September 23, 2025

iSchemaView, Inc.
Jim Rosa
Sr. Directory of Regulatory Affairs, Chief Regulatory and Compliance Officer
1120 Washington Ave.
Ste 200
Golden, CO 80401

Re: K251987
Trade/Device Name: Rapid Aortic Measurements
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 27, 2025
Received: August 28, 2025

Dear Jim Rosa:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-

devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Wenbo Li

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

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.	K251987

Please provide the device trade name(s).

Rapid Aortic Measurements

Please provide your Indications for Use below.

Rapid Aortic Measurements (AM) is an image analysis and measurement device to evaluate aortic and iliac arteries in contrast enhanced and non-contrast CT imaging datasets acquired of the chest, abdomen, and/or pelvis. The module segments the aorta, iliacs, and major branching vessels and provides 2D and 3D visualizations of the segmented vessels.

Outputs of the device include: Centerline measurements of the aorta and iliacs, Aortic Zone Measurements (Maximum Oblique Diameter), Fixed Measurements of the aorta and left and right iliacs, 3D Volume Renderings, Rotations, Curved Planar Reformations (CPRs) of the isolated left and right iliacs, aortic oblique Multiplanar Reconstructions (MPRs), and Longitudinal Tracking visualizations.

Rapid Aortic Measurements is an aid to physician decision making. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

Rapid Aortic Measurements is indicated for adults.

Precautions/Exclusions:
o Series containing excessive patient motion or metal implants may impact module output quality.
o The AM module will not process series that meet the following module exclusion criteria:
- Series acquired w/cone-beam CT scanners (c-arm CT)
- Series that are non-axial or axial oblique greater than 5 degrees
- Series containing improperly ordered or missing slices where the gap is larger than 3 times the median inter-slice distance (e.g., as a result of manual correction by an imaging technician)
- Series with less than 3cm of target anatomical zones (e.g. aorta or right/left iliac artery)
- NCCT, CECT, CTA, or CTPA datasets with:
  1) in-plane X and Y FOV < 160mm
  2) Z FOV (cranio-caudal transverse anatomical coverage) < 144 mm.
  3) in-plane pixel spacing (X & Y resolution) < 0.3 mm or > 1.0 mm.
  4) inter-slice distance of < 0.3 mm or > 3 mm.
  5) slice thickness > 3 mm.
  6) data acquired at x-ray tube voltage < 70kVp or > 150kVp, including single energy, dual energy, or virtual monochromatic datasets

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

iSchemaView, Inc.'s Rapid Aortic Measurements

This document contains the 510(k) summary for the iSchemaView Rapid Aortic Measurements. 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:	Jim Rosa Phone: +13037043374 Email: rosa@ischemaview.com

Summary Preparation Date: September 17, 2025

Device Name and Classification:

Trade Name:	Rapid Aortic Measurements
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 Aortic Measurements is claimed to be substantially equivalent to the following legally marketed predicate device: Rapid Neuro3D (K243350).

Device Description:

Rapid Aortic Measurements (AM) is a Software as a Medical Device (SaMD) image processing module and is part of the Rapid Platform. It provides analysis of chest, abdomen, and pelvis non-contrast CT (NCCT), contrast enhanced (CT, CTP (CT- Pulmonary Angiogram, and CTA (CT-Angiography)) for the reconstructed 3D visualization and measurement of arteries from the aortic root to the iliac arteries.

Rapid AM is integrated into the Rapid Platform which provides common functions and services to support image processing modules such as DICOM filtering and job and interface

management along with external facing cyber security controls. The Integrated Module and Platform can be installed on-premises within customer's infrastructure behind their firewall or in a hybrid on-premises/cloud configuration. The Rapid Platform accepts DICOM images and, upon processing, returns the processed DICOM images to the source imaging modality or PACS.

Indications for Use:

Rapid Aortic Measurements (AM) is an image analysis and measurement device to evaluate aortic and iliac arteries in contrast enhanced and non-contrast CT imaging datasets acquired of the chest, abdomen, and/or pelvis. The module segments the aorta, iliacs, and major branching vessels and provides 2D and 3D visualizations of the segmented vessels.

