iSchemaView Inc.
James Rosa
SVP Regulatory and Quality
433 Park Point Drive, Suite 220
Golden, Colorado 80401

March 15, 2022

Re: K213165
Trade/Device Name: Rapid
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ

Dear James Rosa:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 02/08/2022. Specifically, FDA is updating this SE Letter to change the company name from "*iSchema View Inc.*" to "*iSchemaView Inc.*" as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact CAPT Patrick Hintz, MSIH, CIH, USPHS, OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-6927, Patrick.Hintz@fda.hhs.gov.

Sincerely,

For

CAPT Patrick Hintz, MSIH, CIH, USPHS
Chief
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

iSchema View Inc.
℅ James Rosa
SVP Regulatory and Quality
433 Park Point Drive, Suite 220
GOLDEN CO 80401

February 8, 2022

Re: K213165
Trade/Device Name: Rapid
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: January 4, 2022
Received: January 5, 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.
Assistant 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

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)*

K213165

Device Name
Rapid

Indications for Use *(Describe)*

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.

Rapid provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT, CT Perfusion (CTP), 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 CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue.

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)
Instructions for the 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 the 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:

- 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.

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:	1120 Washington St., Suite 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: `September 24, 2021

Device Name and Classification:

Trade Name:	iSchemaView Rapid
Common Name:	PACS – Picture Archiving Communications System
Classification:	II
Product Code:	Primary: QIH, Secondary: 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 devices:

Primary: qER-Quant (K211222)
Secondary: iSchemaView Rapid (K182130)

Previous Related FDA Submission:

iSchemaView Rapid (K121447)
iSchemaView Rapid (K172477)
iSchemaView Rapid (K182130)

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 a virtual system. It provides viewing, quantification, analysis and reporting capabilities.

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 as a Medical Device (SaMD) consisting of one or more Rapid Servers (dedicated or virtual). The Rapid Server is an image processing engine that connects to a hospital LAN, or 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 server.

Rapid is designed to streamline medical image processing tasks that are time consuming and fatiguing in routine patient workup. Once Rapid is installed it operates with minimal user interaction. Once the CT (NCCT, CT, CTA) or MR (MR, MRA) 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 scanning modality and determine the suitable processing module. The Rapid platform is a central control unit which coordinates the execution image processing modules which support various analysis methods used in clinical practice today:

- Rapid CTP/MRP, DWI, Dynamic Analysis (Original: K121447, Updated with K172477; and K182130);
- Rapid CTA (K172477);
- Rapid ASPECTS(K190395);
- Rapid ICH (K193087);
- Rapid LVO (K200941);

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 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:

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.

Rapid provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CTP), 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 CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue.

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)

Instructions for the 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 the 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:

- 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.
- 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.
- for NCCT images, a motion filter (AI/ML) is employed which provides a textual overlay on an image suspected of having motion artifacts, without distorting the original image
- 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 communications.

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 independent PACS platforms. It supports secure VPN (Virtual Private Network) networking or encapsulated Secure Shell (SSH), and seamlessly integrates into an existing radiological data network.

NCCT Motion Artifact AI/ML Module Performance:

Training was performed on 23066 (Pos:1021, Neg:12877) axial image slices from multiple sites, training validation included 5906 (pos: 422,neg: 5484) with a test set of 3262 (pos:2914, neg:348) images. Slice thickness ranged from 1.2-6.0 mm; The optimal performance for the final engineering solution showing an optimal AUC = 0.95, Sensitivity=0.95, Specificity=0.96. Samples were obtained from Siemens, GE, Toshiba, Philips, and Neurologica.

For final independent validation, an N=619 was used with ground truth established by 3 experienced truthers. Testing was performed independent of the development group to avoid bias. The primary endpoint was passed (weak artifact = 0) with Sensitivity = 0.91(0.83,0.95) and Specificity = 0.86(0.83,0/89) with AUC = 0.96(0.94,0.97). The cases were split Male:55%, Female 45% with an age range or 32-88 years. The samples were primarily from Siemens with GE mixed.

Clinical Characteristics:

The primary users of Rapid 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.

