July 16, 2025

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

Re: K251151
Trade/Device Name: Rapid CTA 360
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: June 20, 2025
Received: June 20, 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.

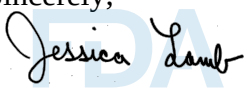
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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, 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)*
K251151

Device Name
Rapid CTA 360

Indications for Use *(Describe)*
Rapid CTA 360 is a radiological computer aided triage and notification software indicated for use in the analysis of CTA adult head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive Large and Medium Vessel Occlusion findings in head CTA images including the ICA (C1-C5), MCA (M1-M3), ACA, PCA, Basilar and Vertebral vascular segments.

Rapid CTA 360 uses an AI software algorithm to analyze images and highlight cases with suspected occlusion 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 LVO and MVO findings. Notifications include compressed preview images. These are meant for informational purposes only and are 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 CTA 360 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.

K251151 510(k) Summary

iSchemaView Rapid CTA 360

This document contains the 510(k) summary for the iSchemaView Rapid CTA 360 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:	July 10, 2025

Device Name and Classification:

Trade Name:	Rapid CTA 360
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 Devices:

The iSchemaview Rapid CTA 360 Triage and Notification Module is claimed to be substantially equivalent to the legally marketed predicate, iSchemaView Rapid LVO (K200941); Rapid Neuro3d (K243350) is referenced as the technology used for vessel segmentation.

Device Description:

Rapid CTA 360 device is a radiological computer-assisted Triage and Notification Software device using AI/ML. The Rapid CTA 360 processing module operates within the integrated Rapid Platform to provide triage and notification of suspected large and medium vessel neuro-occlusions. The Rapid CTA 360 software analyzes input Head and Neck CTA images that are provided in DICOM format and provides notification of suspected positive results. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

Indications for Use:

Rapid CTA 360 is a radiological computer aided triage and notification software indicated for use in the analysis of CTA adult head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive

Large and Medium Vessel Occlusion findings in head CTA images including the ICA (C1-C5), MCA (M1-M3), ACA, PCA, Basilar and Vertebral vascular segments.

Rapid CTA 360 uses an AI software algorithm to analyze images and highlight cases with suspected occlusion 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 LVO and MVO findings. Notifications include compressed preview images. These are meant for informational purposes only and are 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 CTA 360 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.

Technological Characteristics and Substantial Equivalence:

Rapid CTA 360 does not raise new questions of safety or effectiveness compared to the previously cleared Rapid LVO Software (K200941). There are minor differences in intended use and technical characteristics with the predicate device; however, with the minor changes the clinical use for Rapid CTA 360 device is the same with no additional risks. Thus, the Rapid CTA 360 software device is substantially equivalent. Rapid Neuro3d (K243350) is provided as a reference only to the vessel segmentation.

The following table summarizes and compares data on the predicate device (K200941) to the Rapid CTA 360 software device that is the subject of this Traditional 510(k) submission.

Parameter	Rapid LVO (K200941) Predicate Device	Rapid CTA 360 Subject Device
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ Indications for Use	Rapid LVO is a radiological computer aided triage and notification software indicated for use in the analysis of CTA head images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive ICA or MCA-M1 Large Vessel Occlusion (LVO) findings in head CTA images. Rapid LVO uses a software algorithm to analyze images and highlight cases with suspected LVO on a server or standalone desktop application in parallel to the ongoing	Rapid CTA 360 is a radiological computer aided triage and notification software indicated for use in the analysis of CTA adult head images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive Large and Medium Vessel Occlusion findings in head CTA images including the ICA (C1-C5), MCA (M1-M3), ACA, PCA, Basilar and Vertebral vascular segments. Rapid CTA 360 uses an AI software algorithm to analyze images and

	standard of care image interpretation. The user is presented with notifications for cases with suspected LVO findings. Notifications include compressed preview images. These are meant for informational purposes only and are 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 LVO 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.	highlight cases with suspected occlusion 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 LVO and MVO findings. Notifications include compressed preview images. These are meant for informational purposes only and are 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 CTA 360 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.
Input Data Requirements	CTA	CTA
Patient Population	Adult	Adult
DICOM Compliance	Yes	Yes
User Output	Notification w/compressed images	Notification w/compressed images
SW	Traditional	AI/ML
Segments	ICA, MCA-M1	ICA (C1-C5), MCA (M1-M3), ACA, PCA, Basilar and Vertebral
Outputs	Reports, DICOM Secondary Capture Series	Reports, DICOM Secondary Capture Series
Cybersecurity Framework	External I/Fs through Rapid Platform	External I/Fs through Rapid Platform

AI/ML Module Development:

Algorithm development, including training and testing, was performed using 6264 cases from multiple sites (133), primarily US. Cases were selected to cover patient demographics of age and gender; manufacturer distributions (GE, Toshiba, Siemens, and Philips scanners); and confounders including high grade stenosis, aneurysm (treated and untreated), cerebral

edema, hematoma, intracranial atherosclerosis, old stroke, subdural hemorrhage, and traumatic brain injury.

Clinical Characteristics:

The primary users of Rapid CTA 360 are clinicians to support workflow prioritization.

Performance Standards:

Rapid PE 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 Testing and Data:

iSchemaView conducted performance validation testing and software verification and validation testing of the Rapid CTA 360 device. Rapid CTA 360 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.

Final device validation included standalone performance validation, per the special controls. This performance validation testing demonstrated the Rapid CTA 360 device provides effective triage and notification in a range of clinically relevant conditions associated with the intended use of the device. Software performance, validation and verification testing demonstrated that the Rapid CTA 360 device met all design requirements and specifications.

Final performance validation included 403 CTA cases with ground truth established by 3 experts (2:3 concurrence), all cases are independent of the development data.

The primary endpoint analysis passed with Sensitivity 0.921 (95% CI: 0.880, 0.949) and Specificity 0.890 (95% CI: 0.832, 0.929) supporting the finding. The cases were split Male: 51%, Female 47% with an age range or 22 - 90+ years. The samples were mixed from GE, Philips, Toshiba and Siemens scanners, and multiple sites and sources.

A sensitivity analysis with high grade stenosis (HGS) cases was included as a secondary analysis showing Se: 87.4% (95% CI:0.829-0.908) and Sp: 89.0% (95% CI: 0.832-0.929).

The data set used, in addition to HGS (30 cases), was augmented with confounders including: aneurysm (treated and untreated), cerebral edema, hematoma, intracranial atherosclerosis, old stroke, subdural hemorrhage, and traumatic brain injury. All data was collected and blinded prior to use, per internal data management procedures which includes isolation of development and product validation cohorts.

A secondary endpoint analysis showed time to notification of 3.2 minutes, min:1.92 min to 5.35min.

Cybersecurity:

iSchemaView uses the OWASP vulnerability risk process to identify and mitigate cybersecurity risks in conjunction with internal and external periodic assessments. iSchemaView maintains a compliance framework as annually certified by ISO 27001/27701 and conformance with UL-2900-1 through integrated development processes including: SBOM management, Penetration Testing, DAST and lifecycle monitoring.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid CTA 360 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 CTA 360 performance has been validated with case data.

Conclusion:

In conclusion, the iSchemaView Rapid CTA 360 software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Rapid LVO Software (K200941).