iSchemaView, Inc.
% Mr. James Rosa
VP Quality and Regulatory
433 Park Point Drive, Suite 220
GOLDEN CO 80401

July 9, 2020

Re: K200941
Trade/Device Name: Rapid LVO 1.0
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: June 8, 2020
Received: June 9, 2020

Dear Mr. Rosa:

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 and Part 809); 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K200941

Device Name
Rapid LVO 1.0

Indications for Use *(Describe)*
Rapid LVO is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive Large Vessel Occlusion (LVO) findings in head CTA images.
Rapid LVO uses a software algorithm to analyze images and highlight cases with suspected LVO on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. Notifications include compressed preview images, that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.
The results of Rapid LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage /prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Contraindications/Exclusions/Cautions:

- Rapid LVO is one input to physician diagnosis for patients undergoing screening for acute ischemic stroke.
- Excessive patient motion may lead to artifacts that make the scan technically inadequate.
- Identification of suspected findings is not for diagnostic use beyond notification. Images that are previewed through email and the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification.
- Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests.

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

iSchemaView, Inc.'s Rapid LVO 1.0

This document contains the 510(k) summary for the iSchemaView Rapid LVO. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address:

Name:	iSchemaView, Inc.
Address:	433 Park Point Drive Ste. 220 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: June 29, 2020

Device Name and Classification:

Trade Name:	iSchemaView Rapid LVO 1.0
Common Name:	Radiological computer aided triage and notification software
Classification:	II
Product Code:	QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

The iSchemaView Rapid LVO is claimed to be substantially equivalent to the following legally marketed predicate device:

iSchemaView Rapid ICH (K193087)

Device Description:

Rapid LVO 1.0 is a clinical module which operates within the integrated Rapid Platform to provide triage and notification prioritization of suspected Large Vessel Occlusion (LVO). The Rapid LVO module consists of the core Rapid Platform software which provides the administration and services for the Rapid image processing modules; and the Rapid LVO module which functions as one of many image processing modules hosted by the platform.

Rapid LVO acquires (DICOM compliant) medical image data from CTA scanners through the Rapid Platform interface:

Rapid Platform

The Rapid platform is a software package that provides for the visualization and study of changes in tissue using digital images captured by diagnostic imaging systems including CT (Computed Tomography), CTA, XA and MRI (Magnetic Image Resonance), as an aid to physician diagnosis. Rapid can be installed on a customer's Server or it can be accessed online as virtual system. It provides viewing, quantification, analysis and reporting capabilities. The Rapid platform has multiple modules a clinician may elect to run and provide analysis for decision making. The basic architecture supports the general functionality to support the Rapid LVO imaging module such as DICOM interfaces, job management, data base functions and communications. The Rapid Platform and base functions are not under review for this submission.

Indications for Use:

Rapid LVO is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive Large Vessel Occlusion (LVO) findings in head CTA images.

Rapid LVO uses a software algorithm to analyze images and highlight cases with suspected LVO on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. Notifications include compressed preview images, that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of Rapid LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage /prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Contraindications/Exclusions/Cautions:

- Rapid LVO is one input to physician diagnosis for patients undergoing screening for acute ischemic stroke.
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- Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests.

Technological Characteristics:

Rapid Platform performs the following functions in support of Rapid LVO:

- processes DICOM images from multiple sources to provide visualization of changes of tissue perfusion, diffusion and change.

- receives DICOM images from external DICOM image providers (modalities (CT/MRI Scanners), PACS and Workstations) and sends DICOM images to external image consumers.
- processes requests, statuses and results, and references therein, which are stored in a searchable database
- processing status is available through a web browser using HTTP, HTML and PHP.
- can send summary results to the user over email and mobile application. For this, Rapid generally connects to the infrastructure of the medical partner (e.g., the hospital). In particular, Rapid uses a SMTP protocol with security extensions to provide secure emailing.

Rapid is available in the following configurations:

- Standard Rapid, which is installed directly on a customer's Linux-based server and integrated with medical image processing software such as commercial PACS.
- Virtual Rapid, wherein the user accesses Rapid online and uses it to process DICOM images otherwise available on his/her computer.

Rapid Platform is a DICOM-compliant PACS software that provides comprehensive functionality to transfer, process, and display modality specific imaging data. Rapid runs on standard "off-the- shelf' computer and networking hardware. Rapid is entirely independent from CT, XA, MRI, or PACS platforms. It supports secure VPN (Virtual Private Network) networking or encapsulated Secure Shell (SSH), and seamlessly integrates into an existing radiological data network.

The primary users of Rapid PACS software are medical imaging professionals who analyze tissue using CT or MRI images.

Performance Standards:

Rapid has been developed in conformance with the following standards, as applicable:

ISO 14971:2019	Application of Risk Management to Medical Devices
IEC 62304:2015	Medical device software – Software lifecycle processes
IEC 62366:2015	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Performance Data:

Rapid complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1 - 3.20.

