iSchemaView Inc.
℅ James Rosa
SVP Regulatory and Quality
1120 Washington Ave., Ste 200
GOLDEN CO 80401

Re: K221456

September 12, 2022

Trade/Device Name: Rapid ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: August 15, 2022
Received: August 17, 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 and Part 809); 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
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K221456

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, for IPH, IVH, SAH, and SDH Intracranial Hemorrhages (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, which 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 radiologists 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:	1120 Washington Ave., Ste. 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: August 17, 2022

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:

iSchemaView's Rapid ICH device is claimed to be substantially equivalent to the following legally marketed predicate device: iSchemaView's Rapid ICH (K193087).

Device Description:

Rapid ICH is a radiological computer-assisted triage and notification software device. The Rapid ICH module is a non-enhanced CT (NCCT) processing module which operates within the integrated Rapid Platform to provide triage and notification prioritization of suspected intracranial hemorrhage. The Rapid ICH module is an AI/ML module. The output of the module is a priority notification to clinicians indicating the suspicion of ICH based on positive findings. The Rapid ICH module uses the basic services supplied by the Rapid Platform including DICOM processing, job management, imaging module execution and imaging output including the notification and compressed image.

Indications for Use:

Rapid 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, for IPH, IVH, SAH, and SDH Intracranial Hemorrhages (ICH).

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 radiologists are responsible for viewing full images per the standard of care.

Comparison of Technological Characteristics:

Rapid ICH does not raise new questions of safety or effectiveness compared to the previously cleared Rapid ICH (K193087). Both devices are radiological computer-aided triage and notification software applications for use with non-contrast CT input. The minor change causing this filing, is the use of additional data for training and validation; there are no further differences. Thus, the Rapid ICH software is substantially equivalent.

The following table summarizes and compares data on the Rapid ICH (K193087) to the subject device of this Traditional 510(k) submission. A table comparing the key features of the subject and predicate devices is provided below.

Substantial Equivalence Table		
Comparison Feature	Rapid ICH (K193087)	Rapid ICH – Subject Device
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 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 standalone	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, for IPH, IVH, SAH, and SDH Intracranial Hemorrhages (ICH). Rapid ICH uses an artificial intelligence algorithm to analyze

	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.	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, which 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 radiologists 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	AI/ML/Neural Network	AI/ML/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.	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.	The device operates in parallel with the standard of care, which remains.
Primary User(s)	Clinician	Radiologist
Alteration of original image data	No	No
Alters Standard of Care Workflow	In parallel to	In parallel to
Notification/ Prioritization	Yes – PACS, Workstation, email, mobile	Yes – PACS, Workstation, email, mobile

Performance Standards:

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

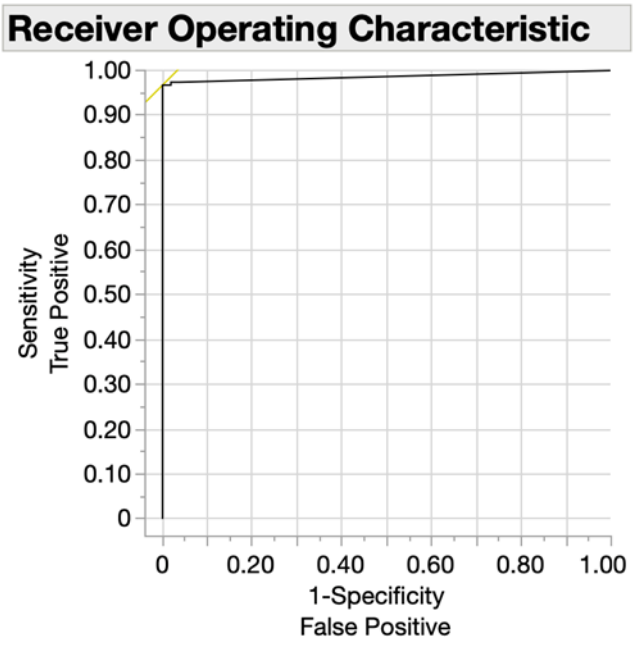
EN ISO 14971:2012	Application of Risk Management to Medical Devices
IEC 62304:2015	Medical device software – Software lifecycle processes
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

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 NCCT head images containing intracranial hemorrhage (ICH) findings in 314 (ICH Pos:148, Neg:166) cases.

Sensitivity and specificity exceeded the 80% performance goal. Specifically, sensitivity was observed to be 96.8% (95% CI: 92.6% - 98.6%) and specificity was observed to be 100% (95% CI: 97.7% - 100%) overall.

AUC is 0.98632 when using Rapid estimated Volume as the predictor of Suspected ICH:



Using Truth Hem (0/1)='1' to be the positive level

AUC
0.98632

In addition, a secondary endpoint measure was Rapid ICH's potential clinical benefit of worklist prioritization for true positive ICH cases. For that purpose, iSchemaView is using the predefined process timeline as defined in the predicate.

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 PACS/Workstation, email and mobile. The standard of care time-to-open-exam consisted of the time from the initial scan of the patient to when the radiologist first opened the exam for review.

Rapid ICH time-to-notification has been documented for all 314 cases. One hundred four-nine (149) cases have been identified as true positive (i.e., identified as positive by Rapid ICH and the ground truth) and the time-to-exam-open is referenced from the predicate.