Outputs of the device include: Centerline measurements of the aorta and iliacs, Aortic Zone Measurements (Maximum Oblique Diameter), Fixed Measurements of the aorta and left and right iliacs, 3D Volume Renderings, Rotations, Curved Planar Reformations (CPRs) of the isolated left and right iliacs, aortic oblique Multiplanar Reconstructions (MPRs), and Longitudinal Tracking visualizations.

Rapid Aortic Measurements is an aid to physician decision making. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment.

Rapid Aortic Measurements is indicated for adults.

Precautions/Exclusions:

o Series containing excessive patient motion or metal implants may impact module output quality.
o The AM module will not process series that meet the following module exclusion criteria:
- Series acquired w/cone-beam CT scanners (c-arm CT)
- Series that are non-axial or axial oblique greater than 5 degrees
- Series containing improperly ordered or missing slices where the gap is larger than 3 times the median inter-slice distance (e.g., as a result of manual correction by an imaging technician)
- Series with less than 3cm of target anatomical zones (e.g. aorta or right/left iliac artery)
- NCCT, CECT, CTA, or CTPA datasets with:
  1) in-plane X and Y FOV < 160mm
  2) Z FOV (cranio-caudal transverse anatomical coverage) < 144 mm.
  3) in-plane pixel spacing (X & Y resolution) < 0.3 mm or > 1.0 mm.
  4) inter-slice distance of < 0.3 mm or > 3 mm.
  5) slice thickness > 3 mm.
  6) data acquired at x-ray tube voltage < 70kVp or > 150kVp, including single energy, dual energy, or virtual monochromatic datasets

Comparison of Technological Characteristics with the Predicate Device:

Rapid Aortic Measurements' predicate device is Rapid Neuro3D (Lumina3D) (K243350), 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 Aortic Measurements is substantially equivalent to the previously cleared Rapid Neuro3D (Lumina3D) device and contains analogous 3D segmentation and 2D/3D vessel visualization outputs (including VRs and CPRs), which have been validated via segmentation quality and accuracy. Measurement accuracy has been validated and compares to the reference device, Rapid RV/LV (K223396).

Rapid Aortic Measurements has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate. Rapid Aortic Measurements raises no new issues of safety or effectiveness when compared with Rapid Neuro3D (Lumina3D). Verification and validation testing confirms the software reliably processes and supports analysis of CECT, CTA, CTPA, and NCCT medical images for 3D and 2D visualization and measurement of the segmented aorta, iliac arteries, and major branching vessels. Thus, Rapid Aortic Measurements software is substantially equivalent.

Product Name	**Rapid Aortic Measurements (AM) (subject device)**	**Rapid Neuro3D (Marketed as Lumina3D) (K243350)**
Regulation	21 CFR 892.2050; Medical image management and processing system	21 CFR 892.2050; Medical image management and processing system
Product Code	QIH	QIH
Intended Use/ Indications for Use Statement	Rapid Aortic Measurements (AM) is an image analysis and measurement device to evaluate aortic and iliac arteries in contrast enhanced and non-contrast CT imaging datasets acquired of the chest, abdomen, and/or pelvis. The module segments the aorta, iliacs, and major branching vessels and provides 2D and 3D visualizations of the segmented vessels. Outputs of the device include: Centerline measurements of the aorta and iliacs, Aortic Zone Measurements (Maximum Oblique Diameter), Fixed Measurements of the aorta and left and right iliacs, 3D Volume Renderings, Rotations, Curved Planar Reformations (CPRs) of the isolated left and right iliacs, aortic oblique Multiplanar Reconstructions (MPRs), and Longitudinal Tracking visualizations. Rapid Aortic Measurements is an aid to physician decision making. Its results are not intended to be used on a stand-alone basis for clinical decision-making or otherwise preclude clinical assessment. Rapid Aortic Measurements is indicated for adults.	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:

