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

May 17, 2022

Re: K220499
Trade/Device Name: Rapid PE Triage and Notification (PETN)
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: April 13, 2022
Received: April 14, 2022

Dear Mr. 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)*

K220499

Device Name
Rapid PE Triage and Notification (PETN)

Indications for Use *(Describe)*

Rapid PE Triage and Notification (PETN) is a radiological computer aided triage and notification software indicated for use in the analysis of CTPA images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of central pulmonary embolism (PE) pathology in adults. The software is only intended to be used on single-energy exams.

Rapid PETN uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of Rapid PETN are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care. Rapid PETN is validated for use on GE, Siemens and Toshiba scanners.

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.

510(k) Summary

iSchemaView, Inc.'s Rapid PE Triage and Notification (PETN)

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

Applicant Name and Address:

Name:	iSchemaView, Inc.
Address:	1120 Washington St., Suite 200 Golden, CO 80401
Official Contact:	Jim Rosa Phone: (303) 704-3374 Email: rosa@ischemaview.com

Summary Preparation Date: February 12, 2022

Device Name and Classification:

Trade Name:	Rapid PE Triage and Notification (PETN)
Common Name:	PACS – Picture Archiving Communications System
Classification:	II
Product Code:	Primary: QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

Predicate Devices:

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

Aidoc Briefcase (K190072)

Device Description:

Rapid PETN is a radiological computer-assisted triage and notification software device. The Rapid PETN module is a contrast enhanced CTPA processing module which operates within the integrated Rapid Platform to provide triage and notification prioritization of suspected Central Pulmonary Emboli (PE). The PETN module is an AI/ML module. The output of the module is a priority notification to clinicians indicating the suspicion of central PE based on positive findings. The Rapid PETN 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 PE Triage and Notification (PETN) is a radiological computer aided triage and notification software indicated for use in the analysis of CTPA images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of central pulmonary embolism (PE) pathology in adults. The software is only intended to be used on single-energy exams.

Rapid PETN uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a server or standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device.

The results of Rapid PETN are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care. Rapid PETN is validated for use on GE, Siemens and Toshiba scanners.

Technological Characteristics and Substantial Equivalence:

Rapid PETN does not raise new questions of safety or effectiveness compared to the previously cleared Briefcase (K190072). Both devices are radiological computer-aided triage and notification software applications for use with CTPA input. There are minor differences in intended use and technical characteristics with the predicate device; however, with the minor change excluding the ICH claims, the clinical use for Rapid PETN is the same as the CTPA indication for the predicate with no additional risk. Thus, the Rapid PETN software is substantially equivalent.

The following table summarizes and compares data on the Briefcase (K190072) to the Rapid PETN that is the subject of this Traditional 510(k) submission.

Parameter	**K190072 - Predicate Device**	**Rapid PETN – Subject Device**
Product Code	QAS	QAS
Regulation	21 CFR §892.2080	21 CFR §892.2080
Intended Use/ Indications for Use	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of non-enhanced head CT and CTPA images. The device is intended to assist hospital networks and trained radiologists in workflow triage by flagging and communication of suspected positive findings of Intracranial Hemorrhage (ICH) and Pulmonary Embolism (PE) pathologies. For the PE pathology, the software is only intended to be used on single-energy exams.	Rapid PE Triage and Notification (PETN) is a radiological computer aided triage and notification software indicated for use in the analysis of CTPA images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communication of suspected positive findings of central pulmonary embolism (PE) pathology in adults. The software is only intended to be used on single-energy exams. Rapid PETN uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a server or

