iSchemaView Inc.
James Rosa
SVP Regulatory and Quality
1120 Washington Ave., Ste 200
GOLDEN, COLORADO 80401

July 27, 2023

Re: K230074
Trade/Device Name: Rapid Aneurysm Triage and Notification
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QFM
Dated: July 10, 2023
Received: July 11, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,
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)*
K230074

Device Name
Rapid Aneurysm Triage and Notification

Indications for Use *(Describe)*
Rapid Aneurysm Triage and Notification (ANRTN) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected saccular aneurysms during routine patient care. Rapid ANRTN uses an artificial intelligence algorithm to analyze images and highlight studies with suspected saccular aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Analyzed images are available for review through the PACS, email and mobile application. When viewed the images are for informational purposes only and not for diagnostic use. The results of Rapid ANRTN, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of saccular aneurysm cases. Radiologists who read the original medical images are responsible for the diagnostic decision. Rapid ANRTN is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Rapid ANRT is limited to detecting saccular aneurysms at least 4mm in diameter in adults.
Inclusion Criteria:

The module shall detect unruptured saccular brain aneurysms greater than or equal to 4 mm in size within the following anatomical region:
- Internal Carotid Artery (ICA): ophthalmic segment to ICA terminus
- Middle Cerebral Artery (MCA): M1 segment through M1/M2 bifurcation
- Anterior Cerebral Artery (ACA): A1 and A2 segments
- Anterior Communicating Artery (ACOM)
- Posterior Communicating Artery (PCOM)
- Posterior Cerebral Artery (PCA): P1 segment
- Vertebral Artery (VA): intracranial portion of the VA through the vertebrobasilar (VB) junction
- Basilar Artery (BA)

Contraindications/Exclusions/Cautions:
- The module shall process only CTA datasets with a patient position of 'headfirst supine'.
- The module shall process only a series within CTA datasets comprised only of axial slices.
- The module shall process only CTA datasets with Z FOV (cranio-caudal transverse anatomical coverage) greater than or equal to 90 mm
- The module shall process only CTA datasets with in-plane pixel spacing (X & Y resolution): 0.2 – 1.0 mm
- The module shall process only CTA datasets with in-plane X FOV: 160-400mm.
- The module shall process only CTA datasets with in-plane Y FOV: 160-400 mm
- The module shall process only CTA datasets with Z slice spacing of 0.2 – 1.25 mm
- The module shall process only CTA datasets with data acquired at x-ray tube voltage 80kVp-140kVp, as reported in the input data DICOM header
- The module shall process only CTA datasets consisting of input slices of continuous order without gaps.
- The module shall process only CTA datasets where the images belong to a single series (i.e., identical SeriesInstanceUID DICOM tag value for all images).
- The module shall not process CTA datasets where the DICOM tags "ImagePositionPatient" (IPP), "ImageOrientationPatient" (IOP), or "PixelSpacing" are missing

- The module shall only process a single series per study, being the largest available that passes the above requirements.
- The module shall accept input files within a parent folder named by a unique identifier for the case.
- The module shall accept axial-oblique CTA datasets with an oblique plane of ≤ 35 degrees.
- Cases with significant motion and/or imaging artifacts.

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.

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K230074 510(k) Summary

iSchemaView, Inc.'s Rapid Aneurysm Triage and Notification

This document contains the 510(k) summary for the iSchemaView Rapid Aneurysm Triage and Notification Device (ANRTN). 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 25, 2023

Device Name and Classification:

Trade Name:	Rapid Aneurysm Triage and Notification
Classification Name:	Radiological computer aided triage and notification software
Classification:	II
Product Code:	QFM
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

The iSchemaView Rapid ANRTN device is claimed to be substantially equivalent to the following legally marketed predicate devices:

Viz.AI's Aneurysm Software (K213319)

Device Description:

Rapid ANRTN software device is a radiological computer-assisted image processing software device. The Rapid ANRTN device is a CTA processing module which operates within the integrated Rapid Platform to determine the suspicion of head saccular aneurysm(s). The ANRTN software analyzes input CTA images that are provided in DICOM format and provides notification of suspected saccular aneurysm(s) and a non-diagnostic, compressed image for preview. Rapid ANRTN is an AI/ML image processing module which integrates within the Rapid Platform.

