iSchemaView Inc.
James Rosa
SVP Regulatory and Quality
1120 Washington Ave., Ste 200
Golden, Colorado 80401

May 31 ,2022

Re: K221248
Trade/Device Name: Rapid LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: April 28, 2022
Received: May 2, 2022

Dear James 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); 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,

Jessica Lamb, Ph.D.
Imaging Software
Division of Radiological Imaging Device and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221248

Device Name
Rapid LVO

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 ICA or MCA-M1 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. These are meant for informational purposes only and are 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.

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.

510(k) Summary

iSchemaView, Inc.'s Rapid LVO

This document contains the 510(k) summary for the iSchemaView Rapid. 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:	1120 Washington Ave Ste. 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: April 29, 2022

Device Name and Classification:

Trade Name:	iSchemaView Rapid LVO
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 iSchemaView's Rapid LVO (K200941)

Device Description:

Rapid LVO is a radiological computer-assisted triage and notification software device. The Rapid LVO module is a contrast enhanced CTA module which operates within the integrated Rapid Platform to provide triage and notification prioritization of suspected ICA and MCA-M1 Large Vessel Occlusion (LVO) based on the following definitions:

ICA Occlusion: A high-grade stenosis or occlusion of the intracranial portion of the ICA.

MCA-M1 Occlusion: A high-grade stenosis or occlusion of the horizontal segment of the MCA-M1, defined as the segment which extends from the ICA terminus until the vessel has turned upward into the Sylvian fissure. This includes post-bifurcation M1 segments in some patients.

The LVO module uses traditional programming algorithms. The output of the module is a priority notification to clinicians indicating the suspicion of LVO based on positive findings. The Rapid LVO module uses the basic services supplied by the Rapid Platform including DICOM processing, job management, imaging module execution and imaging output including the notification and compressed image.

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 ICA or MCA-M1 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. These are meant for informational purposes only and are 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 a triage and notification (CADt) device indicated for workflow prioritization only, not for diagnostic decision making.
- Excessive patient motion may lead to artifacts that make the scan technically inadequate.
- Images previewed through email and the mobile/web applications 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.

Technological Characteristics:

Rapid LVO does not raise new questions of safety or effectiveness compared to the previously cleared Rapid LVO (K200941). Both devices are radiological computer-aided triage and notification software applications for use with CTA input. There are minor differences in intended use to clarify the definition of the vasculature of interest; however, with the minor change the clinical use for Rapid LVO is the same the predicate with no additional risk. Thus, the Rapid LVO device is substantially equivalent.

The following table summarizes and compares data on the Rapid LVO (K200941) to the Rapid LVO that is the subject of this Special 510(k) submission.

Parameter	**Rapid LVO** (K200941)	**Rapid LVO**
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ 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.	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 ICA or MCA-M1 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. These are meant for informational purposes only and are 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	Intracranial Stroke/Head	Same
Region of Interest	ICA and MCA-M1	Same

Parameter	**Rapid LVO** (K200941)	**Rapid LVO**
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	Same
Imaging Type	CT Angiography	Same
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Technical Implementation		
SaMD	Traditional Algorithms	Same
Notification/Workflow		
Pathways	PACS, email, mobile	Same
Preview/Prioritization	Notification Message of Suspected LVO. Presentation of a compressed preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.	Same
SoC Workflow	In parallel to the SoC	Same
Original Image	No Alteration	Same
Primary Users	Clinician	Same

Performance Standards:

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

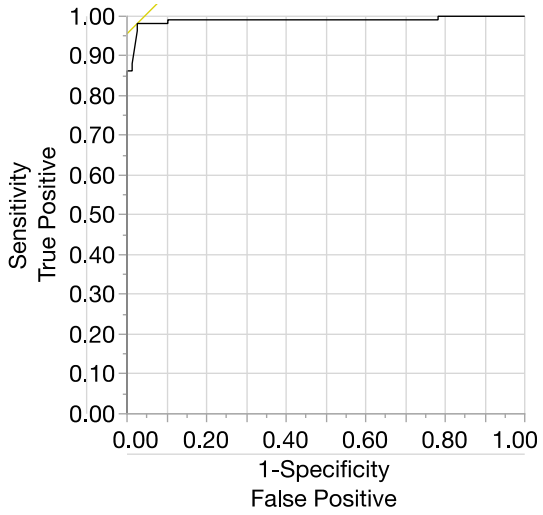
ISO 14971:2019	Application of Risk Management to Medical Devices
IEC 62304:2015	Medical device software – Software lifecycle processes
IEC 62366:2015	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

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: 0.96 (95% CI: 0.91 - 0.97) and Sp: 0.98 (95% CI: 0.93-0.99). Additionally, PPV = 0.98 and NPV = 0.96. The RoC AUC is 0.99:



In addition, an analysis on time to notification using Rapid LVO to notify of suspicion/non-suspicion as 3.18 min (95% CI: 3.11 – 3.25) 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.

Demographic, Scanner and Performance data:

Demographics:

LVO Performance by Geography				
Location	Measure	Estimate	Lower 95% CI	Upper 95% CI
US	Se	0.963	0.897	0.987
	Sp	0.963	0.875	0.990
OUS	Se	0.964	0.823	0.994
	Sp	1.000	0.934	1.000

LVO Performance by Gender				
Location	Measure	Estimate	Lower 95% CI	Upper 95% CI
Female	Se	0.981	0.902	0.997
	Sp	1.000	0.923	1.000
Male	Se	0.963	0.875	0.990
	Sp	0.968	0.890	0.991

Age Group Performance				
Age Groups	Measure	Estimate	Lower 95% CI	Upper 95% CI
20-39	Se	1.000	0.646	1.000
	Sp	1.000	0.722	1.000
40-59	Se	1.000	0.883	1.000
	Sp	0.974	0.868	0.995
60+	Se	0.959	0.886	0.986
	Sp	0.983	0.909	0.997

Scanner/Manufacturer:

Performance by Scanner Manufacturer				
Brand	Measure	Estimate	Lower 95% CI	Upper 95% CI
GE	Se	0.969	0.893	0.991
	Sp	0.970	0.847	0.995
SIEMENS	Se	1.000	0.785	1.000
	Sp	0.978	0.887	0.996
TOSHIBA	Se	0.929	0.774	0.980
	Sp	1.000	0.879	1.000

LVO Performance by Slice Thickness				
Thickness(mm)	Measure	Estimate	Lower 95% CI	Upper 95% CI
≤ 0.65	Se	0.981	0.899	0.997
	Sp	0.959	0.863	0.989
> 0.65	Se	0.965	0.881	0.990
	Sp	1.000	0.939	1.000

Data:

The validation of Rapid LVO included 217 (Pos:135, Neg: 82) scans from 8 sites/studies. The data was truthed using three expert neuroradiologists with a 2:3 concurrence.

Reference LVO by Site				
Location	Study/Site	1	0	All
US	Study/Site 1	65	3	68
	Study/Site 2	0	29	29
	Study/Site 3	16	0	16
	Study/Site 4	0	15	15
	Study/Site 5	0	7	7
OUS	Study/Site 6	1	27	28
	Study/Site 7	11	26	37
	Study/Site 8	16	1	17

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 EN ISO 14971:2019 (risk management). The Rapid LVO (1.0) device performance has been validated through the use of clinical data.

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 LVO (K200941).