Parameter	**K190072 - Predicate Device**	**Rapid PETN – Subject Device**
	BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.	standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of Rapid PETN are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care. Rapid PETN is validated for use on GE, Siemens and Toshiba scanners.
User	Radiologist	Radiologist, Clinician
Basic PACS Functions	Software package which interfaces to a PACS or allows viewing within the application	Same
Computer Platform	PC	Server or Workstation
Software	AI/ML	AI/ML
DICOM Compliance	Yes, using CT and CTPA	Yes, using CTPA
Segmentation	No, Device does not mark, annotate, or direct users' attention to a specific location in the original image	No, Device does not mark, annotate, or direct users' attention to a specific location in the original image
Preview Images	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.	Presentation of a small, compressed, black and white preview image that is labeled "Not for diagnostic use"; The device operates in parallel with the standard of care, which remains the default option for all cases.
Alteration of original image	No	No
Removal of cases from workflow queue	No	No

AI/ML Module Development:

Algorithm development, including development validation, was performed using 600 (Pos:300, Neg:300) CTPA cases from multiple sites. The data was split into 480 (Pos:240, Neg:240) training cases and 120 (Pos:60, Neg:60) development validation cases. The optimal design performance for the final solution showed a Sensitivity = 0.98 and Specificity = 0.97. The development data included the following distributions:

Table 1: Age Distribution for Development & Training				
PE status	Mean age	Median age	Min age	Max age
Positive (N=300)	63	64	22	93
Negative (N=300)	51	51	17	89

Table 2: Gender Distribution for Development & Training			
PE status	Female	Male	Unknown
Positive (N=300)	52%	47%	< 1%
Negative (N=300)	63%	37%	0%

Table 3: Scanner Distribution for Development & Training					
PE status	GE	Siemens	Philips	Toshiba	Unknown
Positive (N=300)	39%	22%	13%	24%	< 2%
Negative (N=300)	72%	9%	< 1%	19%	0%

An additional 276 negative cases were included to further assess the specificity of the final model. The data included the following distributions:

Table 4: Age Distribution for Development Validation				
PE status	Mean age	Median age	Min age	Max age
Negative (N=276)	56	58	19	91

Table 5: Gender Distribution for Development Validation			
PE status	Female	Male	Unknown
Negative (N=276)	55%	45%	0%

Table 6: Scanner Distribution for Development Validation					
PE status	GE	Siemens	Philips	Toshiba	Unknown
Negative (N=276)	25%	4%	0%	72%	0%

Clinical Characteristics:

The primary users of Rapid PETN software are medical imaging professionals who analyze CTPA images. Rapid PETN provides notification to the physicians of suspected Central PE. The physicians must evaluate the cases for determination/confirmation of PE through their normal standard of care review once prioritization is received. The Rapid PETN is intended for Adult cases.

Performance Standards:

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

EN ISO 14971:2019	Application of Risk Management to Medical Devices
IEC 62304:2016	Medical device software – Software lifecycle processes
IEC 62366:2015	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Performance Data:

Rapid PE complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association (NEMA PS 3.1 - 3.20).

iSchemaView conducted extensive performance validation testing and software verification and validation testing of the Rapid PETN module. Final device validation included standalone performance validation. This performance validation testing demonstrated the Rapid PETN device provides accurate representation of key processing parameters under a range of clinically relevant perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid PETN Module met all design requirements and specifications.

Final performance validation included 306 CTPA cases with ground truth established by 3 experts using a 2:3 confirmation. The primary endpoint passed with Sensitivity = 0.96 (0.92,0.98) and Specificity = 0.89 (0.83,0.93). The cases were split Male:47%, Female 53% with an age range of 22-95 years. The samples were mixed from GE, Philips, Toshiba and Siemens scanners. The secondary endpoint was passed at 2.64 minutes (2.34-4.80 min) processing time, with negligible notification time using wireless and cellular communications. The following tables provide sub-stratification for demographic and scanner performance:

Table 1: Gender

Gender	Measure	Estimate	Lower 95% CI	Upper 95% CI
Female (162)	Sensitivity	0.934	0.855	0.972
	Specificity	0.930	0.856	0.968
Male (144)	Sensitivity	0.986	0.927	0.998
	Specificity	0.829	0.724	0.899

