iSchemaView, Inc.
% Mr. Jim Rosa
VP QA/RA
201 Marshall Street, Suite 101
REDWOOD CITY CA 94063

April 19, 2018

Re: K172477
Trade/Device Name: iSchemaView RAPID
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 26, 2018
Received: March 29, 2018

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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K172477

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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**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:** | 201 Marshall Street<br>Ste. 101<br>Redwood City, CA 94063 |
| **Official Contact:** | Jim Rosa<br>Phone: (303) 704-3374<br>Email: rosa@ischemaview.com |


**Summary Preparation Date:** March 18, 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 (K121447)

**Previous FDA Submission:** iSchemaView RAPID (K121447)

**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.

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:

- volumetry of threshold 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 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.

**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.
- 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). 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.

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.

**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) |

**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(K172477) is as safe and effective as the previously cleared RAPID

product (K121447). RAPID(K172477) has the same intended use and similar indications, technological characteristics and principles of operation as its predicate device. The minor differences between the RAPID (K172477) and its predicate (K121447) raise no new issues of safety or effectiveness as demonstrated by the testing conducted with RAPID (K172477) that confirms the software reliably processes and supports analysis of CT and MRI medical images for tissue evaluation. Thus, the RAPID (K172477) software is substantially equivalent. The indications for use has been expanded to include the CTA modality which provides additional information to the physician in support of the original intended use.

Substantial Equivalence Discussion:

| Parameter | ***RAPID*** *(K172477)* | ***RAPID*** *(K121447)* |
|---|---|---|
| Product Code | LLZ | LLZ |
| Regulation | 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.<br><br>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).<br><br>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion - weighted MRI data.<br><br>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. | 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.<br><br>The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWI) Module, a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT).<br><br>The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.<br><br>The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. |
| PACS Functionality | | |
| Basic PACS Functions | 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 | 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 |

| | | |
|---|---|---|
| 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) | Yes |
| | Dynamic Analysis tissue flow (perfusion) and tissue blood volume | Yes |
| CT | CT Perfusion (CTP) | Yes |
| | CTA-large vessel density analysis | No only CT-P Analysis |
| Computed Parameter Maps | | |
| Diffusion MRI | Isotropic DWI (isoDWI) | Yes |
| | ADC | Yes |
| | Trace of diffusion tensor (Trace) | Yes |
| | Fractional Anisotropy (FA) and color FA | Yes |
| Perfusion MRI and Perfusion CT | Cerebral blood flow (CBF) | Yes |
| | Cerebral blood volume (CBV) | Yes |
| | Mean transit time (MTT) | Yes |
| | Tissue residue function time to peak (Tmax) | Yes |
| Measurement Tools | | |
| MRI and CT Tools | Arterial input function (AIF)Venous output function (VOF) | Yes |
| | Time-course | Yes |
| | Mask | Yes |
| | Region of interest (ROI) and Volumetry | Yes |
| | Volumetric comparison between 2 ROIs | Yes |
| | Motion correction | Yes |
| | Export perfusion and diffusion files to PACS and DICOM file systems | Yes |
| | Acquire, transmit, process, and store medical images | Yes |

**Conclusion:**

In conclusion, the iSchemaView RAPID (K172477) is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed predicate device, RAPID (K121447).