iSchemaView, Inc.
Patricia Setti-Laperch
Sr. Directory of Regulatory Affairs
1120 Washington Ave.
Ste 200 Rm 108
Golden, Colorado 80401

January 22, 2025

Re: K243350
Trade/Device Name: Rapid Neuro3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: December 17, 2024
Received: December 17, 2024

Dear Patricia Setti-Laperch:

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, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243350

Device Name

Rapid Neuro3D

Indications for Use *(Describe)*

Rapid Neuro3D (RN3D) is an image analysis software for imaging datasets acquired with conventional CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bone, tissue, and venous vessels, providing a 3D and 2D visualization of the neurovasculature supplying arterial blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformation (CPR) of the isolated left and right internal carotid and vertebral arteries.
Rapid Neuro3D is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation, and follow-up of any such lesion and treatment planning.
Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.
RN3D is indicated for adults.

Precautions/Exclusions:
o Series containing excessive patient motion or metal implants may impact module output quality.

o The RN3D module will not process series that meet the following module exclusion criteria:
- Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU)
- Series acquired w/cone-beam CT scanners (c-arm CT)
- Series that are non-axial
- Series with a non-supine patient position
- Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician)
- CTA datasets with:
  1) in-plane X and Y FOV < 160mm or > 400mm.
  2) Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm.
  3) in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm.
  4) Z slice spacing of < 0.2 mm or > 1.25 mm.
  5) slice thickness > 1.5mm.
  6) data acquired at x-ray tube voltage < 70kVp or > 150kVp.

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 Neuro3D

This document contains the 510(k) summary for the iSchemaView Rapid Neuro3D. 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 Suite 200 Golden, CO 80401
Official Contact:	Patricia Setti-LaPerch Phone: 650-388-9767 Email: settilaperch@ischemaview.com

Summary Preparation Date: October 25, 2024

Device Name and Classification:

Trade Name:	Rapid Neuro3D
Common Name:	Automated Radiological Image Processing Software
Classification:	II
Product Code:	QIH
Regulation No:	21 C.F.R. §892.2050
Classification Panel:	Radiology Devices

Predicate Devices:

iSchemaView's Rapid Neuro3D is claimed to be substantially equivalent to the following legally marketed predicate device: Rapid (K233582).

Device Description:

Rapid Neuro 3D (RN3D) is a Software as a Medical Device (SaMD) image processing module and is part of the Rapid Platform. It allows for visualization of arterial vessels of the head and neck and identifies and segments arteries of interest in patient CTA exams.

The Rapid Platform provides common functions and services to support image processing modules such as DICOM filtering and job and interface management. The Rapid Platform can be installed on-premises within customer's infrastructure behind their firewall or in a hybrid on-

premises/cloud configuration. The software can be installed on dedicated hardware or a virtual machine. The Rapid Platform accepts DICOM images and, upon processing, returns the processed DICOM images to the source imaging modality or PACS.

The RN3D image processing module is based on pre-trained artificial intelligence / machine-learning models and facilitates a 3D visualization of the neurovasculature supplying arterial blood to the brain. The module analyzes input CTA images in DICOM format and provides a corresponding DICOM series output that can be used by a DICOM viewer, clinical workstations, and PACS systems.

Intended Use/Indications for Use Statement:

Rapid Neuro3D (RN3D) is an image analysis software for imaging datasets acquired with conventional CT Angiography (CTA) from the aortic arch to the vertex of the head. The module removes bone, tissue, and venous vessels, providing a 3D and 2D visualization of the neurovasculature supplying arterial blood to the brain.

Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformation (CPR) of the isolated left and right internal carotid and vertebral arteries.

Rapid Neuro3D is designed to support the physician in confirming the presence or absence of physician-identified lesions and evaluation, documentation, and follow-up of any such lesion and treatment planning.

Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

RN3D is indicated for adults.

Precautions/Exclusions:

- Series containing excessive patient motion or metal implants may impact module output quality.
- The RN3D module **will not process** series that meet the following module exclusion criteria:
    - Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU)
    - Series acquired w/cone-beam CT scanners (c-arm CT)
    - Series that are non-axial
    - Series with a non-supine patient position
    - Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician)
    - CTA datasets with:

        1) in-plane X and Y FOV < 160mm or > 400mm.

2) Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm.

3) in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm.

4) Z slice spacing of < 0.2 mm or > 1.25 mm.

5) slice thickness > 1.5mm.

6) data acquired at x-ray tube voltage < 70kVp or > 150kVp.

