Vital Images, Inc.
Susan Atwood
Principal Quality Engineer
5850 Opus Parkway, Suite 300
MINNETONKA, MN 55343-4414

November 20, 2018

Re: K181247
Trade/Device Name: Vitrea CT Brain Perfusion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: October 23, 2018
Received: October 24, 2018

Dear Susan Atwood:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181247

Device Name
Vitrea CT Brain Perfusion

Indications for Use *(Describe)*
Vitrea CT Brain Perfusion is a non-invasive 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).

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510K Summary

This 510(k) summary is submitted in accordance with the requirements of 21 C.F.R. Part 807.92(c).

Basis for the Submission:	Vital Images, Inc. hereby submits this traditional 510(k) to provide a notification submission for proposed software changes in the already 510(k) cleared Vitrea CT Brain Perfusion software (K121213).
Submitter:	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN, 55343-4414, USA
Establishment Registration:	2134213
Contact Person:	Susan Atwood Principal Quality Engineer Phone: 952-487-9759 Fax: 952-487-9510 E-mail: satwood@vitalimages.com **Alternate Contact Person:** Vince Swenson Sr. Director of Quality and Regulatory Phone: 952-487-9548 Fax: 952-487-9510 E-mail: vswenson@vitalimages.com
510(k) Type:	Traditional
Summary Date:	May 8, 2018
Device Trade Name:	Vitrea CT Brain Perfusion
Device Common Name/ Regulatory Description:	Picture Archiving and Communications System
Device Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ
Regulatory Classification:	Class II
Device Panel:	Radiology

Predicate Device

Predicate Device	Manufacturer	FDA 510(k) Number
Vitrea CT Brain Perfusion software	Vital Images, Inc. 5850 Opus Parkway, Suite 300 Minnetonka, MN 55343 USA	K121213

Reference Device

Reference Device	Manufacturer	FDA 510(k) Number
Olea Sphere V3.0	Olea Medical 93 Avenue Des Sorbiers, Zone Athelia Iv La Ciotat, FR 13600	K152602

Device Description

Vitrea CT Brain Perfusion is a 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 perfusion and summary maps, as well as regions of interest and mirrored regions.

Intended Use / Indications for Use

Vitrea CT Brain Perfusion is a non-invasive 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).

Intended for Disease / Condition / Patient Population

Vitrea CT Brain Perfusion is intended for patients with suspected compromised or abnormal cerebral blood flow.

Key Changes from last 510k clearance K121213

The following list contains the key changes since the last 510k. These changes were made to enhance user experience and performance:

- Addition of Bayesian algorithm.
- Enhancements to Region-of-Interest tools (ROI) tools.
- Optimized layouts to include 4-up and 6-up views.
- Support for loading variable time scans for multi-series studies in 2D.
- Support for Jog and Helical Shuttle Thin Slice Brain Perfusion datasets from Canon (formerly Toshiba) Aquilion Prime Scanners.
- Support for Thick Slice “Jog Shuttle” from Philips Scanners (2D Perfusion).
- Support of 2D perfusion for thick slice irregular helical Siemens & GE scans.

- Increased the number of slices allowed per time series for GE & Siemens Helical Shuttle Scans.
- Support for DSA for Jog and Helical datasets.
- Enhancements to 4D thin slice to support axial and helical GE scans and helical Siemens scans.
- Addition of 3D Summary Map view

Regulatory Comparison

Characteristic	Subject Device	Predicate Device	Reference Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	**Vitrea CT Brain Perfusion (K121213)**	**Olea Sphere V3.0 (K152602)**	
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
Regulatory Number	892.2050	892.2050	892.2050	Same
Product Code	LLZ	LLZ	LLZ	Same
Classification	Class II	Class II	Class II	Same
Review Panel	Radiology	Radiology	Radiology	Same
Decision Date	Under Review	Nov. 02, 2012	Mar. 03, 2016	Predicate and reference devices are cleared.

