Avicenna.AI
℅ John Smith
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20004

March 15, 2024

Re: K233342
Trade/Device Name: CINA-ASPECTS
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: February 15, 2024
Received: February 15, 2024

Dear John Smith:

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, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
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OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K233342

Device Name

CINA-ASPECTS

Indications for Use *(Describe)*

CINA-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 reorients images, segments and analyzes ASPECTS Regions of Interest (ROIs). CINA-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.

CINA-ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known MCA or ICA occlusion, 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 (acute) brain tissue injury during image interpretation.

CINA-ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS region definitions and highlighting ROIs and numerical scoring.

Limitations:

1. CINA-ASPECT is not intended for primary interpretation of CT images. It is used to assist physician evaluation.
2. CINA-ASPECT has been validated in patients with known MCA or ICA unilateral occlusion prior to ASPECTS scoring.
3. CINA-ASPECTS is not suitable for use on brain scans displaying neurological pathologies other than acute stroke, such as tumors or abscesses, traumatic brain injuries, hemorrhagic transformation and hematoma.
4. Use of CINA-ASPECT in clinical settings other than brain ischemia within 12 hours from time last known well, caused by known ICA or MCA occlusions has not been tested.
5. CINA-ASPECTS has only been validated and is intended to be used in patient populations aged over 21.
6. CINA-ASPECTS has been validated and is intended to be used with images acquired with Canon Medical Systems Corporation, GE Healthcare, Philips Healthcare and Siemens Healthineers scanners.

Contraindications/Exclusions/Cautions:

- Patient motion: Excessive patient motion leading to artifacts that make the scan technically inadequate.
- Important streak artifacts and noisy images: Presence of important streak artifact and significant noise within the NCCT images that make the scan technically inadequate.
- Hemorrhagic Transformation, Hematoma.

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

AVICENNA.AI's CINA-ASPECTS

Submitter

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Date prepared: February 15, 2024

Device Identification

Name of Device:	CINA-ASPECTS
Classification Name:	Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulation No:	21 CFR § 892.2060
Product Code:	POK
Regulatory Class:	Class II
Classification Panel:	Radiology devices

Predicate Device

The CINA-ASPECTS device is substantially equivalent to the following predicate device with regard to indications for use, performance, and technological characteristics:

510(k):	K200760
Trade Name:	Rapid ASPECTS
Manufacturer:	ISchemaView Inc.
Classification Name:	Radiological computer-assisted diagnostic software for lesions suspicious of cancer
Regulation No:	21 CFR § 892.2060
Product Code:	POK
Regulatory Class:	Class II

Device Description

CINA-ASPECTS is a standalone computer-aided diagnosis (CADx) software that processes non-contrast head CT (NCCT).

CINA-ASPECTS is a standalone executable program that may be run directly from the command-line or through integration, deployment and use with medical image communications devices. The software does not interface directly with any CT scanner or data collection equipment; instead, the software receives non-contrast head CT (NCCT) scans identified by medical image communications devices, processes them using algorithmic methods involving execution of multiple computational steps to provide 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 and overlaid onto brain scan images. 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.

Series are processed by running the CINA-ASPECTS Image Processing Applications on non-contrast head CT images (NCCT) to perform the:

- Reorientation, tilt-correction of the input imaging data;
- Delineation of predefined regions of interest on the corrected input data and computing numerical values characterizing underlying voxel values within those regions;
- Visualizing the voxels which have contributed to the ASPECTS score (also referred to as a 'heat map'); and
- Labeling of these delineated regions and providing a summary score reflecting the number of regions with early ischemic change as per ASPECTS guidelines.

The CINA-ASPECTS User Interface Agent provides the ASPECTS information to the clinician to review and edit. It also requires the confirmation by a clinician that a Large Vessel Occlusion (LVO) is detected. This confirmation is used by the CINA-ASPECTS to limit the detection of areas of early ischemic changes to the infarcted brain hemisphere selected by the user. The final summary score together with the regions selected and underlying voxel values are then stored in DICOM format to be transferred by the medical image communications device for output to a Picture Archiving and Communication System (PACS) or workstation.

The CINA-ASPECTS device is made of two components:

- The CINA-ASPECTS image processing application which reads the input file and generates an automatic ASPECT score and the applications outputs
- A CINA-ASPECTS UI Agent which provides the ASPECTS information to the clinician to review and edit for final archiving.

Intended Use / Indications for Use

CINA-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 reorients images, segments and analyzes ASPECTS Regions of Interest (ROIs). CINA-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.

CINA-ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known MCA or ICA occlusion, 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 (acute) brain tissue injury during image interpretation.

CINA-ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS region definitions and highlighting ROIs and numerical scoring.

