iSchemaView, Inc.
Jim Rosa
SVP Regulatory and Quality
1120 Washington Ave.
Suite 200
Golden, Colorado 80401

January 19, 2024

Re: K232156
Trade/Device Name: Rapid ASPECTS (v3)
Regulation Number: 21 CFR 892.2060
Regulation Name: Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulatory Class: Class II
Product Code: POK
Dated: December 22, 2023
Received: December 26, 2023

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.

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging Devices and Electronic Products
OHT 8: 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.

Submission Number *(if known)*

K232156

Device Name

Rapid ASPECTS (v3)

Indications for Use *(Describe)*

Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of Interest (ROIs). Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT (Alberta Stroke Program Early CT) Score. Rapid ASPECTS is indicated for evaluation of adult patients presenting for diagnostic imaging workup, for evaluation of extent of disease. Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. This device provides information that may be useful in the characterization of early ischemic brain tissue injury for ischemic stroke patient (typically < 24 hours since last known well) during image interpretation following the standard of care. Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. Rapid ASPECTS presents the original and annotated images for concurrent reads.

Limitations:
1. The ASPECTS score should be only used for ischemic stroke patients following the standard of care.
2. Rapid ASPECTS is an adjunct tool and is not intended to replace a clinicians review of the original imaging or their clinical judgement.
3. Physicians should not use the CAD generated output as the primary interpretation without their concurrence.

Contraindications/Exclusions/Cautions:
• 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.

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510(k) Summary

iSchemaView, Inc.'s Rapid ASPECTS (v3) (K232156)

This document contains the 510(k) summary for the iSchemaView Rapid ASPECTS (v3). 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: 9 January 2024

Device Name and Classification:

Trade Name:	Rapid ASPECTS (v3)
Common Name:	CADx
Classification:	II
Product Code:	POK
Regulation No:	21 C.F.R. §892.2060
Classification Panel:	Radiology Devices

Predicate Devices:

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

Rapid ASPECTS (K200760)

Device Description:

Rapid Platform

The Rapid platform is Software as a Medical Device (SaMD), which provides for the visualization and study of changes in tissue and vasculature using digital images captured by diagnostic imaging systems including CT (Computed Tomography), CTA (CT Angiography), MRI (Magnetic Resonance Imaging) and MRA (MR Angiography) as an aid to physician diagnosis. Rapid can be installed on a customer's Server or it can be accessed online as a virtual system. It provides viewing, quantification, analysis, and reporting capabilities. The Rapid platform has multiple modules a clinician may elect to run and provide analysis for decision making.

Rapid ASPECTS Module

Rapid ASPECTS provides an automatic ASPECT Score based on the case input file for the physician. The score includes which ASPECT regions are identified based on regional imaging features derived from Non-Contrast Computed Tomography (NCCT) brain image data. The results are generated based on the Alberta Stroke Program Early CT Score (ASPECTS) guidelines and provided to the clinician for review and verification. At the discretion of the clinician, the scores may be adjusted based on other clinical factors the clinician may integrate though the Rapid Platform Interface.