Indications for Use Comparison with the Predicate Device

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	**Vitrea CT Brain Perfusion (K121213)**	
Indications for Use	Vitrea CT Brain Perfusion is a non-invasive 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	Vitrea CT Brain Perfusion is a non-invasive 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	Same

Criteria	Subject Device	Predicate Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	**Vitrea CT Brain Perfusion (K121213)**	
	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).	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).	
Intended Users	Qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.	Qualified healthcare professionals including, but not restricted to, radiologists, non-radiology specialists, physicians and technologists.	Same
Patient Population	Patients with suspected compromised or abnormal cerebral blood flow.	Patients with suspected compromised or abnormal cerebral blood flow.	Same
Modality Support	CT	CT	Same

Similarities in Technology with the Predicate Device

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	**Vitrea CT Brain Perfusion (K121213)**	
Quantitative brain perfusion maps for: • Regional cerebral blood volume (rCBV) • Regional cerebral blood flow (rCBV) • Mean transit time (MTT) • Time to peak of tissue (TTP) • Delay of tissue response (Delay)	Yes	Yes	Same
Display: • Region of interest (ROI) • Mirrored regions • Time density curves	Yes	Yes	Same

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	Vitrea CT Brain Perfusion (K121213)	
Display of Perfusion Maps in: • MPR orientations • 2D • 3D	Yes	Yes	Same
4D-DSA (digital subtraction angiography) view for visualizing flow of contrast through the vessels	Yes	Yes	Same
Perfusion maps in MPR orientations and 2D	Yes	Yes	Same
Automatic motion correction and curve fitting	Yes	Yes	Same
Region of interest (ROI) templates	Yes	Yes	Same
Midline identification and display	Yes	Yes	Same
Manual and automatic detection of artery and vein locations	Yes	Yes	Same
Automatic calculation of quantitative brain perfusion results	Yes	Yes	Same
Window leveling, edit mid-plane line, display mirrored ROIs, snapshots, time-series batch, movies for physician reporting	Yes	Yes	Same
Report generation for the Brain Perfusion patient study	Yes	Yes	Same
Perfusion measurement averages for multiple ROIs with ability to mirror an ROI from one hemisphere to the other	Yes	Yes	Same
Window leveling, edit mid-plane line, display mirrored ROIs, snapshots, time-series batch, movies for physician reporting	Yes	Yes	Same
Color coded Summary maps	Yes	Yes	Same

Differences in Technology with the Predicate Device

Software Functionality	Subject Device	Predicate Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	Vitrea CT Brain Perfusion (K121213)	
Bayesian Perfusion Algorithm	Yes	No	Subject device provides user with choice to use either the Bayesian algorithm or SVD+ algorithm. Predicate device can use the SVD+ algorithm. Note: The added Bayesian algorithm in the subject device is similar to the Bayesian algorithm in the reference device, Olea Sphere 3.0, which was cleared by the FDA under K152602. Therefore, this added algorithm does not raise different questions of safety and effectiveness.

Similarities in Technology with the Reference Device

Software Functionality	Subject Device	Reference Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	Olea Sphere V3.0 (K152602)	
Bayesian Algorithm: The Bayesian estimation of the hemodynamical parameters integrates a model-based approach especially robust to image noise and fast analytical integration techniques to compute the posterior probabilities of the estimated blood flow, delay, MTT and time concentration curves (residue functions).	Yes	Yes	Same
Motion correction	Yes	Yes	Same
Automatic Arterial Input function and Vein Output function	Yes	Yes	Same

Software Functionality	Subject Device	Reference Device	Comparison
	Vitrea CT Brain Perfusion with Bayesian Algorithm	Olea Sphere V3.0 (K152602)	
Automatic vessel removal	Yes	Yes	Same
Automatic Brain Midline detection	Yes	Yes	Same
Noise reduction is applied before the Bayesian computation.	Yes	Yes	Same
Model based Bayesian estimation of perfusion parameters.	Yes	Yes	Same
Delay insensitive method.	Yes	Yes	Same

Summary of Non-Clinical Tests

The changes to the Vitrea CT Brain Perfusion software were designed, developed, and tested according to written procedures that included risk management. Software verification 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 Brain Perfusion software:

- Risk Management
- Requirements Reviews
- Code Designs
- Code Development Testing
- Code Reviews
- Design Reviews
- Verification of the software
- Validation of the software

Risk Management

Each risk pertaining to the modifications to the Vitrea CT Brain Perfusion software 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 "Improbable." All risks for these modifications were collectively reviewed to determine if the benefits outweigh the risk. Based on Post Market information and because of the risk control measures included in these modifications, it is believed that the risk for these modifications as a whole are extremely low. Considering all risks against the benefits, it has been assessed that the benefits do outweigh the risks for these modifications.

