July 13, 2026

iSchemaview
James Rosa
Chief Regulatory and Compliance Officer
Contact Address

Re: K261085
Trade/Device Name: Rapid Vessel Occlusion (Rapid VO)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: June 15, 2026
Received: June 15, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). 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

Jessica Lamb
Assistant Director
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.	k261085

Please provide the device trade name(s).

Rapid Vessel Occlusion (Rapid VO)

Please provide your Indications for Use below.

Rapid VO 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 Vessel Occlusion findings in head CTA images including the ICA, MCA (M1-M2), and Basilar vascular segments.

Rapid VO 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 occlusion 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 VO 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 VO is for use on Adults.

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)

510(k) Summary

iSchemaView, Inc.'s Rapid Vessel Occlusion (VO)

This document contains the 510(k) summary for the iSchemaView Rapid Vessel Occlusion (Rapid VO) 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:	James Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: 10 July, 2026

Device Name and Classification:

Trade Name:	Rapid Vessel Occlusion (Rapid VO)
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 VO Triage and Notification Module is claimed to be substantially equivalent to the legally marketed predicate, iSchemaView Rapid CTA 360 (K251151).

Device Description:

The Rapid VO device is a radiological computer-assisted Triage and Notification Software device using AI/ML. The Rapid VO processing module operates within the integrated Rapid Platform to provide triage and notification of suspected neuro-vessel occlusions. The Rapid VO 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 VO 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

Vessel Occlusion findings in head CTA images including the ICA, MCA (M1-M2), and Basilar vascular segments.

Rapid VO 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 occlusion 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 VO 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 VO is for use on adults.

Caution(s)/Warnings(s)/Limitation(s)/Exclusion(s)/Contraindications(s):

- Input data image series containing excessive patient motion or metal implants.
- Series containing inadequate contrast agent
- Series that are non-axial or non-axial oblique
- Series with missing slices or improperly ordered slices
- CTA datasets with:
  - in-plane X and Y FOV < 160mm or > 400mm.
  - Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm or > 600 mm
  - y-plane pixel spacing (X & Y resolution) < 0.15 mm or > 0.8 mm.
  - Z slice spacing of < 0.2 mm or > 1.5 mm.
  - lice thickness > 1.5 mm.
  - data acquired at x-ray tube voltage < 70kVp or > 150kVp.
  - data not representing human head or head/neck anatomical regions

Technological Characteristics and Substantial Equivalence:

Rapid VO does not raise new questions of safety or effectiveness compared to the previously cleared Rapid CTA 360 Software (K251151). There are minor differences in intended use and technical characteristics with the predicate device; however, with the minor changes the clinical use for Rapid VO device is the same with no additional risks. Thus, the Rapid VO software device is substantially equivalent.

The following table summarizes and compares data on the predicate device (K251151) to the Rapid VO software device that is the subject of this Traditional 510(k) submission.

Parameter	Rapid CTA 360 (K251151) Predicate Device	Rapid VO Subject Device
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ Indications for Use	Rapid CTA 360 is a radiological computer aided triage and notification software indicated for use in the analysis of CTA adult, including adolescent B, 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 a 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	Rapid VO 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 Vessel Occlusion findings in head CTA images including the ICA, MCA (M1-M2), and Basilar vascular segments. Rapid VO 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 occlusion 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 VO 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

	medical images. Notified clinicians are responsible for viewing full images per the standard of care.	images per the standard of care. Rapid VO is for use on Adults.
Input Data Requirements	CTA	CTA
DICOM Compliance	Yes	Yes
User Output	Notification w/compressed images	Notification w/compressed images
SW	AI/ML	AI/ML
Segments	ICA (C1-C5), MCA (M1-M3), ACA, PCA, Basilar and Vertebral	ICA, MCA (M1-M2), Basilar
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
PCCP	No	Yes

AI/ML Module Development:

Standalone performance validation was conducted on 314 collected CTA cases (282 evaluable: 113 positive including ICA, MCA-M1, and BA; 169 negative; 32 High-Grade Stenosis; 19 rejected on quality grounds) from 33 distinct clinical sites across the United States (99.0%) and one OUS site (1.0%). Development (training and internal validation) used 631 cases from multiple sites. Cases covered GE, Toshiba, Siemens, and Philips scanners across a range of acquisition protocols, slice thicknesses (0.2–1.5 mm), and kVp settings (80–140 kVp). Patient demographics in the performance test dataset: Female 52.9% (n=166), Male 47.1% (n=148); age range 24–90+ years. Confounders in the test dataset included aneurysm (n=18), hypoplasia (n=2), LVO/MeVO outside the cleared indication (n=43), moyamoya (n=8), and stent/coil (n=1), totaling 79 annotated confounder instances.