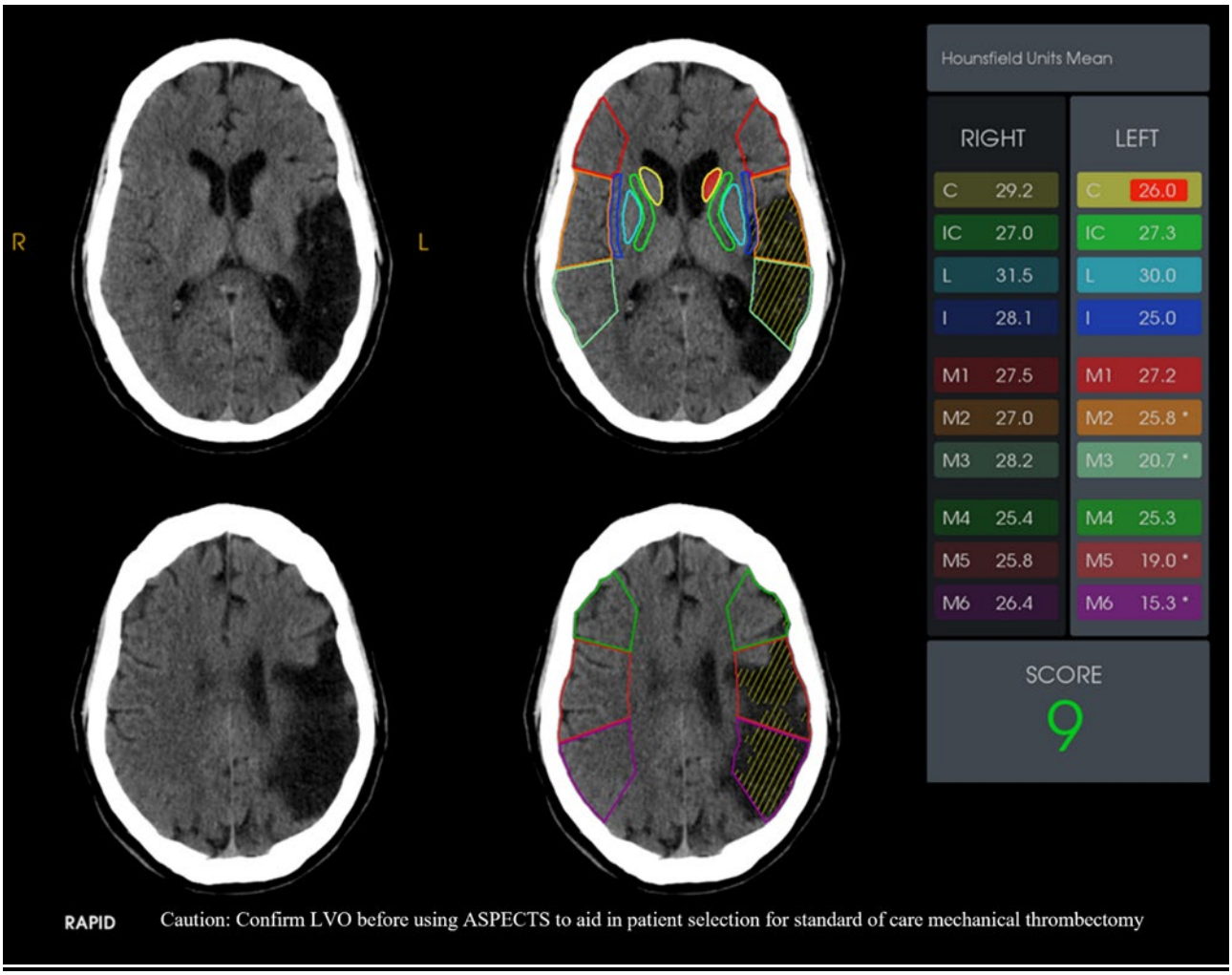
The ASPECTS software module processing pipeline performs four major tasks:

- Orientation and spatial normalization of the input imaging data (rigid registration/alignment with anatomical template).
- Delineation of pre-defined regions of interest on the normalized input data and computing numerical values characterizing underlying voxel values within those regions.
- Identification and highlighting previous/old stroke areas along with areas of early ischemic change; and
- Labeling of these delineated regions and providing a summary score reflecting the number of regions with early ischemic change as per ASPECTS guidelines.

Subsequently, the system notifies the physician of the availability of the ASPECT Score with an overlayed atlas. The ASPECTS information is then available for the physician to review and edit prior to sending the data to a PACS or Workstation. The final summary score together with the regions selected and underlying voxel values are then sent to the Picture Archiving and Communication System (PACS) to become a part of the permanent patient medical record.

Clinical Characteristics

The primary users of Rapid Platform software are medical imaging professionals. The images generated by Rapid ASPECTS provide additional diagnostic information, which is derived from the temporal/diffusion/density features of the native CT images. The following figure provides a general layout of the ASPECTS display image as provided from Rapid ASPECTS.



Indications for Use:

Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of lnterest (ROIs). Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT (Alberta Stroke Program Early CT) Score.

Rapid ASPECTS is indicated for evaluation of adult patients presenting for diagnostic imaging workup, for evaluation of extent of disease. Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. This device provides information that may be useful in the characterization of early ischemic brain tissue injury for ischemic stroke patient (typically < 24 hours since last known well) during image interpretation following the standard of care. Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. Rapid ASPECTS presents the original and annotated images for concurrent reads.

Limitations:

1. The ASPECTS score should be only used for ischemic stroke patients following the standard of care.
2. Rapid ASPECTS is an adjunct tool and is not intended to replace a clinicians review of the original imaging or their clinical judgement.
3. Physicians should not use the CAD generated output as the primary interpretation without their concurrence.