Table 2: Age

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
unknown	Sensitivity	72	0.972	0.904	0.992
	Specificity	4	0.250	0.046	0.699
< 50	Sensitivity	3	1.000	0.439	1.000
	Specificity	34	0.914	0.776	0.970
50 - 70	Sensitivity	33	0.970	0.847	0.995
	Specificity	66	0.924	0.835	0.967
>70	Sensitivity	33	0.970	0.847	0.995

Age	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
	Specificity	66	0.924	0.835	0.967

Table 3: Scanner Brand

Mfr	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
GE	Sensitivity	41	0.976	0.874	0.996
	Specificity	51	0.882	0.766	0.945
TOSHIBA	Sensitivity	21	0.952	0.773	0.992
	Specificity	58	0.966	0.883	0.990
SIEMENS	Sensitivity	16	0.938	0.717	0.989
	Specificity	43	0.860	0.727	0.934

Table 4: Slice Thickness

Slice Thickness	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
<1.5	Sensitivity	96	0.931	0.836	0.973
	Specificity	150	0.910	0.838	0.952
≥1.5	Sensitivity	54	0.978	0.924	0.994
	Specificity	6	0.842	0.726	0.915

Table 5: Detector Rows

Rows	Measure	N	Estimate	Lower 95% CI	Upper 95% CI
Unknown	Sensitivity	2	1.000	-	-
	Specificity	0	-	-	-
16	Sensitivity	3	1.000	0.439	1.000
	Specificity	0	-	-	-
64	Sensitivity	52	0.942	0.844	0.980
	Specificity	39	0.769	0.617	0.874
80	Sensitivity	3	1.000	0.439	1.000
	Specificity	57	0.982	0.907	0.997
128	Sensitivity	4	1.000	0.510	1.000
	Specificity	28	0.786	0.605	0.898
256	Sensitivity	65	0.969	0.895	0.992
	Specificity	20	0.950	0.764	0.991
320	Sensitivity	18	0.944	0.742	0.990
	Specificity	1	0.000	-	-
382	Sensitivity	3	1.000	0.439	1.000
	Specificity	11	1.000	0.741	1.000

Table 6: Scanner Mix w/Convolution Kernel Type

Manufacturer	Reconstruction Method	N	% of Total
GE MEDICAL SYSTEMS	STANDARD	84	27.4%

Manufacturer	Reconstruction Method	N	% of Total
	FC08	2	0.7%
	SOFT	1	0.3%
	B40s	1	0.3%
	B	1	0.3%
	['Br38f', '2']	1	0.3%
	Missing	2	0.7%
SIEMENS	['Br38f', '2']	14	4.6%
	Tr20f	14	4.6%
	['Br40d', '3']	4	1.3%
	Br36f	3	1.0%
	FC08	3	1.0%
	STANDARD	2	0.7%
	['Br40d', '2']	2	0.7%
	['Bv36d', '3']	2	0.7%
	B31s	2	0.7%
	B26s	1	0.3%
	B30f	1	0.3%
	B40s	1	0.3%
	B70s	1	0.3%
	B	1	0.3%
	['Bf37f', '3']	1	0.3%
	['Br36f', '3']	1	0.3%
	['Br38f', '3']	1	0.3%
	Missing	7	2.3%
Toshiba	FC08	54	17.6%
	FC14	11	3.6%
	FC02	2	0.7%
	FC18	2	0.7%
	STANDARD	1	0.3%
	C	1	0.3%
	B	1	0.3%
	Missing	6	2.0%
Other	Other	75	24.3%
Totals	All	306	100.0%

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

Safety & Effectiveness:
Rapid has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with EN ISO 14971:2019 (risk management). The Rapid System performance has been validated with phantom and case data.

Conclusion:

In conclusion, the iSchemaView Rapid PETN device is substantially equivalent in intended use, technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Briefcase (K190072).