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

March 31, 2020

Re: K193087
Trade/Device Name: RAPID ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer-assisted triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: February 25, 2020
Received: March 2, 2020

Dear Mr. Rosa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

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

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)*

K193087

Device Name
RAPID ICH

Indications for Use *(Describe)*

RAPID ICH is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images.

The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH). RAPID ICH uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH findings. Notifications include compressed preview images, that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

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

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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510(k) Summary

iSchemaView, Inc.'s RAPID ICH

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

Applicant Name and Address:

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

Summary Preparation Date: February 25, 2020

Device Name and Classification:

Trade Name:	RAPID ICH
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 ICH is claimed to be substantially equivalent to the following legally marketed predicate device: Aidoc's BriefCase (K180647).

Device Description:

RAPID ICH is a clinical module which operates within the integrated RAPID Platform to provide triage and notification prioritization of suspected intra-cranial hemorrhage (ICH). The RAPID ICH module consists of the core RAPID Platform software which provides the administration and services for the RAPID; and the RAPID ICH module which functions as one of many image processing modules hosted by the platform.

RAPID Platform

The RAPID platform is a software package that provides for the visualization and study of changes in tissue using digital images captured by diagnostic imaging systems including CT (Computed Tomography), CTA, XA3D and MRI (Magnetic Image Resonance), as an aid to physician diagnosis. RAPID can be installed on a customer's Server or it can be accessed

online as virtual system. It provides viewing, quantification, analysis and reporting capabilities. The RAPID platform has multiple modules a clinician may elect to run and provide analysis for decision making.

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

- CT (Computed Tomography)
- CTA (Computed Tomography Angiography)
- MRI (Magnetic Image Resonance) Note: not used in ASPECTS.
- XA3D Multiphase

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

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

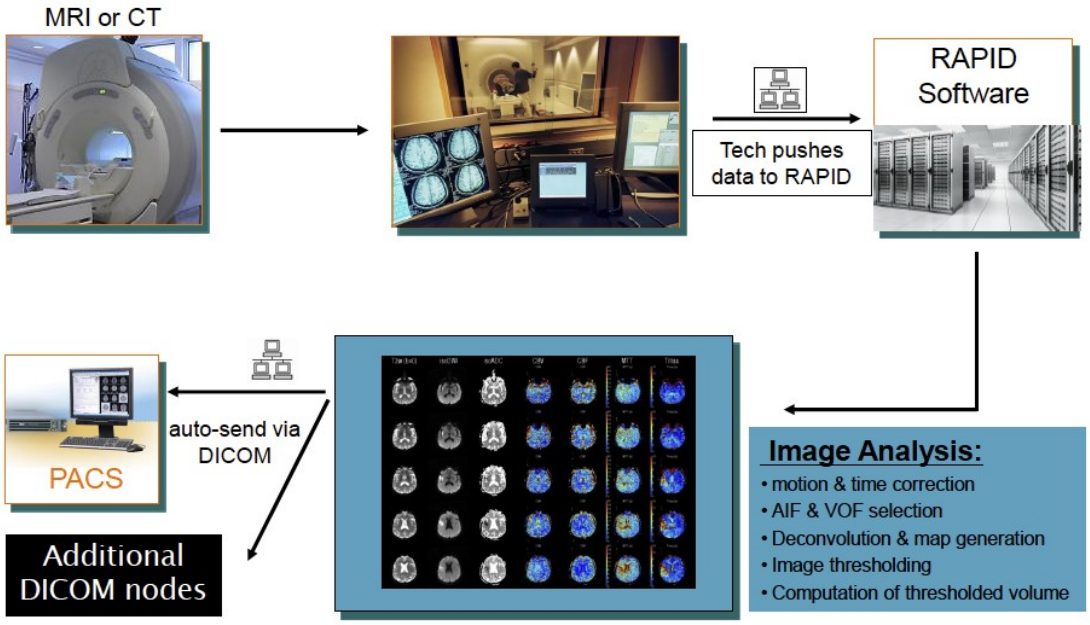
RAPID provides tools for performing the following types of analysis:

- 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
- Imaging features on non-contrast computed tomography
- Imaging features based on density analysis for CT Angiography

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.

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).

RAPID System Overview



RAPID ICH Module

RAPID ICH provides an automatic analysis of received NCCT scan data for the triage and notification of ischemic hemorrhage (ICH). The application is selected via DICOM encoding which is processed by the DICOM handler within the RAPID Platform. Once the DICOM server identifies the selected ICH processing modality, the Job Manager initiates image processing using the ICH Module.

Upon processing a case with suspicion of ICH, the clinical team is notified via messaging, the case has a suspicion of ICH. The notifications are sent to the PACS/Workstation, via email and to a mobile application. The notification provides the attending clinical team physician that suspicion of hemorrhage has been identified and immediate attention to the case should be given. The messaging provides notification and compressed image data of the case. The compressed preview is informational only and labeling identifies it as not to be used for diagnostic use and to review the data within the PACS/Workstation prior to making any diagnostic decisions. No additional information markings are added to the case.