Contraindications/Exclusions/Cautions:

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

Technological Characteristics:

Rapid ASPECTS is a machine learning implementation. Rapid ASPECTS provides an automatic ASPECT score based on the case input file for the physician. The score includes which ASPECT regions are identified based on regional imaging features derived from non-contrast computed tomography (NCCT) brain image data based on the random forest machine learning technique. The results are generated based on the Alberta Stroke Program Early CT Score (ASPECTS) guidelines and provided to the clinician for review and verification. At the discretion of the clinician, the scores may be adjusted based on the clinician's judgment as well as other factors the clinician may integrate though the Rapid Platform User Interface.

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 62366:2015	Application of Usability Engineering to Medical Devices
NEMA PS 3.1 - 3.20	Digital Imaging and Communications in Medicine (DICOM)

Rapid has been designed to meet 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 extensive performance validation testing and software verification and validation testing of the Rapid ASPECTS module as standalone software and as integrated within the Rapid System. This performance validation testing demonstrated that the Rapid ASPECTS module provides accurate representation of key processing parameters under a range of clinically relevant parameters and perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Rapid ASPECTS module met all design requirements and specifications. Design Verification and Validation according to 21 CFR 820.30 passed.

510(k) Summary

The Rapid ASPECTS Standalone Performance and Clinical Validation Protocol (VCP) passed. No deviations were found during the execution of the testing.

Standalone Performance: The percent agreement of Rapid ASPECTS to the reference at the ASPECTS region level and at the scan level is 82.8%. Both are comparable (overlapping CI) to the pairwise agreement between any two of the three experts.

Clinical Validation Reader Improvement: The primary reader improvement endpoint is to demonstrate that reader scoring of the 10 ASPECT regions is more closely aligned with the reference standard when read in conjunction with Rapid ASPECTS than without Rapid ASPECTS. We find that the fixed effect of the Rapid assist increases the percent agreement on average, by about 0.02. That is, agreement increases from 82% without assistance to 84% with assistance excluding the expert, the average agreement increases from 80.4% without assistance to 83.3% with assistance.

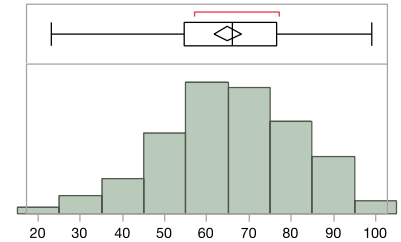
Supplemental Confounder/Mimic Sensitivity Assessment: Additionally, supplemental data was evaluated to further assess confounders which may appear in case processing. The supplemental data included: Abscess (3), Dural AVF (4), Hydrocephalus (4), Hypertensive Encephalopathy (2), Isodense SDH (4), Multiple Sclerosis (3) and Traumatic Brain Injury (3). Five readers were used to review the confounder supplemental cases for 115 reads. Three of the 115 reads (2.6%) changed based on Rapid results, showing minimal effect of confounders/mimics on ASPECTS performance.

Demographic & Clinical Subcategories:

Demographics are provided for the 102 scans used in the reader improvement study and 88 used for the standalone performance. Case counts are included for reference:

Overview of Case Counts			
Case Category	N	Include in Stand Alone	Include in Reader Improvement
Suspected Stroke	88	Yes	Yes
Stroke Mimic (non-ischemic stroke etiology)	14	No	Yes
Technical Exclusion due to contrast	3	No	No
Total	105	88	102

Age: Age ranged from 23 to 99 with a median of 66 years of age.



Quantiles		
100.0%	maximum	99
99.5%		99
97.5%		94.65
90.0%		87.2
75.0%	quartile	76.5
50.0%	median	66
25.0%	quartile	54.5
10.0%		41.6
2.5%		29.25
0.5%		23
0.0%	minimum	23

Summary Statistics	
Mean	64.865979
Std Dev	16.358375
Std Err Mean	1.6609413
Upper 95% Mean	68.162922
Lower 95% Mean	61.569037
N	97
N Missing	8

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Gender:

Gender	N	Column %
F	53	51.96%
M	49	48.04%
All	102	

LVO Status:

Stroke LVO	N	Column %
no	37	36.27%
unknown	14	13.73%
yes	51	50.00%
All	102	100.00%

