



iSchemaView, Inc.
Jim Rosa
VP Quality Assurance and Regulatory Affairs
433 Park Point Drive, Suite 220
GOLDEN, CO 80401

December 27, 2018

Re: K182130
Trade/Device Name: iSchemaView RAPID
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 28, 2018
Received: December 3, 2018

Dear Jim 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/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

Indications for Use

510(k) Number (if known)

K182130

Device Name

iSchemaView RAPID

Indications for Use (Describe)

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 images. Data and images are acquired through DICOM compliant imaging devices.

The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), 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.

RAPID CT-Perfusion and RAPID MR-Perfusion can be used by physicians to aid in the selection of acute stroke patients (with known occlusion of the intracranial internal carotid artery or proximal middle cerebral artery) for endovascular thrombectomy.

Instructions for use of contrast agents for this indication can be found in Appendix A of the User's Manual. Additional information for safe and effective drug use is available in product-specific iodinated CT and gadolinium-based MR contrast drug labeling.

In addition to the RAPID imaging criteria, patients must meet the clinical requirements for thrombectomy, as assessed by the physician, and have none of the following contraindications or exclusions.

Contraindications/Exclusions:

- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Presence of Hemorrhage

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.

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iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

510(k) Summary

iSchemaView, Inc.'s *RAPID*

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

Summary Preparation Date: November 28, 2018

Device Name and Classification:

Trade Name: iSchemaView RAPID
Common Name: PACS – Picture Archiving Communications System
Classification: II
Product Code: LLZ
Regulation No: 21 C.F.R. §892.2050
Classification Panel: Radiology Devices

Predicate Devices:

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

iSchemaView RAPID (K172477)

Previous FDA Submission:

iSchemaView RAPID (K121447)
iSchemaView RAPID (K172477)
iSchemaView Q-Submission Q172046-S001

Device Description:

RAPID 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) 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.

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

RAPID works with the following types of (DICOM compliant) medical image data:

- CT (Computed Tomography)
- MRI (Magnetic Image Resonance)

RAPID acquires (DICOM compliant) medical image data from the following sources:

- DICOM file
- DICOM CD-R
- Network using DICOM protocol

RAPID provides tools for performing the following types of analysis:

- selection of acute stroke patients for endovascular thrombectomy
- volumetry of thresholded maps
- time intensity plots for dynamic time courses
- measurement of mismatch between labeled volumes on co-registered image volumes
- large vessel density

RAPID is a software-only device consisting of one or more RAPID Servers (dedicated or virtual and an iSchemaView Server). The RAPID Server is an image processing engine that connects to a hospital LAN, inside the Hospital Firewall. It can be a dedicated RAPID Server or a VM RAPID appliance, which is a virtualized RAPID Server that runs on a dedicated hospital server. Where available, the RAPID Server is placed logically in the demilitarized zone (DMZ) of the hospital's network to facilitate bidirectional secure connection between the (local) RAPID Server and the centralized iSchemaView Server.

RAPID is a software-only device designed to streamline medical image processing tasks that are time consuming and fatiguing in routine patient workup. RAPID is typically installed on a server running within a hospital's network and operates with minimal user interaction. Once the CT or MR data are acquired, the CT or MRI console operator selects RAPID as the target for the DICOM images, and then the operator selects which study/series data to be sent to RAPID. Based on the type of incoming DICOM data, RAPID will identify the data set as CT or MRI data, and determine the suitable processing module. RAPID is a toolbox of modules which support various analysis methods used in clinical practice today:

- RAPID CTA: used to visualize large cerebral vessels and analyze hemispheric difference via contralateral comparison.
- RAPID MR DWI Module: used to visualize local water diffusion properties of tissue from the analysis of diffusion-weighted MRI data.
- RAPID Dynamic Analysis Module: 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.

The iSchemaView Server is a dedicated server that provides a central repository for RAPID data. All iSchemaView Server data is stored on encrypted hard disks. It also provides a user

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

interface for accessing RAPID data. It connects to a firewalled Data Center Network and has its own firewall for additional cyber/data security. The iSchemaView Server connects to one or more RAPID Servers via WAN. Available types of connection include VPN (Virtual Private Network - RFC2401 and RFC4301 Standards) Tunnel and SSH (Secure Shell).

Indications for Use:

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 images. Data and images are acquired through DICOM compliant imaging devices.

