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

Re: K222884 March 2, 2023
Trade/Device Name: Rapid NCCT Stroke
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: February 9, 2023
Received: February 10, 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, 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)*
K222884

Device Name
Rapid NCCT Stroke

Indications for Use *(Describe)*
Rapid NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) nonenhanced head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) NCCT large vessel occlusion (LVO) of the ICA and MCA-M1.

Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Notifications include compressed preview images that 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 it is not intended to be used as a primary diagnostic device. The results of Rapid NCCT Stroke 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 ultimately responsible for reviewing full images per the standard of care. Rapid NCCT Stroke is for Adults only.

Cautions:
• All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output.
• The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for "Suspected LVO" should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup.

Limitations:
• Rapid NCCT Stroke does not replace the need for CTA or MRA in ischemic stroke workup, it provides workflow prioritization and notification only.
• Rapid ICH has been shown to reliably identify hemorrhages of ≥ 0.4ml.

Contraindications/Exclusions
• Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
• Hemorrhagic Transformation, Hematoma
• Very thin or no Ventricles

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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510(k) Summary

iSchemaView, Inc.'s Rapid NCCT Stroke

This document contains the 510(k) summary for the iSchemaView Rapid NCCT Stroke. 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 Ave., Ste. 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: February 28, 2023

Device Name and Classification:

Trade Name:	Rapid NCCT Stroke
Common Name:	Radiological computer aided triage and notification software
Classification:	II
Product Code:	QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

The Rapid NCCT Stroke device is claimed to be substantially equivalent to the following legally marketed predicate device: Avicenna's CINA device (K200855).

Device Description:

Rapid NCCT Stroke (RNS) is a radiological computer-assisted triage and notification software device. RNS 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 (ICH) and NCCT Large Vessel Occlusion (LVO) of the ICA and MCA-M1. The RNS is an AI/ML SaMD. The output of the module is a priority notification to clinicians indicating the suspicion of ICH or NCCT LVO. ICH analysis uses the ICH Algorithm to identify findings within the ICH algorithm; and the NCCT LVO suspicion uses the combined analysis of the ASPECTS and Hyperdense Vessel Sign (HVS) algorithms. The RNS 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 NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) nonenhanced head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating

suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) NCCT large vessel occlusion (LVO) of the ICA and MCA-M1.

Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Notifications include compressed preview images that 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 it is not intended to be used as a primary diagnostic device. The results of Rapid NCCT Stroke 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 ultimately responsible for reviewing full images per the standard of care. Rapid NCCT Stroke is for Adults only.

Cautions:

- All patients should get adequate care for their symptoms including CTA or MRA and/or other appropriate care per the standard clinical practice, irrespective of the device output.
- The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for "Suspected LVO" should not be viewed as indicating that LVO is excluded. All cases should undergo CTA or MRA, per the standard stroke workup.

Limitations:

- Rapid NCCT Stroke does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification only.
- Rapid ICH has been shown to reliably identify hemorrhages of ≥ 0.4ml.

Contraindications/Exclusions/Cautions:

- Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.
- Very thin or no Ventricles

Comparison of Technological Characteristics:

Rapid NCCT Stroke does not raise new questions of safety or effectiveness compared to the previously cleared CINA device (K200855). Both devices are radiological computer-aided triage and notification software applications for determining suspicion of ICH and LVO. The Avicenna device uses both NCCT for ICH and CTA imaging for LVO, while the Rapid device uses the NCCT Scan for both indications. A significant difference between these devices is that the subject device operates on NCCT images to provide a suspected LVO notification instead of CTA. The benefits include the shorter time to a suspected LVO notification by assessing non-contrast imaging immediately, then CTA follow-up per standard of care for stroke workup. The risks stem from the lower sensitivity of the subject device, which is an inherent limitation of the modality. See SE discussion for assessment of these benefits and risks. A caution has been added to notify the user that CTA should still be considered per standard of care in stroke workup as a reinforcement AHA/ASA guidelines. Thus, the Rapid NCCT Stroke software is substantially equivalent.

510(k) Summary

The following table summarizes and compares data on the Rapid NCCT Stroke device, the subject of this filing, with the Avicenna CINA device (K200855). A table comparing the key features of the subject and predicate devices is provided below.