Performance Standards:

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

EN ISO 14971:2019	Application of Risk Management to Medical Devices
IEC 62304:2016	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.

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 System performance has been validated through the use of phantoms and case data.

Substantial Equivalence:

Rapid is as safe and effective as the previously cleared Rapid (K182130) with an extension of two parameters similar to the hyperdensity defined in qER-Quant (K211222). Rapid has the same intended use and similar indications, technological characteristics and principles of operation as its predicate devices. Rapid raises no new issues of safety or effectiveness compared to qER-Quant (K211222) or Rapid (K182130), as demonstrated by the testing

conducted with Rapid that confirms the software reliably processes and supports 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 to show areas of hypodensity and hyperdensity and NCCT Motion Suspicion (AI/ML).

Substantial Equivalence Discussion:

Parameter	**Rapid** (K182130) – Secondary	**qER-Quant** (K211222) - Primary	**Rapid**
Product Code	LLZ	QIH	QIH, LLZ
Regulation	21 CFR §892.2050	21 CFR §892.2050	21 CFR §892.2050
Intended Use/ 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 Angiography, 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-	The qER-Quant device is intended for automatic labeling, visualization and quantification of segmentable brain structures from a set of Non-Contrast head CT (NCCT) images. The software is intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on NCCT images. qER-Quant provides volumes from NCCT images acquired at a single time point and provides a table with comparative analysis for two or more images that were acquired on the same scanner with the same image acquisition protocol for the same individual at multiple time points. The qER-Quant software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift.	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. Rapid provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT, CT Perfusion (CTP), 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 CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue. 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

	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) Instructions for the 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 the 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		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) Instructions for the 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 the 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
	PACS Functionality		
Basic PACS Functions	Software package which interfaces to a PACS or allows viewing within the application	Viewing through user PACS	Same
Computer Platform	Standard off-the-shelf Hardware: On-Premise	Standard off-the-shelf Hardware: On-Premise and Secure Cloud	Standard off-the-shelf Hardware: On-Premise
Software	Traditional Coding	AI/ML	Mixed Traditional and AI/ML(NCCT Motion Filter)
DICOM Compliance	Yes	Yes	Yes

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	Same
Data/Image Types	Computed Tomography (CT) via DICOM Format	Same	Same
	Magnetic Image Resonance (MRI) via DICOM Format	Not supported	Supported
	Acquisition and Modalities Features		
MRI	Diffusion Weighted Image (DWI)	Not supported	Supported
	Dynamic Analysis tissue flow (perfusion) and tissue blood volume	Not supported	Supported
CT	CT Perfusion (CTP)	Not supported	Supported
	CTA-large vessel density analysis	Not Supported	Supported
	Computed Parameter Maps		
Diffusion MRI	Isotropic DWI (isoDWI)	Not supported	Supported
	ADC	Not supported	Supported
	Trace of diffusion tensor (Trace)	Not supported	Supported
	Fractional Anisotropy (FA) and color FA	Not supported	Supported
Perfusion MRI and Perfusion CT	Cerebral blood flow (CBF)	Not supported	Supported
	Cerebral blood volume (CBV)	Not supported	Supported
	Mean transit time (MTT)	Not supported	Supported
	Tissue residue function time to peak (Tmax)	Not supported	Supported
	Measurement Tools		
MRI and CT Tools	Arterial input function (AIF)Venous output function (VOF)	Not supported	Supported
	Time-course	Not supported	Supported
	Mask	Not supported	Supported
	Region of interest (ROI) and Volumetry	Not supported	Supported
	Volumetric comparison between 2 ROIs	Not supported	Supported
	Motion correction	Not supported	Supported
	Export perfusion and diffusion files to PACS and DICOM file systems	Not supported	Supported

	Acquire, transmit, process, and store medical images	Not supported	Supported
Thrombectomy	Selection of Patients meeting criteria for Thrombectomy	Supported	Supported
NCCT	Hyperdensity (Not included)	Supported	Supported
	Hypodensity (Not included)	Not supported	Supported
	Motion Artifact Filter (Not included)	Not supported	Supported

Conclusion:

In conclusion, the iSchemaView Rapid is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed predicate devices, qER-Quant (K211222) and Rapid (K182130).