iSchemaView, Inc.
Jim Rosa
SVP Regulatory and Quality
1120 Washington Ave.
Suite 200
Golden, Colorado 80401

October 25, 2023

Re: K232436
Trade/Device Name: Rapid SDH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: October 5, 2023
Received: October 5, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

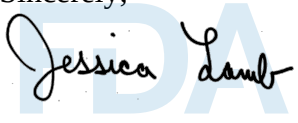
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232436

Device Name
Rapid SDH

Indications for Use *(Describe)*
Rapid SDH is a radiological computer aided triage and notification software indicated for use in the triage and notification of hemispheric SDH in non-enhanced head images. The device is intended to assist trained radiologists in workflow triage by providing notification of suspected findings of hemispheric Subdural Hemorrhage (SDH) in head CT images. Rapid SDH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected hemispheric SDH 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 hemispheric SDH 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 SDH 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 SDH is one input to physician diagnosis for patients >21 years old undergoing screening for hemispheric SDH, both acute and chronic.
• Rapid SDH is validated against hemispheric SDH ≥ 1ml.
• Subdural hygroma, subdural empyema, and subdural effusion mimics were not included in the validation data set.
• Excessive patient motion may lead to artifacts that make the scan technically inadequate.
• For use with non-contrast scans. Presence of intravenous contrast may lead to false positive indication of suspected hemispheric SDH.
• 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.

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.

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510(k) Summary

iSchemaView, Inc.'s Rapid SDH

This document contains the 510(k) summary for the iSchemaView Rapid SDH. 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 11, 2023

Device Name and Classification:

Trade Name:	Rapid SDH
Common Name:	Radiological Computer-Assisted Triage And Notification Software (CADt)
Classification:	II
Product Code:	QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

The iSchemaView Rapid is claimed to be substantially equivalent to the following legally marketed predicate device: Rapid ICH (K221456).

Device Description:

Rapid SDH is a radiological computer-assisted triage and notification software device. The Rapid SDH module is a Non-Contrast Computed Tomography (NCCT) processing module which operates within the integrated Rapid Platform to provide triage and notification prioritization of suspected hemispheric sub-dural hemorrhage (SDH). The Rapid SDH module is an AI/ML module. The output of the module is a priority notification to clinicians indicating the suspicion of SDH based on positive findings. The Rapid SDH 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 SDH is a radiological computer aided triage and notification software indicated for use in the triage and notification of hemispheric SDH in non-enhanced head images. The device is intended to assist trained radiologists in workflow triage by providing notification of suspected findings of hemispheric Subdural Hemorrhage (SDH) in head CT images.

Rapid SDH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected hemispheric SDH 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 hemispheric SDH 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 SDH 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 SDH is one input to physician diagnosis for patients >21 years old undergoing screening for hemispheric SDH, both acute and chronic.
- Rapid SDH is validated against hemispheric SDH ≥ 1ml.
- Subdural hygroma, subdural empyema, and subdural effusion mimics were not included in the validation data set.
- Excessive patient motion may lead to artifacts that make the scan technically inadequate.
- For use with non-contrast scans. Presence of intravenous contrast may lead to false positive indication of suspected hemispheric SDH.
- 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.

Comparison of Technological Characteristics:

Rapid SDH does not raise new questions of safety or effectiveness compared to the previously cleared predicate, Rapid ICH (K221456). Both devices use machine learning algorithms to determine the presence of intracranial hemorrhage and notify clinicians to the suspicion without removing the case from normal workflow processing. Rapid SDH has a minor difference from Rapid ICH, regarding a singular indication for the hemispheric sub-

dural hemorrhage (SDH) subtype vs multiple hemorrhage types within the predicate. Based on the comparison the subject device is substantially equivalent to the predicate device. The features are compared in the following table:

Substantial Equivalence Table		
Comparison Feature	Rapid ICH (K221456)	Rapid SDH
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 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.	Rapid SDH is a radiological computer aided triage and notification software indicated for use in the triage and notification of hemispheric SDH in non-enhanced head images. The device is intended to assist trained radiologists in workflow triage by providing notification of suspected findings of hemispheric Subdural Hemorrhage (SDH) in head CT images. Rapid SDH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected hemispheric SDH 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 hemispheric SDH 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 SDH 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. Note: See limitations in IFU statement above
Stroke/Head	Hemorrhagic Stroke/Head	Hemispheric Sub-Dural Hemorrhage/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	Radiologist
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 has been developed in conformance with the following standards, as applicable:

ISO 14971:2019	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)

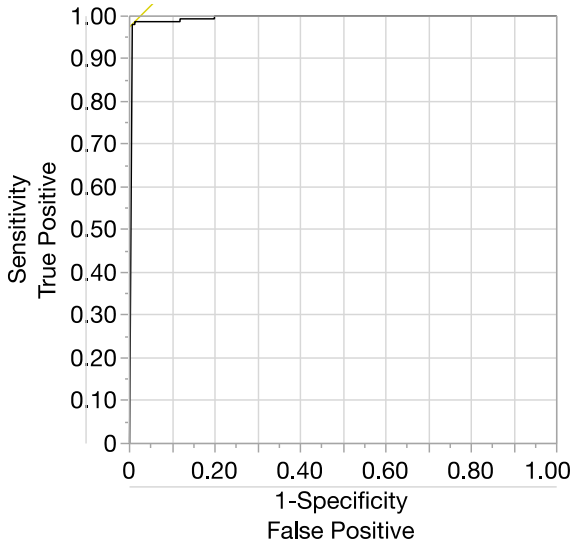
Rapid has been designed to meet the cybersecurity requirements using design Vulnerability Assessments, SBOM's, and PEN Testing.