The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), 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.

RAPID CT-Perfusion and RAPID MR-Perfusion can be used by physicians to aid in the selection of acute stroke patients (with known occlusion of the intracranial internal carotid artery or proximal middle cerebral artery) for endovascular thrombectomy.

Instructions for use of contrast agents for this indication can be found in Appendix A of the User's Manual. Additional information for safe and effective drug use is available in product-specific iodinated CT and gadolinium-based MR contrast drug labeling.

In addition to the RAPID imaging criteria, patients must meet the clinical requirements for thrombectomy, as assessed by the physician, and have none of the following contraindications or exclusions.

Contraindications/Exclusions:

- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Presence of Hemorrhage.

Technological Characteristics:

RAPID performs the following functions:

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

Section 5: 510(k) Summary

- 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. 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 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, 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.

Clinical Characteristics:

The primary users of RAPID PACS software are medical imaging professionals who analyze tissue using CT or MRI images. The images generated by RAPID provide additional diagnostic information, which is derived from the temporal/diffusion/density features of the native CT or MRI images.

RAPID CT Perfusion and RAPID MRI can be used by physicians to select acute stroke patients for endovascular thrombectomy. The recommended selection criteria are listed in the table below. Patients must meet the clinical requirements for thrombectomy as assessed by the physician and have no contraindications or exclusions:

RAPID THROMBECTOMY SELECTION GUIDE							
Known Neurologic Baseline (KNB)(Hrs)	Modality	RAPID Map	Lesion Volume	DBF/DWI		Tmax	
				Threshold (rCBF/ADC)	Volume (ml)	Threshold (sec)	Mismatch Ratio*
MISMATCH BASED INDICATIONS							
KNB ≤ 6	CTP	Mismatch	CBF/Tmax	<0.3	≤ 70	> 6	≥ 1.2 CBF
	MRI	Mismatch	DWI/Tmax	<620	≤ 50	> 6	≥ 1.8 DWI
6 < KNB ≤ 16	CTP	Mismatch	CBF/Tmax	<0.3	≤ 70	> 6	≥ 1.8 CBF
	MRI	Mismatch	DWI/Tmax	<620	≤ 70	> 6	≥ 1.8 DWI
ISCHEMIC CORE RELATED INDICATIONS							
Patient ≥ 80 yrs AND NIHSS ≥ 10							
6 ≤ KNB ≤ 24	CTP	Mismatch	CBF	<0.3	≤ 20	NA	NA
	MRI	Mismatch/DWI	DWI	<620	≤ 20	NA	NA
Patient < 80 yrs AND NIHSS 10-19							
6 ≤ KNB ≤ 24	CTP	Mismatch	CBF	<0.3	≤ 30	NA	NA
	MRI	Mismatch/DWI	DWI	<620	≤ 30	NA	NA
Patient ≤ 80 yrs AND NIHSS ≥ 20							
6 ≤ KNB ≤ 24	CTP	Mismatch	CBF	<0.3	≤ 50	NA	NA
	MRI	Mismatch/DWI	DWI	<620	≤ 50	NA	NA
*Note: A Mismatch volume ≥ 15ml is recommended							

Contraindications/Exclusions:

- Bolus Quality: absent or inadequate bolus.
- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Presence of Hemorrhage.

Performance Standards:

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

EN ISO 14971:2012	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)

Section 5: 510(k) Summary

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.

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 14971:2012 (risk management). The RAPID System performance has been validated through the use of phantoms.

Substantial Equivalence:

RAPID is as safe and effective as the previously cleared RAPID product (K172477). RAPID has a similar intended use with an added indication, technological characteristics and principles of operation as its predicate device. There are no technological differences between the RAPID and its predicate (K172477) and no new issues of safety or effectiveness have been identified. The testing during the 4.8 baseline release is provided as verification and validation. The testing conducted with RAPID confirms the software reliably processes and supports the analysis of CT and MRI medical images for tissue evaluation. Thus, the RAPID software is substantially equivalent. The claims have been expanded to include the use of RAPID in selection of acute stroke patients for endovascular thrombectomy, based on retrospective clinical data evaluation.

Visualization and quantitative results delivered by RAPID can be used, upon applicable clinical and technical training of the users, in the diagnostic and patient treatment process.