During the design review, the following conclusions were reached:

- The medical benefits of the device outweigh the residual risk for each individual risk and all risks together
- All risks have been reduced as low as possible
- The overall residual risk for the software product 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, requirements and risk mitigations. Verification testing confirmed the software functions according to its requirements and all risk mitigations are functioning properly.

Validation

The software validation team's primary goal was to assure that 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 properly to conform to the intended use.

Algorithm Testing

Algorithm testing was performed to validate the proper function of the Bayesian algorithms within Vitrea CT Brain Perfusion. The Vitrea CT Brain Perfusion Bayesian algorithm has passed all the verification and validation and is therefore considered validated and acceptable.

External Validation

During the external validation of the Vitrea CT Brain Perfusion software, physicians evaluated if the Brain Perfusion with Bayesian algorithm (subject device) was substantially equivalent with the Brain Perfusion with SVD+ algorithm (K121213, predicate device). Based on the scores provided by the physicians, Vital concluded the Brain Perfusion with Bayesian algorithm is as safe and effective as the already cleared Brain Perfusion with SVD+ algorithm and fulfills its intended use.

Summary of Clinical Tests

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

Cyber and Information Security

The Vitrea CT Brain Perfusion software follows internal documentation which includes information based on the FDA Guidance: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Internal documentation covers the following:

1. Hazard analysis, mitigations, and design considerations pertaining to intentional and unintentional cybersecurity risks associated with the device, including:
    - A specific list of all cybersecurity risks that were considered in the design of the device;

- A specific list and justification for all cybersecurity controls that were established for the device.

2. A traceability matrix that links the actual cybersecurity controls to the cybersecurity risks that were considered;
3. A summary describing the plan for providing validated software updates and patches as needed throughout the lifecycle of the medical device to continue to assure its safety and effectiveness. The FDA typically will not need to review or approve medical device software changes made solely to strengthen cybersecurity.
4. A summary describing controls that are in place to assure that the medical device software will maintain its integrity (e.g. remain free of malware) from the point of origin to the point at which that device leaves the control of the manufacturer; and
5. Device instructions for use and product specifications related to recommended cybersecurity controls appropriate for the intended use environment (e.g. anti-virus software, use of firewall).

Performance Standards

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

The Vitrea CT Brain Perfusion software complies with the following voluntary recognized consensus standards:

Standard No.	Standards Organization	Standard Title	Version	Date
PS 3.1- 3.20 (2016) (Recognition Number 12-300)	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (Radiology)	3	06/27/2016
ISO 14971:2007 /(R)2010 (Recognition Number 5-70)	AAMI / ANSI / ISO	Medical Devices - Applications of Risk Management to Medical Devices	2007	06/27/2016
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, Inc. believes the Vitrea CT Brain Perfusion software with Bayesian algorithm has a similar intended use, indications for use, principle of operation, and technological characteristics as the legally marketed, predicate device Vitrea CT Brain Perfusion with SVD+ algorithm (K121213). In addition, the Bayesian perfusion algorithm added to the Vitrea CT Brain Perfusion software is similar to the Bayesian perfusion algorithm in the reference device, Olea Sphere V3.0, which was cleared by the FDA under K152602.

Furthermore, the verification and validation testing performed demonstrates the subject device is as safe and effective as the predicate device and does not raise any different questions of safety and effectiveness. Therefore, Vital believes the enhancements in the Vitrea CT Brain Perfusion software do not alter the fundamental scientific technology, safety or intended use of the device.

Each change was evaluated for the impact to the safety and effectiveness of the software. It was concluded that the changes do not raise any different questions of safety or effectiveness when used as labeled. The implemented design controls, risk management activities, labeling, and performed verification and validation tests demonstrate the safety and efficacy of the subject device. Based on the comparison information provided above, Vital Images, Inc. believes the subject device should be found substantially equivalent to the predicate device.