Limitations:

1. CINA-ASPECT is not intended for primary interpretation of CT images. It is used to assist physician evaluation.
2. CINA-ASPECT has been validated in patients with known MCA or ICA unilateral occlusion prior to ASPECTS scoring.
3. CINA-ASPECTS is not suitable for use on brain scans displaying neurological pathologies other than acute stroke, such as tumors or abscesses, traumatic brain injuries, hemorrhagic transformation and hematoma.
4. Use of CINA-ASPECT in clinical settings other than brain ischemia within 12 hours from time last known well, caused by known ICA or MCA occlusions has not been tested.
5. CINA-ASPECTS has only been validated and is intended to be used in patient populations aged over 21.
6. CINA-ASPECTS has been validated and is intended to be used with images acquired with Canon Medical Systems Corporation, GE Healthcare, Philips Healthcare and Siemens Healthineers scanners.

Contraindications/Exclusions/Cautions:

- Patient motion: Excessive patient motion leading to artifacts that make the scan technically inadequate.
- Important streak artifacts and noisy images: Presence of important streak artifact and significant noise within the NCCT images that make the scan technically inadequate.
- Hemorrhagic Transformation, Hematoma.

Summary of Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

CINA-ASPECTS 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.

Avicenna.AI conducted extensive performance validation testing and software verification and validation testing of the CINA-ASPECTS device as standalone software. CINA-ASPECTS is tested against its user needs and intended use by the successful execution of planned software

verification and validation testing included in this submission.

Software performance, validation and verification testing demonstrated that the CINA-ASPECTS met all design requirements and specifications associated with the intended use of the software.

Standalone Performance Testing

Standalone performance testing was conducted to comply with special controls for this device type.

Avicenna.AI conducted a retrospective, multicenter, multinational, multi-vendor and blinded Pivotal Standalone Testing Performance study of CINA-ASPECTS v1.5 software used to assist the clinicians in the assessment and characterization of brain tissues' abnormalities using CT image data.

The Standalone Performance Testing demonstrated that the proposed device provides accurate representation of key processing parameters under a range of clinically relevant parameters.

The Standalone Performance Testing dataset included 200 clinical anonymized NCCT cases from 5 clinical sites, distributed in two countries: US and France. It was acquired by 4 different scanner makers (GE, Siemens, Canon and Philips) and 27 different scanner models. The validation dataset was separated from the one used for the algorithm training/testing and has never been used in any way in the development of the software device.

The Standalone Performance Testing study demonstrated that CINA-ASPECTS achieved its primary endpoint and established that CINA-ASPECTS performances generalize to a range of typical patient demographics, Clinical parameters, ASPECTS regions, and image acquisition parameters encountered in multiple clinical sites and scanner makers and models.

The performance testing of the CINA-ASPECTS device establishes that the subject device is safe and effective, meets its intended use statement and is compatible with clinical use. The CINA-ASPECTS device performed properly and matched with the ground truth. Finally, the important heterogeneity of the dataset used for the device Pivotal Standalone Performance Testing and the good provided global and stratified performance results should guarantee enough robustness for generalization of its use for the intended population, ensuring the device reliability.

Clinical studies

Additionally, Avicenna.AI conducted a retrospective, multicenter, multinational, multi-vendor and blinded Clinical Multi-Reader Multi-Case (MRMC) Performance study of CINA-ASPECTS v1.5 software used to assist the clinicians in the assessment and characterization of brain tissues' abnormalities using CT image data.

The MRMC study evaluated the performance of 8 clinical readers in the assessment of ASPECTS for NCCT retrospective scans with and without the aid of CINA-ASPECTS. The 8 readers scored each of the 10 ASPECTS regions of the 200 cases independently. The panel of readers consisted of 4 expert neuroradiologists and 4 non-experts from different specialties (stroke neurologist, general radiologist, neurointensivist, vascular neurologist), representing the intended use population.

With CINA-ASPECTS the readers agreed, on average, with almost ½ a region (4.1%, [95% CI: 3.3% - 4.9%]) more per scan than without CINA-ASPECTS. These findings are similar to the results reported for the predicate device.

In addition, the overall readers' ROC AUC also improved significantly from 0.75 (Unaided arm) to 0.79 (Aided arm). The range in the ROC AUC between users was also narrower when assisted by the software, indicating a reduction in the variation of performance between different readers when the device's outputs were available.

Finally, the mean time spent per case among all readers was significantly reduced when using CINA-ASPECTS, indicating that the end-users' were not only more accurate in the assessment of ASPECTS but also faster when the device outputs were available.

As the study used retrospective data, there were no specific safety endpoints in the reader study.