In version 4.8, RAPID provides the following:

- CT-Perfusion, MR-Perfusion and MR-Diffusion datasets, with the possibility to compute semi-quantitative (relative blood flow, volume, mean transit time, arterio-tissue delay time T_{max}) and quantitative (apparent diffusion coefficient) parameters and compute volumes of tissue with parameters within certain ranges;
- CT-Angiography datasets, where, after skull stripping, the system provides transverse, coronal and sagittal views of the intra-cranial vasculature, as well as hemispheric comparison of the blood vessel density in these datasets.

In version 4.8.3, RAPID provides the indications identified in version 4.8 plus the addition of a special case of CT-Perfusion and MR. RAPID provides guidance to physicians for acute

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

stroke patient selection for endovascular thrombectomy using specific parametric settings, as described in Table in paragraph 3.2.

The following table summarizes and compares data on the iSchemaView RAPID (K172477) to the RAPID (K182130) that is the subject of this Traditional 510(k) submission.

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

Substantial Equivalence Discussion:

Parameter	RAPID (K182130)	RAPID (K172477)
Product Code	LLZ	LLZ
Regulation	21 CFR §892.2050	21 CFR §892.2050
Intended Use/ Indications for Use	<p>iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.</p> <p>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 images. Data and images are acquired through DICOM compliant imaging devices.</p> <p>The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT).</p> <p>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion - weighted MRI data.</p> <p>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.</p> <p><u>Change to K172477:</u></p> <p>RAPID CT-Perfusion and RAPID MR-Perfusion can be used by physicians to aid in the selection of acute stroke patients (with known occlusion of the intracranial internal carotid artery or proximal middle cerebral artery) for endovascular thrombectomy.</p> <p>Instructions for use of contrast agents for this indication can be found in Appendix A of the User's Manual. Additional information for safe and effective drug use is available in product-specific iodinated CT and gadolinium-based MR contrast drug labeling.</p> <p>In addition to the RAPID imaging criteria, patients must meet the clinical requirements for thrombectomy, as assessed by the</p>	<p>iSchemaView's RAPID is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.</p> <p>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 images. Data and images are acquired through DICOM compliant imaging devices.</p> <p>The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT).</p> <p>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion - weighted MRI data.</p> <p>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.</p>

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

	<p>physician, and have none of the following contraindications or exclusions.</p> <p>Contraindications/Exclusions:</p> <ul style="list-style-type: none"> • Bolus Quality: absent or inadequate bolus. • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Presence of Hemorrhage. 	
PACS Functionality		
Basic PACS Functions	View, process and analyze medical images. Performs standard PACS functions with respect to querying and listing.	Same
Computer Platform	Standard off-the-shelf PC workstation/server	Same
	Virtual platform such as VMware	Same
DICOM Compliance	Yes	Same
Functional Overview	RAPID is a software package that provides for the visualization and study of changes of tissue in digital images captured by CT and MRI. RAPID provides viewing and quantification.	Same
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Data/Image Types	Computed Tomography (CT) via DICOM Format	Same
	Magnetic Image Resonance (MRI) via DICOM Format	Same
Acquisition and Modalities Features		
MRI	Diffusion Weighted Image (DWI)	Same
	Dynamic Analysis tissue flow (perfusion) and tissue blood volume	Same
CT	CT Perfusion (CTP)	Same
	CTA-large vessel density analysis	Same
Computed Parameter Maps		
Diffusion MRI	Isotropic DWI (isoDWI)	Same
	ADC	Same
	Trace of diffusion tensor (Trace)	Same
	Fractional Anisotropy (FA) and color FA	Same
Perfusion MRI and Perfusion CT	Cerebral blood flow (CBF)	Same
	Cerebral blood volume (CBV)	Same
	Mean transit time (MTT)	Same

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

	Tissue residue function time to peak (Tmax)	Same
Measurement Tools		
MRI and CT Tools	Arterial input function (AIF) Venous output function (VOF)	Same
	Time-course	Same
	Mask	Same
	Region of interest (ROI) and Volumetry	Same
	Volumetric comparison between 2 ROIs	Same
	Motion correction	Same
	Export perfusion and diffusion files to PACS and DICOM file systems	Same
	Acquire, transmit, process, and store medical images	Same

iSchemaView - Traditional 510(k) RAPID

Section 5: 510(k) Summary

Conclusion:

In conclusion, the iSchemaView RAPID is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed predicate device, RAPID (K172477).