Viz.ai, Inc.
% Mr. Gregory Ramina
Director of Regulatory Affairs
855 El Camino Real Suit 13A-252
PALO ALTO CA 94301

April 20, 2018

Re: K180161
Trade/Device Name: Viz CTP
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 5, 2018
Received: April 5, 2018

Dear Mr. Ramina:

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.

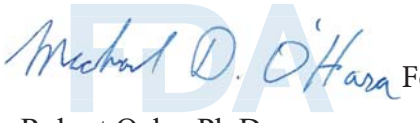
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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.

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 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 on last page

510(k) Number *(if known)*

K180161

Device Name

Viz CTP

Indications for Use *(Describe)*

Viz CTP is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices.

Viz CTP provides both analysis and communication capabilities for dynamic imaging datasets that are acquired with CT Perfusion imaging protocols. Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated from a raw CTP scan are exported in the standard DICOM format and may be viewed on existing radiological imaging viewers.

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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510(k) SUMMARY

Viz.ai, Inc.'s Viz CTP

Applicant Name: Viz.ai, Inc.
855 El Camino Real Suite 13A-252
Palo Alto, CA 94301

Contact Person: Gregory Ramina
Director of Regulatory Affairs
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San Francisco, CA 94107
Tel. (415) 663-6130
Greg@viz.ai

Date Prepared: April 5, 2018

Name of Device: Viz CTP

Common or Usual Name: PACS – Picture Archiving and Communications System

Classification:

Classification Panel: Radiology

Regulation No: 21 C.F.R. § 892.2050

Regulatory Class: Class II

Product Code: LLZ

Predicate Devices

iSchemaView Inc.'s RAPID (K121447)

Device Description

Viz CTP is a standalone software package that is comprised of several modules including DICOM receiving and sending modules, a study processor, image analysis algorithm, as well as software system components including a DICOM storage database and system health-monitoring. Viz CTP allows for bi-directional communication of data and may be implemented to allow a DICOM-compliant device to send files directly from the imaging modality, through a node on a local network, or from a PACS server. The device is designed to automatically receive, identify, extract, and analyze a CTP study of the head embedded in DICOM image data. The software outputs parametric maps related to tissue blood flow (perfusion) and tissue blood volume that are written back to the source DICOM. Following such analysis, the software automatically sends the results of analysis to a preconfigured destination point. The software allows for repeated use and continuous processing of data and

can be deployed on a supportive infrastructure that meets the minimum system requirements.

Viz CTP image analysis includes calculation of the following perfusion related parameters:

- Cerebral Blood Flow (CBF)
- Cerebral Blood Volume (CBV)
- Mean Transit Time (MTT)
- Residue function time-to-peak (TMax)
- Arterial Input Function (AIF)

The primary users of Viz CTP are medical imaging professionals who analyze dynamic CT perfusion studies. The results of image analysis produced by Viz CTP should be viewed through appropriate diagnostic viewers when used in clinical decision making.

Intended Use / Indications for Use

Viz CTP is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices.

Viz CTP provides both analysis and communication capabilities for dynamic imaging datasets that are acquired with CT Perfusion imaging protocols. Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated from a raw CTP scan are exported in the standard DICOM format and may be viewed on existing radiological imaging viewers.

Difference in Indications for Use with Respect to the Predicate Device:

Viz CTP differs from it's predicate, IschemaView's RAPID (K121447), in that the Viz CTP is limited to analysis of CT Perfusion imaging data sets. Viz CTP does not include the functionality, and is therefore not indicated for processing or analyzing images acquired through Magnetic Resonance Imaging (MRI) protocols. As such, Viz CTP is indicated for a subset of functionality when compared with the predicate device, however Viz CTP is indicated for the same functionality as the predicate device with respect to CT Perfusion datasets, *i.e.* for performing analysis which includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. As Viz CTP is only indicated to be used with CT Perfusion imaging datasets, the difference in indications between Viz CTP and the predicate device limit the Viz CTP's functional or computational capabilities with respect to the device's indicated clinical use to a subset of functionalities provided by the predicate device. These differences,

however, between the indications for use of the predicate and Viz CTP devices do not affect the Viz CTP device's diagnostic effect and do not raise any new issues of safety or efficacy.

Substantial Equivalence

	Viz CTP	**iSchemaView RAPID**
Product Code	LLZ	LLZ
Regulation	21 C.F.R. § 892.2050	21 C.F.R. § 892.2050
Intended Use / Indications for Use	Viz CTP is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image processing, analysis, and communication of computed tomography (CT) perfusion scans of the brain. Data and images are acquired through DICOM-compliant imaging devices. Viz CTP provides both analysis and communication capabilities for dynamic imaging datasets that are acquired with CT Perfusion imaging protocols. Analysis includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Results of image processing which include CT perfusion parameter maps generated from a raw CTP scan are exported in the standard DICOM format and may be viewed on existing radiological imaging viewers.	iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians. The software runs on a standard "off-the-shelf" computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing and analysis of brain images. Data and images are acquired through DICOM compliant imaging devices. iSchemaView's RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWI)Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume.
PACS Functionality		
Basic PACS Functions	Yes	Same
Computer	Standard "Off-the-Shelf" PC	Same

Platform	Workstation or VMWare	
DICOM Compliance	Yes	Yes
Functional Overview	Viz CTP is a software package that provides for the visualization and study of changes of tissue perfusion in digital images captured by CT. Viz CTP allows viewing and quantification.	Same
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities.	Same
Data/Image Types	Computed Tomography (CT)	Same
Acquisition and Modalities Features		
CT	CT Perfusion (CTP)	Yes
Computed Parameter Maps		
Perfusion CT	Cerebral Blood Flow (CBF)	Yes
	Cerebral Blood Volume (CBV)	Yes
	Mean Transit Time (MTT)	Yes
	Tissue residue function time to peak (TMax)	Yes
Measurements/Tools		
CT Tools	Arterial Input Function (AIF)	Yes
	Brain mask	Yes
	Export perfusion files to PACS and DICOM file systems	Yes
	Acquire, transmit, process, and store medical images.	Yes

Performance Data

Viz CTP complies with DICOM (Digital Imaging and Communications in Medicine), developed by the American College of Radiology and the National Electrical Manufacturers Association. NEM PS 3.1-3.20 (2016).

Viz.ai Inc. performed software verification and validation testing of the device and additional performance testing on a commercially available simulated dataset (digital phantom) generated by simulating tracer kinetic theory, and includes a wide range of clinically relevant values of perfusion parameters as ground truth. Correlations between the output of the Viz CTP device and the ground truth values were calculated, and compared to published correlations between the ground truth and the outputs of 7 other commercially available and academic CTP post-processing software.

The results of performance testing showed that the Viz CTP device achieved the pre-established performance goals for AIF detection, soft matter extraction, and each

perfusion parameter: cerebral blood flow (CBF), cerebral blood volume (CBV), mean transit time (MTT), and time to maximum residue (TMax).

Thus, the performance testing demonstrated that the Viz CTP device provides accurate computation of perfusion parameters, similar to other, commercially available or academic software aimed for the computation of the same perfusion parameters. Together with software verification and validation, this performance evaluation demonstrates that the device satisfies all design requirements and device specifications.

Conclusions

The Viz CTP device is as safe and effective as the RAPID (K121447). The Viz CTP has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device with respect to CTP functionalities. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Viz CTP device and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Viz CTP is as safe and effective as the predicate, iSchemaView's RAPID for performing CTP analysis. Thus, the Viz CTP device is substantially equivalent.