September 4, 2025

iSchemaView Inc.
James Rosa
Chief Regulatory and Compliance Officer
1120 Washington Ave.
Suite 200
Golden, CO 80401

Re: K251533
Trade/Device Name: Rapid Obstructive Hydrocephalus, Rapid OH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: August 5, 2025
Received: August 6, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251533

Device Name
Rapid OH

Indications for Use *(Describe)*
Rapid OH is a radiological computer aided triage and notification software indicated for suspicion of Obstructive Hydrocephalus (OH) in non-enhanced CT head images of adult patients. The device is intended to assist trained clinicians in workflow prioritization triage by providing notification of suspected findings in head CT images.

Rapid OH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected OH 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 OH 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 OH 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/Limitations/Exclusions:
• Rapid OH is intended for use for adult patients.
• Input data image series containing excessive patient motion or metal implants may impact module analysis accuracy, robustness and quality.
• Ventriculoperitoneal shunts are contraindicated

Exclusions:
• Series with missing slices or improperly ordered slices
• data acquired at x-ray tube voltage < 100kVp or > 140kVp.
• data not representing human head or head/neck anatomical regions

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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K251533 510(k) Summary

iSchemaview, Inc.'s Rapid OH

This document contains the 510(k) summary for the iSchemaview Rapid OH device. 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: August 5, 2025

Device Name and Classification:

Trade Name:	Rapid Obstructive Hydrocephalus, Rapid OH
Common Name:	Medical image management and processing system
Classification:	II
Product Code:	Primary: QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

The iSchemaview Rapid OH Analysis Module is claimed to be substantially equivalent to the legally marketed predicate, Rapid SDH (K232436).

Device Description:

Rapid OH software device is a radiological computer-aided triage and notification software device using AI/ML. The Rapid OH device is a non-contrast CT (NCCT) processing module which operates within the integrated Rapid Platform to provide a notification of suspected findings of obstructive hydrocephalus (OH). The Rapid OH device is SaMD which analyzes input NCCT images that are provided in DICOM format for notification of suspected findings for workflow prioritization.

Indications for Use:

Rapid OH is a radiological computer aided triage and notification software indicated for suspicion of Obstructive Hydrocephalus (OH) in non-enhanced CT head images of adult patients. The device is intended to assist trained clinicians in workflow prioritization triage by providing notification of suspected findings in head CT images.

510(k) Summary

Rapid OH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected OH 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 OH 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 OH 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/Limitations/Exclusions:

- Rapid OH is intended for use for adult patients.
- Input data image series containing excessive patient motion or metal implants may impact module analysis accuracy, robustness and quality.
- Ventriculoperitoneal shunts are contraindicated

Exclusions:

- Series with missing slices or improperly ordered slices
- data acquired at x-ray tube voltage < 100kVp or > 140kVp.
- data not representing human head or head/neck anatomical regions

Technological Characteristics and Substantial Equivalence:

Rapid OH is a radiological computer-assisted triage and notification software device. The Rapid OH 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 obstructive hydrocephalus (OH). The Rapid OH module is an AI/ML module. The output of the module is a priority notification to clinicians indicating the suspicion of OH based on positive findings. The Rapid OH 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. The following table summarizes and compares data on the predicate device (K232436) to the Rapid OH software device that is the subject of this Traditional 510(k) submission.

Parameter	Rapid SDH (K232436) Predicate Device	Rapid OH – Subject Device
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ 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	Rapid OH is a radiological computer aided triage and notification software indicated for suspicion of Obstructive Hydrocephalus (OH) in non-enhanced CT head images of adult patients. The device is intended to assist trained clinicians in workflow prioritization

	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.	triage by providing notification of suspected findings in head CT images. Rapid OH uses an artificial intelligence algorithm to analyze images and highlight cases with suspected OH 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 OH 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 OH 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. <u>Contraindications/Limitations/Exclusions:</u> • Rapid OH is intended for use for adult patients. • Input data image series containing excessive patient motion or metal implants may impact module analysis accuracy, robustness and quality. • Ventriculoperitoneal shunts are contraindicated <u>Exclusions:</u> • Series with missing slices or improperly ordered slices • data acquired at x-ray tube voltage < 100kVp or > 140kVp.

		• data not representing human head or head/neck anatomical regions
Input Data Requirements	Non-Contrast CT images	Non-Contrast CT images
DICOM Compliance	Yes	Yes
Anatomical Focus	Head	Head
SW	AI ML	AI ML
Removal of Cases from worklist queue	No	No
Outputs	Notifications, Reports, DICOM Secondary Capture Series	Notifications, Reports, DICOM Secondary Capture Series
Notification/ Prioritization	PACS, Workstation, email, mobile	PACS, Workstation, email, mobile

AI/ML Module Development:

Algorithm development was performed using 3340 cases from 74 sites, multiple manufactures (Siemens, GE, Toshiba, Philips) and split demographic (M/F, Age) characteristics which have disease variability to support generalization across hospital use cases. The training data and validation data sets are independently managed per internal data management procedures.

Clinical Characteristics:

The primary users of Rapid OH software are medical professionals who use analysis of brain tissue and artifacts to assess patient conditions on presentation to the hospital for neuro disease symptoms related to obstructive hydrocephalus. Rapid OH is used in workflow prioritization, not to make primary diagnostic or treatment decisions. Rapid OH is for analysis of adult patients.

Performance Standards:

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

EN ISO 14971:2019 (R2021)	Application of Risk Management to Medical Devices
IEC 62304:2006 (R2015)	Medical device software – Software lifecycle processes
IEC 62366:2015 (R2020)	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Performance Data:

Rapid OH 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; and was tested in accordance with the 820.20 Verification and Validation requirements and successfully passed.

iSchemaView conducted extensive performance validation testing and software verification and validation testing of the Rapid OH device. Final device validation included standalone

performance validation. This performance validation testing demonstrated the Rapid OH device provides accurate representation of key processing parameters under a range of clinically relevant conditions associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid OH device met all design requirements and specifications.

Standalone performance primary endpoint passed with sensitivity (Se) of 89.5% (95% CI:0.837-0.935) and specificity (Sp) of 97.6% (95% CI:0.940-0.991); the secondary endpoint demonstrated time to notification time of 30.3 seconds (range 10.5-55.5 seconds).

The performance validation was performed using 320 cases with diversity amongst demographics (M: 45%, F: 54%); Sites (and manufacturers (GE, Philips, Siemens, Toshiba) and confounders (ICH, Ischemic Stroke, Tumor, Cyst, Aqueductal stenosis, Mass effect, Brain atrophy and Communicating hydrocephalus). Truthing was established using 2:3 experts.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid OH has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements and the risk is managed through design meeting the requirements associated with EN ISO 14971:2019 (risk management). Overall risk analysis and design implementation shows the Rapid OH as safe and effective as the predicate.

Conclusion:

In conclusion, the Rapid OH software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Rapid SDH Software (K232436).