Additionally, iSchemaView conducted extensive performance validation testing and software verification and validation testing of the Rapid system. This performance validation testing demonstrated that the Rapid system provides accurate representation of key processing parameters under a range of clinically relevant parameters and perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid system met all design requirements and specifications.

iSchemaView performed standalone performance in accordance with the 892.2080 special controls to show acceptance of the clinical performance of the Rapid LVO module. The Standalone Performance exceeded the 80% Goal using the lower bound of the 95% Confidence Interval for Sensitivity (Se) and Specificity (Sp). The observed results are Se: Sensitivity (Se) of 0.970 (95% CI: 0.933,0.987) and Specificity (Sp) 0.956 (95% CI: 0.919, 0.977) with a ROC AUC of 0.99 (95% CI:0.972, 0.995). Additionally, at a prevalence of 45%, PPV = 0.95 (95% CI: 0.90, 0.97) and NPV = 0.98 (95% CI 0.94, 0.99)

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In addition, an analysis on time to notification using Rapid LVO to notify of suspicion/non-suspicion as 2.86 min (95% CI: 2.79, 2.92) was achieved meeting the goal of ≤ 3.5min established by the predicate. The Rapid LVO time-to-notification includes the time to get the DICOM exam, de-identify it (if required), analyze and send a notification to the attending physician(s) email and mobile. The time to notification consists primarily of the processing time, as the notification time via electronic transmission is considered in seconds via email and mobile.

Prescriptive Statement:

Caution: Federal law restricts this device to sale by or on the order of a physician.

Safety & Effectiveness:

Rapid has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 (risk management). The Rapid System performance has been validated through the use of phantoms (Rapid core indications) and clinical data (Rapid LVO).

Substantial Equivalence:

Rapid LVO is as safe and effective as the previously cleared Rapid ICH (K193087). The subject and predicate devices are radiological computer-assisted triage and notification software programs. Both devices are implemented in software algorithms, LVO using traditional and ICH using machine learning software implementations for use with CTA scanners, PACS, and workstations. Both devices process images intended to aid in prioritization and triage of radiological medical images. The subject and predicate differ in imaging input, the subject device process CTA images and the predicate NCCT images for indication. Both devices are intended to provide notifications and preview head images of potential findings to radiologists and other clinicians for the purpose of treatment planning and follow up.

Both software devices notify a designated list of clinicians of the availability of time sensitive radiological medical images for review based on computer aided image analysis performed by the device's algorithm. The subject and predicate device sends notifications and compressed previews to the workstations' desktop. Additionally, the subject device sends an email (normal processing within Rapid Platform and previously cleared and mobile notification (similar to the predicate's predicate device. Those notifications work in parallel to the standard of care. They prompt the clinician to start preemptive triage of a flagged case, upon which they may decide after observing the preview, to turn to the local PACS/Workstation to perform the evaluation. If a notification is found to be non-suspicious of LVO, the case still remains in the queue to be handled per the standard of care.

As a system, the Rapid LVO raises the same types of safety and effectiveness questions as the predicate; namely, accurate detection of findings within the reviewed and processed study on which a clinician can base a clinically useful triage/prioritization assessment considering all available clinical information.

It is important to note that, like the predicate, the device does not remove cases from a reading queue. Again, both devices operate in parallel with the standard of care, which remains the default option for all cases.

A table comparing the key features of the subject and predicate devices is provided below.

Substantial Equivalence Discussion:

Parameter	**Rapid ICH** (K193087)	**Rapid LVO** (K200941)
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ Indications for Use	Rapid ICH is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive Intracranial Hemorrhage (ICH) findings in head CT images, namely Intracranial Hemorrhage (ICH). Rapid ICH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected ICH on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH findings. Notifications include compressed preview images, that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of Rapid ICH are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage /prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	Rapid LVO is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive Large Vessel Occlusion (LVO) findings in head CTA images. Rapid LVO uses a software algorithm to analyze images and highlight cases with suspected LVO on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. Notifications include compressed preview images, that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of Rapid LVO are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage /prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.
PACS Functionality		
Stroke/Head	Hemorrhagic Stroke/Head	Intracranial Stroke/Head

Parameter	**Rapid ICH** (K193087)	**Rapid LVO** (K200941)
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Computer Platform	Standard off-the-shelf PC workstation/server	Same
	Virtual platform such as VMware	Same
DICOM Compliance	Yes	Yes
Imaging Type	Non-Contrast CT	CT Angiography
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Technical Implementation		
SaMD	Yes – Machine Learning	Yes – Traditional Algorithms
Notification/Workflow		
Pathways	PACS, email, mobile	PACS, email, mobile
Preview/Prioritization	Notification Message of Suspected Hemorrhage. Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.	Notification Message of Suspected LVO. Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.
SoC Workflow	In parallel to the SoC	In parallel to the SoC
Original Image	No Alteration	No Alteration
Primary Users	Clinician	Clinician

Conclusion:

In conclusion, the iSchemaView Rapid LVO is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Rapid ICH (K193087) with a focus on LVO analysis only.