

Summary of Non-Clinical Tests:

VitreaAdvanced was designed, developed, and tested according to written procedures that included applying risk management. Testing included verification, validation, and evaluation of previously acquired medical images.

The following quality assurance measures were applied to the development of VitreaAdvanced:
- Risk analysis
- Requirements reviews
- Design reviews
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Software Testing:

The primary focus of the Verification and Validation team during development was producing, reviewing and executing manual and automated test cases to ensure the product conformed to new and previously defined specifications and also to ensure that risks were properly mitigated during testing. The Requirement Traceability Matrix (RTM) provides a mapping between requirements, risks, test cases, and shows related test results. The RTM confirms that there was a test case authored and executed for all requirements and any applicable risks. In addition, the Verification and Validation Team demonstrated clinical features to several Radiologists and 3D Technologists to gather feedback and formal acceptance.

Manual Tests:

Manual tests cases were executed to verify and validate the CT Body Perfusion, CT Liver Analysis and CT Brain Perfusion applications, and to determine the impact of any changes. All manual tests and steps were executed to prove the product conformed to specifications and to mitigate risks.

Verification:

The software verification team had a primary goal of assuring that software fully satisfies all expected system requirements and features. Test cases were executed against the system features and requirements. As 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.

Automated Integration Level Build Verification Tests (BVT):

Automated integration level Build Verification Tests (BVT) were developed to exercise mainstream functionality and provide an assessment of the stability and testability of the VitreaAdvanced software. Automated software rendering tests were used to verify correctness of images generated by the rendering engine. Automated algorithm smoke tests and automated algorithm regression tests were executed. Automated performance tests were used to verify that response times and throughput were acceptable. Automated regressions tests were used to verify correctness of measurements, orientation markers, and other core features of VitreaAdvanced.

Validation:

The software validation team had a primary goal of assuring that software conforms to user needs and intended uses. The result of the validation team's efforts was evidence, produced by workflow testing, that system requirements and features were implemented, reviewed and met.

Internal Validation:

The software validation team provided internal validation of VitreaAdvanced. Internal validation included internal beta testing and internal user acceptance testing.

External Validation:

Vitrea® CT Body Perfusion
During external validation of CT Body Perfusion application of VitreaAdvanced, an external cardiologist confirmed that the CT Body Perfusion application's deformable (non-rigid) registration for dynamically scanned organs produces similar results to what is available on the scanner console. It was also confirmed that it takes the same amount of time or less to complete registration.

The results of the qualitative analysis (visual verification), performed as part of validation, support the feedback received from the cardiologist during external validation regarding the visual similarity of images produced by the VitreaAdvanced registration to the registration applied at the scanner. In addition, a cardiologist also confirmed the measurements produced were clinically acceptable and that the software was ready for general release. Based on the results of the qualitative analysis, and feedback gathered during external validation, the CT Body Perfusion application has passed validation.

Vitrea® CT Liver Analysis
During external validation of CT Liver Analysis application of VitreaAdvanced, two external 3D Technicians evaluated the functionality, usability and performance of the CT Liver Analysis application. Based on their evaluation, the software passed external validation.

Vitrea® CT Brain Perfusion
During external validation of CT Brain Perfusion of VitreaAdvanced, an external radiologist evaluated the functionality and performance of the summary map feature and the correlation of each summary map with his interpretation of that summary map's associated perfusion maps. He confirmed that the software has met the intended use and effectively provides a summary image of the data displayed in the perfusion maps as well as when used in conjunction with the perfusion maps, the summary map enables the user to characterize the brain tissue and communicate their findings.

Summary of Clinical Tests:

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

Cyber and Information Security:

- *Confidentiality*
  Vitrea platform 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*
  Vitrea platform complies with the DICOM standard for transfer and storage of this data and does not modify the contents of DICOM instances. Vitrea platform identifies the data it produces, marking and encoding the appropriate DICOM fields.

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

- *Accountability*
  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.

Measurement Accuracy:

Measurements and orientations in VitreaAdvanced were verified using various imaging phantoms. These imaging phantoms contain markers at known positions, distances, and angles from one another. The known positions, distances, and angles were used as input into expected results for verification tests that verified the spatial accuracy of image rendering of 2D and 3D images, the accuracy of distance, angular measurement, and navigational tools, as well as the accuracy of orientation markers within VitreaAdvanced.

Performance Standard:

No applicable mandatory performance standards or special controls exist for this device. However, the software is designed to meet NEMA PS 3.1 – 3.18 Digital Imaging and Communications in Medicine (DICOM) standard.

Conclusion:

The testing reported in this 510(k) establishes that VitreaAdvanced is substantial equivalent to the predicate devices and is safe and effective for its intended use.

Mr. Daniel Biank
Regulatory Affairs Manager
Vital Images, Inc.
5850 Opus Parkway, Suite 300
Minnetonka, MN 55343

NOV 2 2012

Re: K121213
 Trade/Device Name: VitreaAdvanced
 Regulation Number: 21 CFR 892.2050
 Regulation Name: Picture archiving and communications system
 Regulatory Class: II
 Product Code: LLZ
 Dated: October 5, 2012
 Received: October 9, 2012

Dear Mr. Biank:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such
additional controls. Existing major regulations affecting your device can be found in Title 21,
Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,
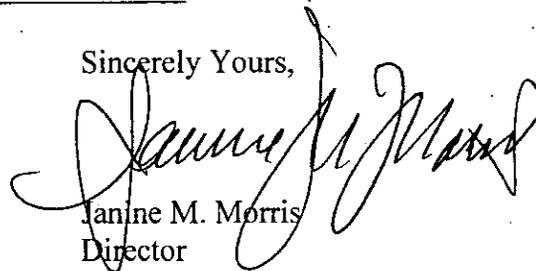
Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K121213**

Device Name: VitreaAdvanced

Indications for Use:

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Prescription Use __X__   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (21 CFR 807 Subpart C)
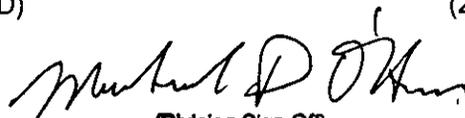
(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K121213