Clinical Characteristics:

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

Performance Standards:

Rapid VO 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

Training Data:

Rapid VO development used 6264 (3256 Normal; 3002 Non-normal) cases. The non-normal cases included 2535 ICA, MCA (M1-M2) and Basilar cases; and 467 confounders. The data was from a broad range of US and international sites and split 49% Male, 51% Female.

Performance Data:

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

The primary endpoint was evaluated on 282 cases (113 positive: ICA, MCA-M1, and BA; 169 negative) from 314 collected cases (32 HGS excluded, 19 rejected). Ground truth was established by consensus of three independent board-certified neuroradiologists using a 2-of-3 majority rule. The primary endpoint passed with Sensitivity 0.956 (95% CI: 0.901, 0.981) and Specificity 0.905 (95% CI: 0.852, 0.941).

Secondary endpoints: (1) BA-Off (ICA/MCA-M1 only): Se 0.968 (0.910–0.989), Sp 0.920 (0.873–0.951). (2) High-Grade Stenosis, BA-On: Se 0.869 (0.804–0.914). (3) Time to Notification BA-On: mean 3.3 min (160–262 s); BA-Off: 3.2 min (154–249 s). Acceptance threshold: <196 s.

Subgroup Performance:

The following subgroup analyses were performed on the 282 evaluable cases (HGS excluded). Results are point estimate (95% CI). These values constitute the authorized performance baseline for all future PCCP modification non-inferiority evaluations per ISV-R-R-PCCP, Revision B.

Subgroup	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Scanner Manufacturer	GE — Se	35	0.971	0.855	0.995
	GE — Sp	139	0.935	0.882	0.966
	Philips — Se	17	1.000*	0.816	1.000
	Siemens — Se	58	0.948	0.859	0.982
	Toshiba — Se	3	0.667*	0.208	0.939
	Toshiba — Sp	16	0.750	0.505	0.898
Gender	Female — Se	50	0.940	0.838	0.979
	Female — Sp	101	0.911	0.839	0.952
	Male — Se	63	0.968	0.891	0.991

	Male — Sp	68	0.897	0.802	0.949
Age Group	<40 — Se	3	1.000*	0.439	1.000
	40–59 — Se	30	0.967	0.833	0.994
	≥60 — Se	80	0.950	0.878	0.980
Slice Thickness	<0.625mm — Se	25	0.840	0.653	0.936
	0.625–0.8mm — Se	70	1.000	0.948	1.000
	>0.8mm — Se	18	0.944	0.742	0.990
Occlusion Location (Se)	ICA	41	0.976	0.874	0.996
	MCA-M1	30	1.000	0.886	1.000
	MCA-M2	23	0.957	0.790	0.992
	BA	19	0.842	0.624	0.945

** Small n — interpret with caution. Demographics: Female 52.9%, Male 47.1%; age range 24–90+ years; 33 clinical sites; US 99.0%, OUS 1.0%.*

Reference Standard (Truthing Process):

Ground truth for all 314 collected validation cases was established by consensus of three independent US board-certified neuroradiologists. Specific adjudication rules for tandem lesions and proximal-lesion hierarchy were defined in the Validation Study Protocol and applied uniformly. All readers were blinded to each other's assessments and to device outputs.

Training and Test Data Independence:

Training and test datasets were sourced from distinct, non-overlapping clinical sites. The performance test dataset comprised 33 distinct clinical sites (US 99.0%; OUS 1.0%); one consecutive-series site (n=45) confirmed sequential sampling. Training data spanned 74 sites.

Predetermined Change Control Plan (PCCP):

Rapid VO has an authorized Predetermined Change Control Plan (PCCP). All modification types are restricted to the CT Angiography (CTA); no modification(s) will introduce a new imaging modality.

Approved Planned Modifications: (1) Device Input Compatibility — DICOM pre-processing and compatibility adjustments, no algorithm weight change; (2) CTA 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 CTA 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 bound 95% CI; co-primary non-inferiority per subgroup (scanner manufacturer, age cohort 18–65 and >65 years, sex, occlusion location M1/M2/ICA/BA,

slice thickness) with approved margins. Processing Time (Type 4): mean TTN <196 s with identical case-level classification results vs. 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 VO 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 VO performance has been validated with case data.

Conclusion:

In conclusion, the iSchemaView Rapid VO software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Rapid CTA 360 (K251151).