Indications for Use:

Rapid Aneurysm Triage and Notification (ANRTN) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is

intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected saccular aneurysms during routine patient care.

Rapid ANRTN uses an artificial intelligence algorithm to analyze images and highlight studies with suspected saccular aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

Analyzed images are available for review through the PACS, email and mobile application. When viewed the images are for informational purposes only and not for diagnostic use. The results of Rapid ANRTN, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of saccular aneurysm cases. Radiologists who read the original medical images are responsible for the diagnostic decision. Rapid ANRTN is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Rapid ANRT is limited to detecting saccular aneurysms at least 4mm in diameter in adults.

Inclusion Criteria:

The module shall detect unruptured saccular brain aneurysms greater than or equal to 4 mm in size within the following anatomical region:

- Internal Carotid Artery (ICA): ophthalmic segment to ICA terminus
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Contraindications/Exclusions/Cautions:

- The module shall process only CTA datasets with a patient position of 'headfirst supine'.
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- The module shall not process CTA datasets where the DICOM tags "ImagePositionPatient" (IPP), "ImageOrientationPatient" (IOP), or "PixelSpacing" are missing
- The module shall only process a single series per study, being the largest available that passes the above requirements.
- The module shall accept input files within a parent folder named by a unique identifier for the case.
- The module shall accept axial-oblique CTA datasets with an oblique plane of ≤ 35 degrees.
- Cases with significant motion and/or imaging artifacts.

Technological Characteristics and Substantial Equivalence:

Rapid ANRTN does not raise new questions of safety or effectiveness compared to the previously cleared Viz.AI ANX Software (K213319). There are minor differences in technical characteristics with the predicate device; however, with the minor changes the clinical use for Rapid ANRTN device is the same with no additional risks. Thus, the Rapid ANRTN device is substantially equivalent.

The following table summarizes and compares data on the Viz.AI ANX Software (K213319) to the Rapid ANRTN device that is the subject of this Traditional 510(k) submission.

Parameter	**Rapid ANRTN (Subject Device)**	**Viz Aneurysm (Predicate Device)**
Product Code	QFM	QFM
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ Indications for Use	Rapid Aneurysm Triage and Notification (ANRTN) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected saccular aneurysms during routine patient care. Rapid ANRTN uses an artificial intelligence algorithm to analyze images and highlight studies with suspected saccular aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational purposes only and not intended for	Viz ANEURYSM (Viz ANX) is a radiological computer-assisted triage and notification software device for analysis of CT images of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and prioritizing studies with suspected aneurysms during routine patient care. Viz ANEURYSM uses an artificial intelligence algorithm to analyze images and highlight studies with suspected aneurysms in a standalone application for study list prioritization or triage in parallel to ongoing standard of care. The device generates compressed preview images that are meant for informational

Parameter	**Rapid ANRTN (Subject Device)**	**Viz Aneurysm (Predicate Device)**
	diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Analyzed images are available for review through the PACS, email and mobile application. When viewed the images are for informational purposes only and not for diagnostic use. The results of Rapid ANRTN, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of saccular aneurysm cases. Radiologists who read the original medical images are responsible for the diagnostic decision. Rapid ANRT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Rapid ANRT is limited to detecting saccular aneurysms at least 4mm in diameter in adults. *<inclusions and limitations provided above>*	purposes only and not intended for diagnostic use. The device does not alter the original medical image and is not intended to be used as a diagnostic device. Analyzed images are available for review through the standalone application. When viewed through the standalone application the images are for informational purposes only and not for diagnostic use. The results of Viz ANEURYSM, in conjunction with other clinical information and professional judgment, are to be used to assist with triage/prioritization of medical images. Radiologists who read the original medical images are responsible for the diagnostic decision. Viz ANEURYSM is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz ANEURYSM is limited to detecting aneurysms at least 4mm in diameter.
Anatomical Region	Head	Head
Independent Standard of Care	Yes	Yes
Notification/ Prioritization	Yes	Yes
Identify patients with pre-specified clinical condition	Yes	Yes
Clinical Condition	Aneurysm	Aneurysm
Intended User	Radiologist	Radiologist

Parameter	**Rapid ANRTN (Subject Device)**	**Viz Aneurysm (Predicate Device)**
DICOM	Yes	Yes
Imaging Modality	CTA	CTA
Alteration of Image	No	No
Preview Images	Non-diagnostic	Non-diagnostic

AI/ML Module Development:

Algorithm development was performed using 698 (633training, 65 validation) CTA cases from multiple sites. Cases selected covered a wide range of suspected saccular aneurysms. Cases were obtained from Siemens, GE, Toshiba, and Philips scanners.