US/OUS Status

US/OUS	N	Column %
OUS	21	20.59%
US	81	79.41%
All	102	100.00%

Last Known Well

Last Known Well (6 Hour Splits)	N	Column %
<6	27	31.03%
≥6 - <16	21	24.14%
≥16 - 24	5	5.75%
UNK	34	39.08%
All	87	100.00%

Data Distribution:

Demographics are provided for the 102 scans used in the reader improvement study and 88 used for the standalone performance. The data was distributed from GE (23), Siemens (28), Cannon/Toshiba (22) and Philips (29). The data included 14 confounders/mimics in the primary data set with non-stroke etiology. Standalone Performance cases included US (75) vs OUS (13) for 85% US. Additionally, supplemental data was evaluated to further assess sensitivity of confounders which may appear in case processing. The supplemental data included: Abscess (3), Dural AVF (4), Hydrocephalus (4), Hypertensive Encephalopathy (2), Isodense SDH (4), Multiple Sclerosis (3) and Traumatic Brain Injury (3).

Prescriptive Statement:

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

Safety & Effectiveness:

Rapid ASPECTS 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).

Substantial Equivalence:

Rapid ASPECTS (K200760) under regulation 21 C.F.R. §892.2060 CADx is the predicate device for Rapid ASPECTS v3. The disease and clinical use are identical and substantially equivalent. There are slight differences between the two versions which do not provide new risks. The Rapid ASPECTS assists the radiologists (clinicians) in the assessment and characterization of morphological features of their respective focus areas using imaging data. The software registers, segments, and analyzes regions of interest (ROI) to provide computer analytics. The identified/extracted features are then synthesized by artificial intelligence algorithms into clinical reference scores. Rapid ASPECTS provides localization information showing which ASPECTS regions are affected. The features are compared in the following table, as well as the Risk Benefit Analysis in the next paragraph is comparative to the predicate:

Substantial Equivalence Table		
Comparison Feature	Rapid ASPECTS (K200760)	Rapid ASPECTS v3
Indications for Use	Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of lnterest (ROIs). Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT (Alberta Stroke Program Early CT) Score. Rapid ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known MCA or ICA occlusion, for evaluation of extent of disease.	Rapid ASPECTS is a computer-aided diagnosis (CADx) software device used to assist the clinician in the assessment and characterization of brain tissue abnormalities using CT image data. The Software automatically registers images and segments and analyzes ASPECTS Regions of lnterest (ROIs). Rapid ASPECTS extracts image data for the ROI(s) to provide analysis and computer analytics based on morphological characteristics. The imaging features are then synthesized by an artificial intelligence algorithm into a single ASPECT (Alberta Stroke Program Early CT) Score. Rapid ASPECTS is indicated for evaluation of adult patients presenting for diagnostic imaging workup, for evaluation of extent of disease. Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. This device

	Extent of disease refers to the number of ASPECTS regions affected which is reflected in the total score. This device provides information that may be useful in the characterization of early ischemic brain tissue injury during image interpretation (within 6 hours). Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. Limitations: 1. Rapid ASPECTS is not intended for primary interpretation of CT images; it is used to assist physician evaluation. 2. Rapid ASPECTS has been validated in patients with known MCA or ICA Occlusion prior to ASPECT scoring. 3. Use of the Rapid ASPECTS Module in clinical settings other than early brain ischemia (within 6 hours) caused by known ICA or MCA occlusions has not been tested. 4. Rapid ASPECTS has been validated and is intended to be used on GE Lightspeed VCT Scanners. Contraindications/Exclusions/Cautions: • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma • Very thin or no Ventricles	provides information that may be useful in the characterization of early ischemic brain tissue injury for ischemic stroke patient (typically < 24 hours since last known well) during image interpretation following the standard of care. Rapid ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS atlas definitions and atlas display including highlighted ROIs and numerical scoring. Rapid ASPECTS presents the original and annotated images for concurrent reads. Limitations: 1. The ASPECTS score should be only used for ischemic stroke patients following the standard of care. 2. Rapid ASPECTS is an adjunct tool and is not intended to replace a clinicians review of the original imaging or their clinical judgement. 3. Physicians should not use the CAD generated output as the primary interpretation without their concurrence. Contraindications/Exclusions/Cautions: • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma • Very thin or no Ventricles
Clinical Application/Anatomical Region	Stroke/Head	Stroke/Head
Standard of Care Representation	ASPECT Scoring	ASPECT Scoring