510(k) Summary

Product Name	**Rapid Aortic Measurements (AM) (subject device)**	**Rapid Neuro3D (Marketed as Lumina3D) (K243350)**
	Precautions/Exclusions: o Series containing excessive patient motion or metal implants may impact module output quality. o The AM module will not process series that meet the following module exclusion criteria: • Series acquired w/cone-beam CT scanners (c-arm CT) • Series that are non-axial or axial oblique greater than 5 degrees • Series containing improperly ordered or missing slices where the gap is larger than 3 times the median inter-slice distance (e.g., as a result of manual correction by an imaging technician) • Series with less than 3cm of target anatomical zones (e.g. aorta or right/left iliac artery) • NCCT, CECT, CTA, or CTPA datasets with: 1) in-plane X and Y FOV < 160mm 2) Z FOV (cranio-caudal transverse anatomical coverage) < 144 mm. 3) in-plane pixel spacing (X & Y resolution) < 0.3 mm or > 1.0 mm. 4) inter-slice distance of < 0.3 mm or > 3 mm. 5) slice thickness > 3 mm. 6) data acquired at x-ray tube voltage < 70kVp or > 150kVp, including single energy, dual energy, or virtual monochromatic datasets	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 < 70 kVp or >150 kVp.
Intended Users	Radiologists, cardiothoracic surgeons, vascular surgeons, endovascular specialists, ED physicians, or users with similar training.	Radiologists, neurovascular and neurosurgical specialists, such as vascular neurosurgeons, neuro-interventional specialists, ED physicians, or users with similar training.
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: Cloud Hybrid	Standard off-the-shelf Hardware: On-Premises or Cloud Hybrid
Technical Implementation	AI/ML; traditional	AI/ML
Input DICOM Imaging Modality	CECT, CTA, CTPA, NCCT	CTA
Imaging Type	Chest, Abdomen, and/or Pelvis (aorta and iliacs)	Neurological (aortic arch to the vertex of the head)

510(k) Summary

Product Name	Rapid Aortic Measurements (AM) (subject device)	Rapid Neuro3D (Marketed as Lumina3D) (K243350)
Software Outputs	• 2D/3D vessel visualization (VRs, CPRs, MPRs) • Automated segmentation and removal of obstructive bones and/or vessels • Automated vessel centerlines and measurements • Comparison/longitudinal tracking	• 2D/3D vessel visualization (Thins, MIPS, VR, CPR) • Automated segmentation and removal of obstructive bones and/or vessels

Performance Standards:

Rapid Aortic Measurements 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 Aortic Measurements 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 Aortic Measurements device. Software performance testing demonstrated that the device met all design requirements and specifications. Final device validation included 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 design used 108 NCCT, CTA, or CECT/CTPA cases (54 US, 24 OUS; 30 unknown) from 115 patients (70 male; 38 female; aged from 22 to 90+) to compare the Rapid AM segmentation outputs against source DICOM images. All three technologically unique output types [3D volume rendering images (VR), 2D curved/multiplanar reformation images (CPR and MPR) and measurement reports] were assessed. VR, Stretched and

510(k) Summary

Straightened CPRs, Oblique MPRs, and Measurement outputs were assessed for a total of 2,268; 756 (each); 324; and 666 vessel segments, respectively.

For assessment of VR outputs, the primary endpoint, segmentation quality/clinical accuracy, as determined by the consensus of up to three clinical experts against the source DICOM images, passed with 100% agreement. For assessment of CPR/MPR outputs, the primary endpoint, CPR/MPR quality, passed with 100% agreement. The secondary endpoint, anatomical labeling, passed with 100% agreement between readers for all labels reviewed across imaging types.

For assessment of zone measurement outputs, the primary endpoint, maximum oblique diameter location accuracy, passed with 100% agreement between readers for all segments reviewed across imaging types. All longitudinal results were deemed to have clinically accurate measurements placed within their respective zones for physician comparison.

The segmentation accuracy study used the previously detailed 108 cases to quantitatively assess Rapid AM segmentation and measurement outputs against ground truth.

For VR outputs, the primary endpoint passed with an average Dice coefficient of 0.93 and average Hausdorff distance of 0.54 mm. For CPR and MPR visualizations, the primary endpoint (centerline accuracy) passed with an average Hausdorff distance of 0.59mm. The secondary endpoint, reproducibility of generating ground truths, showed an average Dice coefficient of 0.95, demonstrating strong reproducibility of ground truth segmentations.
For Measurement reports, AM measurements were compared to measurements taken from approved ground truth segmentations using a validated technique and the mean absolute error (MAE) was found to be 0.22 cm, which compares favorably with the reference device.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid Aortic Measurements 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 Aortic Measurements system met all design requirements.

Conclusion:

Based on the shared technological characteristics and intended use, iSchemaView's Rapid Aortic Measurements is substantially equivalent to the legally marketed predicate device, Rapid Neuro3D (K243350). The results of performance validation and software verification/validation testing support the safety and performance of Rapid Aortic Measurements.