Substantial Equivalence Table		
Comparison Feature	Avicenna CINA (K200855)	Rapid NCCT Stroke – Subject Device
Indications for Use	CINA is a radiological computer aided triage and notification software indicated for use in the analysis of (1) non-enhanced head CT images and (2) CT angiographies of the head. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) CT angiographies of the head for large vessel occlusion (LVO). CINA uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) LVO on a standalone Web application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings. Notifications include compressed preview images that 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 it is not intended to be used as a diagnostic device. The results of CINA 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 ultimately responsible for	Rapid NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) nonenhanced head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) NCCT large vessel occlusion (LVO) of the ICA and MCA-M1. Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Notifications include compressed preview images that 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 it is not intended to be used as a primary diagnostic device. The results of Rapid NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical

	reviewing full images per the standard of care.	images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Rapid NCCT Stroke is for Adults only. Cautions: • All patients should get adequate care for their symptoms including CTA or MRA and/or other appropriate care per the standard clinical practice, irrespective of the device output. • The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for "Suspected LVO" should not be viewed as indicating that LVO is excluded. All cases should undergo CTA or MRA, per the standard stroke workup. Limitations: • Rapid NCCT Stroke does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification only. • Rapid ICH has been shown to reliably identify hemorrhages of ≥ 0.4ml. Contraindications/Exclusions/Cautions: • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma • Very thin or no Ventricles
User	Radiologist	Clinician
Anatomy	Head	Head
Input Data	NCCT (ICH) and CTA(LVO)	NCCT (ICH and LVO)
Technology	AI/ML/Neural Network	AI/ML/Neural Network
Segmentation of ROI	The device does not highlight or direct a user's attention to a specific location in the image file.	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. The device operates in parallel with the standard of care.	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care.
Annotation / Localization	Device does not mark, highlight, or direct users' attention to a specific location in the original image	Device does not mark, highlight, or direct users' attention to a specific location in the original image
Prioritization Notification	Yes	Yes
Clinical SoC Workflow	In parallel to	In parallel to
Technical Pipeline	Two independent Algorithms	Two cascaded functions (ICH then LVO) using three integrated algorithms
Removal of Cases from SoC review	No	No

Performance Standards:

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

EN ISO 14971:2012	Application of Risk Management to Medical Devices
IEC 62304:2015	Medical device software – Software lifecycle processes
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Performance Data:

iSchemaView conducted a retrospective, blinded, multicenter, multinational study with the Rapid NCCT Stroke device with the primary endpoint to evaluate the software's performance in identifying NCCT head images containing intracranial hemorrhage (ICH) and large vessel occlusion (LVO) findings in 254 (ICH Pos:26, LVO Pos: 115, Neg to ICH, LVO:103, Excluded: 10 for age and technical inadequacy) cases.

Sensitivity and specificity exceeded the pre-specified performance goals for ICH and NCCT LVO. Specifically, ICH performance was observed at Se:0.962, Sp:0.974, consistent with the ICH standalone module performance (K221456); and LVO was observed at Se:0.635 (95% CI: 0.544 - 0.717) and Sp: 0.951 (95% CI: 0.891 – 0.979).

In addition, secondary clinical endpoints were used to show expert non-inferiority and non-expert superiority. Rapid NCCT Stroke passed both conditions with a Se for all readers (experts and non-experts) of 0.436, with difference in Se between NCCT Stroke and all readers of 0.199(95%CI: 0.055-0.34); Se for general radiologists of 0.409, with difference in Se of 0.226(95%CI: 0.071-0.381).

510(k) Summary

The Rapid NCCT time-to-notification analysis includes the time to get the DICOM exam, de-identify it (if required), analyze and send a notification back to the PACS/Workstation, email and mobile. The standard of care time-to-open-exam consisted of the time from the initial scan of the patient to when the radiologist first opened the exam for review.

