August 26, 2025

iSchemaView, Inc.
James Rosa
Chief Regulatory and Compliance Officer
1120 Washington Ave., Suite 200
Golden, Colorado 80401

Re: K252526
Trade/Device Name: Rapid DeltaFuse
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 5, 2025
Received: August 11, 2025

Dear James Rosa:

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

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

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, 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)*
K252526

Device Name
Rapid DeltaFuse

Indications for Use *(Describe)*
Rapid DeltaFuse is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.

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 DeltaFuse provides both viewing and analysis capabilities for imaging datasets acquired with Non-Contrast CT (NCCT) images.

The CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue including overlays of time differentiated scans of the same patient.

Rapid DeltaFuse is intended for use for adults.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

iSchemaView, Inc.'s Rapid DeltaFuse

This document contains the 510(k) summary for the iSchemaView Rapid DeltaFuse device. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Applicant Name and Address:

Name:	iSchemaView, Inc.
Address:	1120 Washington Ave Suite 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: +13037043374 Email: rosa@ischemaview.com

Summary Preparation Date: August 7, 2025

Device Name and Classification:

Trade Name:	Rapid DeltaFuse
Common Name:	Medical image management and processing system
Classification:	II
Product Code:	LLZ
Regulation No:	21 C.F.R. §892.2050
Classification Panel:	Radiology Devices

Predicate Devices:

iSchemaView's Rapid DeltaFuse is claimed to be substantially equivalent to the following legally marketed predicate device: Rapid (K213165).

Device Description:

Rapid DeltaFuse (DF) is a Software as a Medical Device (SaMD) image processing module and is part of the Rapid Platform. It provides visualization of time differentiated neuro hyperdense and hypodense tissue from Non-Contrast CT (NCCT) images.

Rapid DF 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

510(k) Summary

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.

Intended Use/Indications for Use Statement:

Rapid DeltaFuse is an image processing software package to be used by trained professionals, including but not limited to physicians and medical technicians.

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 DeltaFuse provides both viewing and analysis capabilities for imaging datasets acquired with Non-Contrast CT (NCCT) images.

The CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue including overlays of time differentiated scans of the same patient.

Rapid DeltaFuse is intended for use for adults.

Comparison of Technological Characteristics with the Predicate Device:

Rapid DeltaFuse' predicate device is Rapid (K213165), under regulation 21 CFR §892.2050. Both are SaMD and share the same intended use regarding the mapping of hyperdense and hypodense regions as Automated Radiological Image Processing Software utilized when reviewing neurological images. Rapid DeltaFuse is substantially equivalent to the previously cleared Rapid device when limited to the hyperdense and hypodense mapping using Hounsfield Unit (Hu) Maps. The primary difference in the subject device is the time differentiated overlays of hyperdense and hypodense regions whereas the Rapid Platform provides additional independent analysis not included in the subject device. The devices have similar technological characteristics, and principles of operation regarding the limited features provided in the subject device. Rapid DeltaFuse raises no new issues of safety or effectiveness when compared with Rapid. Verification and validation testing confirms the software reliably processes and supports analysis of NCCT medical images for visualization of change. Thus, Rapid DeltaFuse software is substantially equivalent, when compared to the specific hyperdense and hypodense features of the predicate.

Product	**Predicate: Rapid (K213165)**	**Subject Device: Rapid DeltaFuse**
Regulation	21 CFR 892.2050; Medical image management and processing system	21 CFR 892.2050; Medical image management and processing system
Product Code	LLZ, QIH	LLZ
IFU	Rapid is an image processing software package to be used by	Rapid DeltaFuse is an image processing software package to be

Product	Predicate: Rapid (K213165)	Subject Device: Rapid DeltaFuse
	trained professionals, including but not limited to physicians and medical technicians. 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 provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT, CT Perfusion (CTP), CT Angiography (CTA), and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT). 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	used by trained professionals, including but not limited to physicians and medical technicians. 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 DeltaFuse provides both viewing and analysis capabilities for imaging datasets acquired with Non-Contrast CT (NCCT) images. The CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue including overlays of time differentiated scans of the same patient. Rapid DeltaFuse is intended for use for adults.

Product	Predicate: Rapid (K213165)	Subject Device: Rapid DeltaFuse
	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 • Presence of hemorrhage	
Intended Users	Trained professionals, including but not limited to physicians and medical technicians.	Same
Output	Software package (SaMD) which interfaces to a PACS/Viewer or allows viewing within the application; and email.	Software package (SaMD) which interfaces to a PACS/Viewer or allows viewing within the application; and email.
Computer Platform	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.	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.
Technical Implementation	AI/ML; traditional Coding	Traditional Coding

510(k) Summary

Product	Predicate: Rapid (K213165)	Subject Device: Rapid DeltaFuse
Input DICOM Imaging Modality	CT, CTP, MR, NCCT	NCCT
Imaging Region	Brain, Head or Head and Neck	Same
Functionality Supported	CT and MRI Perfusions, MR Diffusion, MR Dynamic Analysis, NCCT hyperdensity and Hypodensity, Motion Artifact Filter.	NCCT Hyperdensity and Hypodensity with overlay.

Performance Standards:

Rapid DeltaFuse 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)

Rapid DeltaFuse 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 DeltaFuse device in accordance with 21 CFR 820. Software performance testing demonstrated that the device performance met all design requirements and specifications. Final device validation included co-registration validation.

The co-registration analysis showed a DICE of 0.94 (LB 0.93) using 14 cases to show the correlation of slice overlays.

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid DeltaFuse 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. The Rapid DF performance has been validated with a 0.95 DICE coefficient for the overlay addition to validate the overlay performance, validation and verification testing demonstrated that the Rapid DeltaFuse system met all design requirements.

Conclusion:

Based on the shared technological characteristics and intended use, iSchemaView's Rapid DeltaFuse is substantially equivalent to the legally marketed predicate device, Rapid (K213165) features on Hyperdensity and Hypodensity display with the addition of image overlay. The results of performance validation and software verification/validation testing supports the comparative safety and performance of Rapid DeltaFuse.