Comparison of Technological Characteristics with the Predicate Device:

Rapid Neuro3D's predicate device is Rapid (K233582), under regulation 21 CFR §892.2050. Both are SaMD and share the same intended use as Automated Radiological Image Processing Software utilized when reviewing neurological images. Rapid Neuro3D is substantially equivalent to the previously cleared Rapid (K233582) device and contains analogous CTA software outputs (e.g. 2D/3D vessel visualization and MIPS) facilitated by the automated segmentation and removal of obstructive bones and/or vessels.

Rapid Neuro3D has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate. Rapid Neuro3D raises no new issues of safety or effectiveness when compared with Rapid (K233582). Verification and validation testing confirms the software reliably processes and supports analysis of CTA medical images for visualization of the neurovasculature supplying arterial blood to the brain. Thus, Rapid Neuro3D software is substantially equivalent.

Product Name	**Rapid Neuro3D (Subject Device)**	**Rapid (including Rapid CTA) (K233582)**
Regulation	21 CFR 892.2050; Medical image management and processing system	21 CFR 892.2050; Medical image management and processing system
Product Code	QIH	LLZ, QIH
Intended Use/ Indications for Use Statement	Rapid Neuro3D (RN3D) is an image analysis software for imaging datasets acquired with conventional CT Angiography (CTA) from the aortic arch to the vertex of the head). The module removes bone, tissue, and venous vessels, providing a 3D and 2D visualization of the neurovasculature supplying arterial blood to the brain. Outputs of the device include 3D rotational maximum intensity projections (MIPS), volume renders (VR), along with the curved planar reformation (CPR) of the isolated left and right internal carotid and vertebral arteries. Rapid Neuro3D is designed to support the physician in confirming the presence	Rapid is an image processing software package to be used by trained professionals, including but not limited to physicians (medical analysis and decision making) and medical technicians (administrative case processing). The software runs on a standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Rapid is indicated for Adults only. Rapid provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT, CT Perfusion (CTP), CT Angiography (CTA), C-arm CT Perfusion and MRI including a Diffusion

Product Name	Rapid Neuro3D (Subject Device)	Rapid (including Rapid CTA) (K233582)
	or absence of physician-identified lesions and evaluation, documentation, and follow-up of any such lesion and treatment planning. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment. RN3D is indicated for adults. <u>Precautions/Exclusions:</u> Series containing excessive patient motion or metal implants may impact module output quality. The RN3D module will not process series that meet the following module exclusion criteria: • Series containing inadequate contrast agent (<0.3 mL of right-hemisphere intracranial arterial contrast media or <0.3 mL of left-hemisphere intracranial arterial contrast media, above 120 HU) • Series acquired w/cone-beam CT scanners (c-arm CT) • Series that are non-axial • Series with a non-supine patient position • Series containing missing or improperly ordered slices (e.g., as a result of manual correction by an imaging technician) • CTA datasets with: 1) in-plane X and Y FOV < 160mm or > 400mm. 2) Z FOV (cranio-caudal transverse anatomical coverage) < 90 mm. 3) in-plane pixel spacing (X & Y resolution) < 0.2 mm or > 1.0 mm. 4) Z slice spacing of < 0.2 mm or > 1.25 mm. 5) slice thickness > 1.5mm. 6) data acquired at x-ray tube voltage < 70kVp or > 150kVp.	Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI, CT, and C-arm CT). Rapid C-arm CT Perfusion can be used to qualitatively assess cerebral hemodynamics in the angiography suite. The CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue. The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion -weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Rapid CT Perfusion and Rapid MR Perfusion can be used by physicians to aid in the selection of acute stroke patients (with known occlusion of the intracranial internal carotid artery or proximal middle cerebral artery). Instructions for the use of contrast agents for this indication can be found in Appendix A of the User's Manual. Additional information for safe and effective drug use is available in the product-specific iodinated CT and gadolinium-based MR contrast drug labeling. In addition to the Rapid imaging criteria, patients must meet the clinical requirements for thrombectomy, as assessed by the physician, and have none of the following contraindications or exclusions: • Bolus Quality: absent or inadequate bolus. • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate.