Rapid NCCT Stroke time-to-notification has been documented for all 254 cases with results shown in the following table. The time time-to-exam-open is referenced from DEN170073 which was for LVO only and did not take into account the time from initial CT to CTA; however, the time indicates from image complete to notification which is similar to the subject device in referencing SoC time. The predicate does not reference combined timelines, only individual time for each portion of the device:

The standard of care time-to-exam-open (58.72 minutes: 95% CI 51.5,71.23 is significantly longer than the parallel time-to-notification of the Rapid NCCT Stroke software.

Parameter	Mean	95% CI Lower	95% CI Upper
Time to open in standard of care (Minutes)	58.72	51.50	71.23
Time to notification of Rapid NCCT Stroke (Minutes)	2.5	2.4	2.6
Difference (Minutes)	70.08	NA	NA

Performance across subgroups:

Subgroup analyses were conducted for the LVO indication. The ICH algorithm is the same as the device cleared under K221456.

Performance Metrics by Gender

Gender	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Female	Sensitivity	57	0.579	0.450	0.698
	Specificity	54	0.981	0.902	0.997
Male	Sensitivity	58	0.690	0.562	0.794
	Specificity	45	0.933	0.821	0.977

Performance Metrics by Age Groups

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 50	Sensitivity	12	0.583	0.320	0.807
	Specificity	21	0.905	0.711	0.973
50 - 70	Sensitivity	41	0.610	0.457	0.743
	Specificity	42	0.976	0.877	0.996
>70	Sensitivity	62	0.661	0.537	0.767
	Specificity	35	0.971	0.855	0.995

Performance Metrics by Slice Thickness (LVO)

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
< 4.0	Sensitivity	29	0.724	0.543	0.853
	Specificity	55	0.964	0.877	0.990

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
≥ 4.0	Sensitivity	86	0.605	0.499	0.701
	Specificity	48	0.938	0.832	0.979

Performance Metrics by Manufacturer (LVO)

Manufacturer	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE	Sensitivity	37	0.730	0.570	0.846
	Specificity	11	1.000	0.741	1.000
PHILIPS	Sensitivity	11	0.545	0.280	0.787
	Specificity	22	1.000	0.851	1.000
SIEMENS	Sensitivity	32	0.500	0.336	0.664
	Specificity	59	0.915	0.816	0.963
TOSHIBA	Sensitivity	35	0.686	0.520	0.814
	Specificity	11	1.000	0.741	1.000

In summary, performance validation data, combined with real-world evidence, establish the achievement of effective triage by the Rapid NCCT Stroke device as well as effective notification functionality of the application, as compared to the standard of care for improved time-to-exam-open of a notified case. Due to the lower estimates of performance on Philips and Siemens scanners, additional analysis was performed across subgroups including sites to further assess performance. The assessment of performance on these subgroups of scanners did not reveal any systematic errors related to the device design.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid NCCT Stroke 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) and the software development process conforms to ISO 62304:2015. The Rapid NCCT Stroke performance has been validated through retrospective case data based on expert reader truthing of the data and reader testing.

Substantial Equivalence Discussion:

The subject device has the same intended use as the predicate device to provide triage and prioritization of time-sensitive suspected findings on radiological medical images. The subject device has a new indication compared to the predicate of flagging and triaging suspected LVO of the ICA and MCA-M1 on NCCT. This is expected to result in faster overall notification since NCCT is generally performed first in suspected stroke patient imaging workup. This benefit may be significant for local practices that defer ordering CTA for suspected stroke patients in their workflow.

The lower sensitivity of the device could lead to a greater risk of mis-prioritization of patients under circumstances where delay of additional imaging or treatment could reasonably be expected to worsen outcomes; it may also limit the effectiveness of the device. The risk of mis-

prioritization is mitigated by inclusion of specific language in the notification for cases not suspected of LVO, by the device on NCCT, to clearly indicate that LVO cannot be excluded without CTA or MRA. The risk mitigation also includes additional performance testing to demonstrate that the device is superior to the general radiologists and non-inferior to overall readers, including both neuroradiologists and general radiologists, when triaging the LVO based on NCCT. These mitigations in combination with the significant time-sensitive nature of LVO detection and treatment lead to comparable benefit-risk profile to the predicate, and the device being substantially equivalent for the labeled intended use.

Conclusion:

In conclusion, iSchemaView's Rapid NCCT Stroke is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Avicenna CINA (K200855).