As shown in the table below, the predicate analysis demonstrated that standard of care time-to-exam-open (72.6 minutes: 95% CI 45.0-100.2) is significantly longer than the parallel time-to-notification of the Rapid ICH software (0.65 minutes: 95% CI 0.63 – 0.67).

Parameter	Mean	95% CI Lower	95% CI Upper
Time to open in standard of care (Minutes)	72.58	45.02	100.14
Time to notification of Rapid ICH (Minute)	0.65	0.63	0.67
Difference (Minutes)	71.93	NA	NA

Performance across subtype differentiation shows:

Performance Metrics by Gender

Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Female	Sensitivity	63	1.000	0.943	1.000
	Specificity	64	1.000	0.943	1.000
Male	Sensitivity	72	0.932	0.849	0.970
	Specificity	97	1.000	0.962	1.000

Performance Metrics by Age Groups

Age Group	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Age ≤ 50	Sensitivity	27	0.926	0.766	0.979
	Specificity	26	1.000	0.871	1.000
50 < Age < 70	Sensitivity	54	0.963	0.875	0.990
	Specificity	62	1.000	0.942	1.000
Age ≥ 70	Sensitivity	63	0.984	0.915	0.997
	Specificity	70	1.000	0.948	1.000

Performance by ICH Subtype

Subtype	N	Se	Se LCL	Se UCL
IPH	45	1.000	0.921	1.000
IVH	4	1.000	0.510	1.000
IPH, IVH	41	1.000	0.914	1.000
SAH	11	1.000	0.741	1.000
SDH	19	0.895	0.686	0.971
Multiple	24	1.000	0.862	1.000
Other	9	0.667	0.354	0.879

Performance Metrics by Volume

Volume Group	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
All	Sensitivity	159	0.937	0.888	0.965
Vol ≥ 0.4	Sensitivity	153	0.967	0.926	0.986
Vol ≥ 1	Sensitivity	145	0.966	0.922	0.985
Vol ≥ 5	Sensitivity	112	1.000	0.967	1.000

Performance Metrics by Slice Thickness

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Slice Thickness ≤ 2.5	Sensitivity	47	0.936	0.828	0.978
	Specificity	67	1.000	0.946	1.000
2.5 < Slice Thickness < 5	Sensitivity	39	0.974	0.868	0.995
	Specificity	34	1.000	0.898	1.000
Slice Thickness = 5	Sensitivity	67	0.985	0.920	0.997
	Specificity	60	1.000	0.940	1.000

Performance Metrics by Manufacturer

Manufacturer	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE	Sensitivity	74	0.973	0.907	0.993
	Specificity	25	1.000	0.867	1.000
PHILIPS	Sensitivity	21	0.950	0.764	0.991
	Specificity	57	1.000	0.937	1.000
TOSHIBA	Sensitivity	30	0.967	0.833	0.994
	Specificity	31	1.000	0.890	1.000
SIEMENS	Sensitivity	28	1.000	0.879	1.000
	Specificity	48	1.000	0.926	1.000

Performance within Make/Model of Scanners

Make/Model	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE MEDICAL SYSTEMS LightSpeed VCT	Sensitivity	22	0.909	0.722	0.975
	Specificity	15	1.000	0.796	1.000
GE MEDICAL SYSTEMS Other	Sensitivity	52	1.000	0.931	1.000
	Specificity	10	1.000	0.722	1.000
Philips iCT 256	Sensitivity	3	1.000	NA	NA
	Specificity	32	1.000	0.893	1.000
Philips *Ingenuity CT*	Sensitivity	4	0.500	NA	NA
	Specificity	25	1.000	0.867	1.000
Philips Other	Sensitivity	14	1.000	0.785	1.000
	Specificity	0	NA	NA	NA
SIEMENS SOMATOM *Definition AS+*	Sensitivity	14	1.000	0.785	1.000
	Specificity	29	1.000	0.883	1.000
SIEMENS Other	Sensitivity	14	1.000	0.785	1.000
	Specificity	19	1.000	0.832	1.000

Make/Model	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
TOSHIBA Aquilion	Sensitivity	20	0.950	0.764	0.991
	Specificity	20	1.000	0.839	1.000
TOSHIBA Other	Sensitivity	11	1.000	0.741	1.000
	Specificity	11	1.000	0.741	1.000

Performance within Reconstruction Methods of Make/Model of Scanners

Make/Model	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE Standard	Sensitivity	74	0.973	0.907	0.993
	Specificity	22	1.000	0.851	1.000
Philips UB	Sensitivity	18	0.889	0.672	0.969
	Specificity	57	1.000	0.937	1.000
Siemens H40s	Sensitivity	17	1.000	0.816	1.000
	Specificity	17	1.000	0.816	1.000
Other	Sensitivity	45	0.978	0.884	0.996
	Specificity	65	0.996	1.000	0.944

In summary, performance validation data, combined with real-world evidence, establish the achievement of effective triage by the Rapid ICH image analysis algorithm as well as effective notification functionality of the Rapid ICH application, as compared to the standard of care for improved time-to-exam-open of a notified case.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid ICH 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 based on expert 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, Rapid ICH (K193087).