510(k) Summary

Product Name	Rapid Neuro3D (Subject Device)	Rapid (including Rapid CTA) (K233582)
		• Presence of hemorrhage. • C-Arm CTP is not used in the Rapid Thrombectomy indication for patient selection criteria, other modalities should be consulted. <u>Caution</u> CBV and CBT are not absolute and CBT, CBV, MTT and Tmax are supported for qualitative interpretation of the perfusion maps only.
Intended Users	Radiologists, neurovascular and neurosurgical specialists, such as vascular neurosurgeons, neuro-interventional specialists, ED physicians, or users with similar training.	Medical imaging professionals who analyze tissue using CT or MRI images
Technological Characteristics		
Functionality	Software package (SaMD) which interfaces to a PACS/Viewer or allows viewing within the application.	Software package (SaMD) which interfaces to a PACS/Viewer or allows viewing within the application.
Computer Platform	Standard off-the-shelf Hardware: On-Premises or Cloud Hybrid	Standard off-the-shelf Hardware: On-Premises or Cloud Hybrid
Technical Implementation	AI/ML	Mixed - Traditional Coding and AI/ML
Input DICOM Imaging Modality	CTA	CT, CTP, CTA, C-arm CT, MRI, NCCT
Imaging Type	Neurological (aortic arch to the vertex of the head)	Neurological
Software Outputs	• 2D/3D vessel visualization (Thins, MIPS, VR, CPR) • Automated segmentation and removal of obstructive bones and/or vessels	• Digital image processing, visualization, and analysis tools (various detailed in IFU above, including tissue flow (perfusion), tissue blood volume, etc.) Specifically for Rapid CTA: • 2D/3D vessel visualization (MIPS, colored overlay indicating reduction of vessel density) • Automated segmentation and removal of obstructive bones and/or vessels

Performance Standards:

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

ISO 14971:2019	Application of Risk Management to Medical Devices
IEC 62304:2015	Medical Device software – Software lifecycle processes
IEC 62366-1:2015 +A1:2020	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)
ISO 15223-1:2021	Symbols to be Used with Information to be Supplied by the Manufacturer

Rapid has been designed to meet the cybersecurity requirements using design Vulnerability Assessments, SBOM's, and PEN Testing.

Performance Data:

Rapid 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 performance validation testing and software verification and validation testing of the Rapid Neuro3D device. Software performance testing demonstrated that the device met all design requirements and specifications. Final device validation included standalone performance validation (segmentation quality and segmentation accuracy).

All major CT scanner manufacturers (incl. Siemens, GE, Toshiba/Canon, and Philips) were represented in the data. Patient demographics included representative age/gender distribution and incorporated data to assess the influence of potential confounders (abnormalities/anomalies/ anatomical variants) on performance. The test dataset was independent from the data used during model training per internal data quality control processes.

The segmentation quality study used 120 CTA cases (104 US, 16 OUS) from 115 patients (65 female; 50 male; aged from 27 to 90+) to compare the Rapid Neuro3D segmentation outputs against source DICOM images. All four output image types were evaluated: 3D rotational maximum intensity projection (MIP) images, 3D volume rendering (VR) images, a source series-equivalent (SSE) with all tissue/bone/vein removed, and 2D curved planar reformation (CPR) images. MIP, VR, and SSE images were assessed for a total of 1,920 segments; CPR images included 480 segments.

The primary endpoint, clinical accuracy, as determined by the consensus of up to three clinical experts against the source DICOM images, passed for all RN3D outputs with 99.8% agreement for MIP images, 98.6% agreement for VR images, 100.0% agreement for SSE images, and 100.0% agreement for CPR.

The secondary endpoint, labeling, passed with 100% of the anatomical labels applied found to be accurate for the vessels visualized.

510(k) Summary

The segmentation accuracy study used 50 CTA cases (43 US, 7 OUS) from 48 patients (24 female; 24 male; aged from 27 to 90+) to quantitatively assess the Rapid Neuro3D segmentation outputs against ground truth.

The assessment for 3D visualizations was divided by anatomical region: extracranial and intracranial. For the extracranial region, the primary endpoint, segmentation accuracy, was met with an average Dice Coefficient of 0.89 and an average Hausdorff Distance of 0.44 mm between the module and ground truth. For the intracranial region, the primary endpoint, substantial equivalence, was met with an average Dice Coefficient of 0.97 and an average Hausdorff Distance of 0.44mm between the module and the predicate device.

The secondary endpoint, reproducibility (of ground truths), showed a within case variance of 1%, demonstrating strong reproducibility of ground truth segmentations.

For the CPR visualizations, the primary endpoint, centerline accuracy, was met with an average Hausdorff Distance of 0.31 mm between the module and ground truth.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid Neuro3D 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 IEC 62304:2015. Software performance, validation and verification testing demonstrated that the Rapid Neuro3D system met all design requirements.

Conclusion:

Based on the shared technological characteristics and intended use, iSchemaView's Rapid Neuro3D is substantially equivalent to the legally marketed predicate device, Rapid (K233582). The results of performance validation and software verification/validation testing support the safety and performance of Rapid Neuro3D.