Clinical Characteristics:

The primary users of Rapid ANRTN software are medical professionals including radiologists, neuroradiologists, emergency physicians, neurologists, neurosurgeons, etc., who may review CTA scans of the head for indication of aneurysm.

Performance Standards:

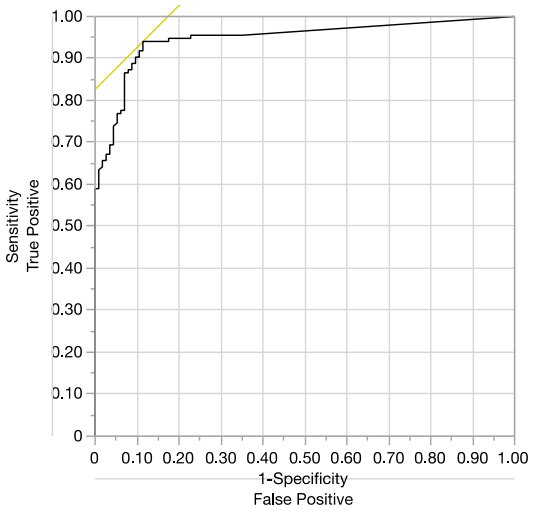
Rapid ANRTN has been developed in conformance with the following standards, as applicable:

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 ANRTN 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 extensive performance validation testing and software verification and validation testing of the Rapid ANRTN device. Final device validation included standalone performance validation. This performance validation testing demonstrated the Rapid ANRTN device provides accurate representation of key processing parameters under a range of clinically relevant perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid ANRTN device met all design requirements and specifications. Final performance validation included 266 (151 pos, 115 neg) CTA cases with ground truth established by 3 experts. The primary endpoint passed with AUC $\geq$ 0.95 for high performance per the QFM product code definition. Additionally, Sensitivity (0.933) and Specificity(0.868) supported the finding. Age range evaluated was 21-99 with mean 64. Sub-segmented performance by scanners have different performance levels which are affected by sample sizes as seen in the confidence interval spread.



The following performance is seen across the indicated sub analysis:

Manufacturer	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE	Sensitivity	37	0.973	0.862	0.995
	Specificity	32	0.875	0.719	0.950
PHILIPS	Sensitivity	19	0.842	0.624	0.945
	Specificity	21	0.857	0.654	0.950
SIEMENS	Sensitivity	36	0.889	0.747	0.956
	Specificity	33	0.818	0.656	0.914
TOSHIBA	Sensitivity	42	0.976	0.877	0.996
	Specificity	28	0.929	0.774	0.980
Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Female	Sensitivity	96	0.958	0.898	0.984
	Specificity	53	0.868	0.752	0.935
Male	Sensitivity	36	0.861	0.713	0.939
	Specificity	51	0.902	0.790	0.957
ANR Size	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
[4, 5)	Sensitivity	41	0.927	0.806	0.975
[5, 7)	Sensitivity	54	0.944	0.849	0.981
[7, 10)	Sensitivity	28	0.893	0.728	0.963
[10, 25)	Sensitivity	11	1.000	0.741	1.000
ANR Location	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
ACA	Sensitivity	8	1.000	0.676	1.000
ACOM	Sensitivity	29	0.931	0.780	0.981
Basilar/PCA	Sensitivity	18	0.944	0.742	0.990
ICA	Sensitivity	40	0.900	0.769	0.960
MCA	Sensitivity	33	0.939	0.804	0.983
VA/PICA	Sensitivity	6	1.000	0.610	1.000

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

Safety & Effectiveness:
Rapid ANRTN 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 14971:2019 (risk management). The Rapid ANRTN performance has been validated with case data.

Rapid ANRTN has been developed using the cybersecurity framework defined within the FDA Draft Guidance: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Conclusion:

In conclusion, the iSchemaView Rapid ANRTN software device is substantially equivalent in intended use, technological characteristics, safety and performance characteristics to the legally marketed predicate device, Viz.AI ANX Software (K213319).