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.

iSchemaView conducted a retrospective, blinded, multicenter, multinational study with Rapid SDH with the primary endpoint to evaluate the software's performance in identifying CT scans containing sub-dural intracranial hemorrhage (SDH). The performance data is derived from 310 samples with 147 positives and 163 negatives. Truth was established using three (3) expert neuro-radiologists.

The primary endpoint of the study was to exceed 80% performance goal. Sensitivity (Se) was measured at Se: 0.924 (95% CI: 0.871 – 0.956) and Sp: 0.987 (95% CI: 95477 – 0.996). The RoC/AUC analysis using Rapid SDH Volume estimate as a predictor of Suspected SDH is AUC: 0.995 (0.986, 1.0):



In addition, a secondary endpoint was to show median processing time to notify the clinician of 45 seconds with min of 33 seconds and maximum of 107 seconds.

Performance across subtype differentiation shows:

Performance Metrics by Gender

Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Female	Sensitivity	43	0.930	0.814	0.976
	Specificity	67	0.985	0.920	0.997
Male	Sensitivity	103	0.932	0.866	0.967
	Specificity	84	0.988	0.936	0.998

Performance Metrics by Age Groups

Age Group	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Age ≤ 50	Sensitivity	18	0.778	0.548	0.910
	Specificity	26	1.000	0.871	1.000
50 < Age < 70	Sensitivity	51	0.922	0.815	0.969
	Specificity	55	1.000	0.935	1.000
Age ≥ 70	Sensitivity	80	0.950	0.878	0.980
	Specificity	62	0.968	0.891	0.991

Performance by SDH Subtype: Chronic, Acute, Mixed

Type	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Chronic	Sensitivity	47	0.915	0.801	0.966
Acute	Sensitivity	48	0.875	0.753	0.941
Mixed†	Sensitivity	62	0.968	0.890	0.991

Performance by Hemorrhage Mix

Hemorrhage Subtype	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Subdural Only	Sensitivity	119	0.933	0.873	0.966
Subdural + Other	Sensitivity	38	0.895	0.759	0.958
Other, non-subdural	Specificity	50	1.00	0.929	1.00

Performance Metrics by Volume

Volume	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 10 ml	Sensitivity	29	0.724	0.543	0.853
≥ 10.0 ml	Sensitivity	128	0.969	0.922	0.988

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	52	0.942	0.844	0.980
	Specificity	35	1.000	0.901	1.000
PHILIPS	Sensitivity	19	0.789	0.567	0.915
	Specificity	41	1.000	0.914	1.000
TOSHIBA	Sensitivity	47	0.915	0.801	0.966
	Specificity	35	1.000	0.901	1.000
SIEMENS	Sensitivity	39	0.974	0.868	0.995
	Specificity	42	0.952	0.842	0.987

Site based information.

Many of the sites have inclusion of either positive or negative cases (blinded information during validation), for the positive case biased sites Se is provided; for the non-positive case sites Sp is provided in those sites where enough samples are included to provide statistical relevance:

Source	TP	FP	FN	TN	Total	Measure	Estimate	95% LCI	95% UCI
Gradient	59	0	4	1	64	Se	0.937	0.848	0.975
Riverside Regional Medical Center	5	1	0	37	43	Sp	0.974	0.865	0.995
Image Core Lab	8	0	3	25	36	Sp	1.000	0.867	1.000
Augusta University Medical Center	0	0	2	31	33	Sp	1.000	0.890	1.000
Ascension	31	0	0	0	31	Se	1.000	0.890	1.000
D3	1	0	0	27	28	Sp	1.000	0.875	1.000
Segmed	22	0	1	0	23	Se	0.957	0.790	0.992
Baptist	0	0	1	13	14	Sp	1.000	0.772	1.000
Hospital de Clinicas de POA	4	0	0	10	14	Sp	1.000	0.722	1.000
Stanford CA	7	0	1	3	11	Se	0.875		

Source	TP	FP	FN	TN	Total	Measure	Estimate	95% LCI	95% UCI
Ospedale Regionale di Lugano	7	1	0	0	8	Se	1.000		
NYU	0	0	0	3	3				
Flagler Hospital	0	0	0	1	1				
MUSC	1	0	0	0	1				

The performance validation for achievement of effective triage by the Rapid SDH image analysis algorithm as well as effective notification functionality of the Rapid SDH application, as compared to the standard of care for improved time-to-exam-open of a notified case was met.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid SDH 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.

Conclusion:

In conclusion, iSchemaView's Rapid SDH is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Rapid SDH (K221456).