The notifications are pop-up messages or email with the appropriate case information and suspicion or non-suspicion of ICH labelled. In all cases, the normal standard of care workflow is adhered to, this ensures the case is still reviewed when non-suspicion is determined.

Indications for Use:

RAPID ICH is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images.

The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive Intracranial Hemorrhage (ICH) findings in head CT images, namely Intracranial Hemorrhage (ICH).

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

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

Contraindications/Exclusions/Cautions:

- RAPID ICH is one input to physician diagnosis for patients undergoing screening for acute hemorrhage or acute stroke.
- Excessive patient motion may lead to artifacts that make the scan technically inadequate.
- Presence of subacute stroke with mild hemorrhagic transformation may not be detected as suspected ICH.
- For use with non-contrast scans. Presence of intravenous contrast may lead to false positive indication of suspected ICH.
- Identification of suspected findings is not for diagnostic use beyond notification. Images that are previewed through email and the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification.
- Notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests.
- RAPID ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. 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.

Comparison of Technological Characteristics:

The subject and predicate devices are radiological computer-assisted triage and notification software programs. Both devices are artificial intelligence algorithms incorporated software packages for use with CT scanners, PACS, and workstations. Both devices process images intended to aid in prioritization and triage of radiological medical images. The subject and predicate device process NCCT images for ICH indication. Both devices are intended to provide

notifications and preview head images of potential findings to radiologists and other clinicians for the purpose of treatment planning and follow up.

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

The predicate and subject devices process CT images using similar techniques and a similar artificial intelligence algorithm. Specifically, the subject and predicate software utilize a deep learning algorithm trained on medical images. The deep-learning process allows for high accuracy in the detection of initial suspect locations. As a system, the RAPID ICH raises the same types of safety and effectiveness questions as the predicate; namely, accurate detection of findings within the reviewed and processed study on which a clinician can base a clinically useful triage/prioritization assessment considering all available clinical information.

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

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

Substantial Equivalence Table		
Comparison Feature	Aidoc Briefcase (K180647)	RAPID ICH
Indications for Use	Aidoc Briefcase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH).	RAPID ICH is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of pathologies in head CT images, namely Intracranial Hemorrhage (ICH).

	Aidoc Briefcase uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of Aidoc Briefcase 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 ICH uses an artificial intelligence algorithm to analyze images and highlight cases with detected ICH on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of RAPID ICH are intended to be used in conjunction with other patient information and based on professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.
Stroke/Head	Stroke/Head	Stroke/Head
Removal of cases from worklist queue	No	No
Primary Imaging Modalities	NCCT	NCCT
Technical Implementation	ML/AI/Neural Network	ML/AI/Neural Network
Segmentation of ROI	No, the device does not highlight or direct a user's attention to a specific location in the image file.	No, the device does not highlight or direct a user's attention to a specific location in the image file.

Preview Images	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care, which remains.
Primary User(s)	Radiologist	Clinician
Alteration of original image data base	No	No
Alters Standard of Care Workflow	In parallel to	In parallel to
Notification/ Prioritization	Yes – PACS, Workstation	Yes – PACS, Workstation, email, mobile

Performance Standards:

RAPID ICH 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
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Performance Data:

iSchemaView conducted a retrospective, blinded, multicenter, multinational study with the RAPID ICH software with the primary endpoint to evaluate the software's performance in identifying noncontrast CT head images containing intracranial hemorrhage (ICH) findings in 336 cases from US (4 Sites and 1 Multisite Study) and OUS sites (1 site, 1 multisite). There were approximately an equal number of positive and negative cases (images with ICH versus without ICH) included in the analysis.

Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be Se: 0.899 (95% CI: 0.847 – 0.935) and Sp: 0.943 (95% CI: 0.895 – 0.970).

In addition, a secondary endpoint measure was RAPID ICH's time to notification of suspicion non-suspicion as 2.28 min (95% CI: 2.24 - 2.33) was achieved.

The RAPID ICH time-to-notification includes the time to get the DICOM exam, de-identify it (if required), analyze and send a notification back to the attending physician(s) email and mobile.

Prescriptive Statement:

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

Safety & Effectiveness:

RAPID ASPECTS 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) and the software development process conforms to ISO 62304:2015. The RAPID ICH performance has been validated through the use of phantoms and retrospective case data and through the use of reader truthing of the data.

Conclusion:

In conclusion, iSchemaView's RAPID ICH is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, BriefCase (K180647); the two devices vary slightly in the notification pathway, the subject device has a mobile interface to allow messaging.

The RAPID ICH is thus substantially equivalent to the BriefCase predicate device.