October 9, 2026

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

Re: K262301
Trade/Device Name: Rapid ICH (v4.0)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: September 7, 2026
Received: September 8, 2026

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), Rapid ICH Predetermined Change Control Plan, Version C. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262301

Please provide the device trade name(s).

Rapid ICH (v4.0)

Please provide your Indications for Use below.

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 Intracranial Hemorrhage (ICH) pathologies in head CT images, including IPH, IVH, SAH, and SDH/EDH intracranial hemorrhages.

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.

Rapid ICH is for use in ≥18 yr olds.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

iSchemaView, Inc.'s Rapid ICH

This document contains the 510(k) summary for the iSchemaView Rapid ICH (v4) 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: 6 June, 2026

Device Name and Classification:

Trade Name:	Rapid ICH (v4.0)
Common Name:	Radiological Computer Aided Triage and Notification Software
Classification:	II
Product Code:	Primary: QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Device:

The iSchemaview Rapid ICH (v4) Triage and Notification Module is claimed to be substantially equivalent to the legally marketed predicate, iSchemaView Rapid ICH (v3) (K221456).

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 Intracranial Hemorrhage (ICH) pathologies in head CT images, including IPH, IVH, SAH, and SDH/EDH intracranial hemorrhages.

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.

Rapid ICH is for use in ≥18 yr olds.

Substantial Equivalence and Comparison of Technological Characteristics:

Rapid ICH (v4) does not raise new questions of safety or effectiveness compared to the previously cleared Rapid ICH (v3 under K221456). Both devices are radiological computer-aided triage and notification software applications for use with non-contrast CT input. The minor change for this filing is the update to include recent training data and validation. Thus, the Rapid ICH (v4) software is substantially equivalent.

The following table summarizes and compares data on the Rapid ICH (K221456) 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(v3) (K221456)	Rapid ICH (v4) – 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, 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	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/EDH 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

Substantial Equivalence Table		
Comparison Feature	Rapid ICH(v3) (K221456)	Rapid ICH (v4) – Subject Device
	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	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
Anatomy	Head	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.
Primary User(s)	Clinician	Radiologist
Alteration of original image data	No	No
Alters Standard of Care	In parallel to	In parallel to

Substantial Equivalence Table		
Comparison Feature	Rapid ICH(v3) (K221456)	Rapid ICH (v4) – Subject Device
Workflow		
Notification / Prioritization	Yes – PACS, Workstation, email, mobile	Yes – PACS, Workstation, email, mobile

AI/ML Module Development:

The training data (4399 cases) from a diverse group of sites in the US and OUS included selected confounders and phantoms to train against a range of cases for generalization to cover the subgroup demographics and equipment manufacturers. Phantoms were used to address specific technical characteristics such as motion detection.

Clinical Characteristics:

The primary users of Rapid ICH are radiologists to support workflow prioritization.

Performance Standards:

Rapid ICH 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)
UL 2900-1 (2017)	Standard for Safety for Cybersecurity Network-Connected Products

Performance Data:

Performance validation was conducted through a retrospective, blinded, multicenter, multinational study with Rapid ICH with the primary endpoint to evaluate the software's performance in CT scans containing intracranial hemorrhage (ICH). The performance data is derived from 320 samples with 311 used for the primary endpoint, 9 Cases were removed due to exclusion criteria. The primary endpoint was exceeded with Se: 0.949 (0.899,0.975) and Sp: 0.977 (0.942, 0.991). Secondary endpoint was met, with a median processing time of 127s and a range of 114s to 773s; 90% of cases processed in under 3 minutes. Reported processing times are observed values for this version and dataset and are not acceptance criteria.

All validation data was Truthed using three (3) expert neuro-radiologists. The data was obtained from 21 sources: 13 named clinical institutions, of which 4 are outside the United States, and 8 data providers, imaging core laboratories or multicentre study datasets. Sources of the latter kind aggregate more than one contributing institution, so the number of contributing sites exceeds the number of sources listed. Of the 311 analysed cases, 250 (80.4%) are of United States origin and 61 (19.6%) are not. Confounders included:

Calcification, Foreign Object(s), Hyperdense Vasculature, Infarct, Meningeal Hyperdensity and Tumor. As a sub-analysis, Truthers identified 47 cases specific to trauma related injury which showed Se: 1.00 (0.896,1.0) and Sp: 0.929 (0.685,0.987).

Subgroup Performance:

Additional subgroup analysis was performed against age, gender, manufacturer, scanner model, reconstruction kernel, US/OUS, slice thickness, ICH subtype, hemorrhage volume and confounder presence, showing acceptable performance for generalization. Subtype and volume results rest on small samples in some categories and are reported descriptively; the weakest is subarachnoid hemorrhage at Se 0.800 (0.490, 0.943) on 10 cases.

Predetermined Change Control Plan (PCCP):

Rapid ICH has an authorized Predetermined Change Control Plan (PCCP). All modification types are restricted to non-enhanced head CT; no modification will introduce a new imaging modality or a new acquisition type.

Approved Planned Modifications: (1) Device Input Compatibility — DICOM pre-processing and compatibility adjustments, no algorithm weight change; (2) CT Scanner Expansion — algorithm retraining to add new CT scanner models or reconstruction methods within CT modality only; (3) Performance Improvement via Data Expansion — algorithm retraining on expanded CT datasets triggered by >10% Se or Sp drift; (4) Processing Time Optimization — latency reduction (DICOM pipeline refactoring, inference quantization, parallelization, model pruning with confirmed output equivalence) with no change to algorithm weights or clinical outputs.

Testing Methods and Acceptance Criteria: Retraining modifications (Types 2 and 3): three-part sub-analysis (Original / New Cases / Integrated); primary endpoint aggregate Se and Sp ≥80% lower bound97.5%% CI; non-inferiority per subgroup (scanner manufacturer; age cohort 18–21, 22–50, 51–69 and ≥70 years; sex; ICH subtype IPH, IVH, SAH, SDH, EDH) with approved margins. Processing Time (Type 4): mean Time to Notification non-inferior to the prior authorized version.

User Notification: Software updates are deployed manually; updated labeling accompanies each update with a description of the modification, current Se/Sp and Time to Notification metrics, and a version history of all PCCP-authorized changes. Hospital installation personnel are notified at time of deployment.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid ICH is 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 14971:2019 (risk management). The Rapid ICH performance has been validated with case data.

Conclusion:

In conclusion, the iSchemaView Rapid ICH (v4) software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Rapid ICH (K221456).