510(k) Summary

Imaging	CT	CT
Technical Implementation	AI/Random Forest	AI/Random Forest
Image Overlay	ASPECTS Atlas ROIs, highlighted by algorithms	ASPECTS Atlas ROIs, highlighted by algorithms
Primary User(s)	Neuroradiologist/Clinician	Neuroradiologist/Clinician
Alteration of original image data base	No	No
Alters Standard of Care Workflow	In parallel to	In parallel to
Analysis Window	⩽ 6 hours	⩽ 24 hours

Risk Benefit Analysis:

Risk Benefit Summary	
Summary of Benefits:	This device provides a systematic, automated analysis of NCCT scans of the head to provide a standardized, automated ASPECT score for Stroke workup. The clinical reader study, which included 1 expert neuroradiologist and 5 non-expert typical readers demonstrated a statistically significant improvement in the accuracy of the 6 readers' scores when scoring was performed in conjunction with the Rapid ASPECTS output. In a subgroup analysis, the benefit of the software was most substantial among the non-neuroradiologist expert reader which typically evaluates CT scans in community hospitals and primary stroke centers. These non-expert readers also evaluate CT scans in comprehensive centers, particularly in the acute setting, when expert neuroradiologists are not immediately available. The software allows the non-expert physician to perform at the expert-like level. Use of the system did not appear to have any significant impact (either positive or negative) on the score of the expert neuroradiologist included in the test reader group. Overall, this system should provide a more consistent and timely benefit of standardized reads regardless of physician and center specialty.
Summary of the Risks	There are minimal potential risks associated with the use of the device.
	Incorrect scoring which may result in false positive results and results to incorrect patient management with possible adverse effects such as, unnecessary additional

Risk Benefit Summary	
	medical imaging and/or unnecessary additional diagnostic workup.
	Incorrect scoring which may result in false negative results may lead to complications, including incorrect diagnosis and delay in disease management.
	The device could be misused to analyze images from an unintended patient population or on images acquired with incompatible imaging hardware or incompatible image acquisition parameters, leading to inappropriate diagnostic information being displayed to the user.
	Device failure could lead to the absence of results, delay of results or incorrect results, which could likewise lead to inaccurate patient assessment.
	However, based on the performance data and the application of mitigating measures (general controls and special controls established for this device type), use of the device is unlikely to decrease diagnostic performance of the user and possible misuse of the device does not present additional risks compared with misuse of other types of radiological image processing devices.
Summary of other Factors	The study was enriched to cover the range of ASPECT scores and scanner manufacturers and the readers in practice may not experience a significant improvement in determining ASPECTS.
Conclusions: Do the probable benefits outweigh the probable risks.	Yes. The probable benefits outweigh the probable risks, given the combination of required general controls and the special controls established for this device. The Special Controls will sufficiently assist in managing risks associated with incorrect brain tissue characterization determining ASPECT scoring, application of the device results to the wrong patient population, analysis of incompatible images, and/or device failure by ensuring proper performance and use of the device. By providing a systematic, automated analysis of NCCT scans of the head to provide a standardized, automated ASPECT score for Stroke workup. The Rapid ASPECTS analytics calculates morphological characteristics of brain tissue using the historical training data and providing results which the attending physician may evaluate and modify based on other presenting conditions of the patient. In addition to the Rapid

Risk Benefit Summary	
	ASPECTS clinical module, other clinical information is easily accessible within the Rapid System framework such as CTA and CTP to inform the clinical decision-making process. The clinical reader study demonstrates a statistically significant improvement of ASPECTS reads among a diverse sample of 6 typical readers representing multiple specialties, years of practice, and practice settings. Overall, this system should provide a more consistent and timely benefit of standardized reads regardless of physician and center specialty. Therefore, given the available information concerning the benefits, risks, and supporting data; the probable benefits outweigh the probable risks, given the combination of required general controls and special controls established for this device.

Conclusion:

The Rapid ASPECTS subject to this filing is equivalent to the predicate. It is intended to aid in the assessment of a specific disease state using standard of care scoring using machine learning/artificial intelligence algorithms. The device uses ROI based assessments. The Rapid ASPECTS ROIs are based on an ASPECTS defined atlas. The device is a SaMD with algorithm development approaches using variants of artificial intelligence implementations. The device analyzes highlights morphological and feature differences. The minor differences to extend the analysis window based on the current standard of care and to expand scanner brands does not add additional risk.

The Rapid ASPECTS (v3) with minor differences is substantially equivalent to the Rapid ASPECTS predicate.