This study demonstrates substantial equivalence of the CINA-ASPECTS software for improving reader accuracy, compared to the predicate device. The results showed statistically significant improvement in the readers' accuracy when using the software compared to the conventional manual method used in routine clinical practice.

Substantial Equivalence

Both proposed and predicate devices have the same intended use. Both devices are computer-aided diagnosis (CADx) software devices used to assist clinicians in the assessment and characterization of brain tissue abnormalities using CT image data.

Both devices segment and identify ASPECTS regions and use machine learning algorithms to analyze image data to facilitate the evaluation of extent of disease and to identify and count the affected ASPECTS regions to generate an ASPECTS score. Both devices display and highlight the affected ASPECTS regions along with the automatically generated ASPECTS score.

Both devices are not intended for primary interpretation of CT images and both require that cases processed meet prerequisite criteria such that a primary diagnosis of ICA or MCA occlusion has already been made by clinicians prior to accessing the processing results and the resulting ASPECTS score.

Both devices include a gating condition requiring users to confirm that the case in question is for a confirmed ICA or MCA occlusion before processing results are made available.

Both devices include pre-processing steps to normalize NCCT scan orientation in order to identify and segment ASPECTS regions on the subject NCCT scan.

In both cases, the algorithms identify signs indicative of ischemic damage and relate these to the segmented ASPECTS regions in order to determine whether or not individual ASPECTS regions are included as contributing to a reduced ASPECT score. In both cases, the segmented ASPECTS regions are labelled and presented to users in the software User Interface with the regions highlighted depending on whether they have been determined to affect the ASPECT score or not. In both cases, users can manually edit and override the automated result for one or more ASPECTS regions by selecting the regions.

Both predicate and proposed devices use trained machine learning AI algorithms to analyze NCCT scans to identify signs indicative of ischemic damage.

The following principal difference exists between CINA-ASPECTS and the predicate device:

- CINA-ASPECTS is indicated for cases within 12 hours from time last known well.
- CINA-ASPECTS uses machine learning algorithms based on deep learning techniques.
- CINA-ASPECTS has only been validated and is intended to be used in patient populations aged over 21.
- CINA-ASPECTS has been validated and is intended to be used on Canon Medical Systems Corporation, GE Healthcare, Philips Healthcare and Siemens Healthineers scanners whereas Rapid ASPECTS has been validated and is intended to be used on GE Lightspeed VCT Scanners.

Table 1 compares the key features of the subject and the predicate devices.

Table 1: Comparison of key features between CINA-ASPECTS and predicate device (ISchemaView Inc. Rapid ASPECTS)

Key Feature	**Subject device: CINA-ASPECTS Software**	**Predicate device: ISchemaView Inc. Rapid ASPECTS Software (K200760)**
Intended Use / Indications for Use	CINA-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 reorients images, segments and analyzes ASPECTS Regions of Interest (ROIs). CINA-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. CINA-ASPECTS is indicated for evaluation of patients presenting for diagnostic imaging workup with known MCA or ICA occlusion, 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	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 patients presenting for diagnostic imaging workup, or 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 during image

Key Feature	Subject device: CINA-ASPECTS Software	Predicate device: ISchemaView Inc. Rapid ASPECTS Software (K200760)
	(acute) brain tissue injury during image interpretation. CINA-ASPECTS provides a comparative analysis to the ASPECTS standard of care radiologist assessment using the ASPECTS region definitions and highlighting ROIs and numerical scoring Limitations: 1. CINA-ASPECT is not intended for primary interpretation of CT images. It is used to assist physician evaluation. 2. CINA-ASPECT has been validated in patients with known MCA or ICA unilateral occlusion prior to ASPECTS scoring. 3. CINA-ASPECTS is not suitable for use on brain scans displaying neurological pathologies other than acute stroke, such as tumors or abscesses, traumatic brain injuries, hemorrhagic transformation and hematoma. 4. Use of CINA-ASPECT in clinical settings other than brain ischemia within 12 hours from time last known well, caused by known ICA or MCA occlusions has not been tested. 5. CINA-ASPECTS has only been validated and is intended to be used in patient populations aged over 21. 6. CINA-ASPECTS has been validated and is intended to be used with images acquired with Canon Medical Systems Corporation, GE Healthcare, Philips Healthcare and Siemens Healthineers scanners. Contraindications/Exclusions/Caution: ▪ Patient motion: Excessive patient motion leading to artifacts that make the scan technically inadequate. ▪ Important streak artifacts and noisy images: Presence of important streak artifact and	interpretation. 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/Caution: • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma • Very thin or no Ventricles

Key Feature	Subject device: CINA-ASPECTS Software	Predicate device: ISchemaView Inc. Rapid ASPECTS Software (K200760)
	significant noise within the NCCT images that make the scan technically inadequate. ▪ Hemorrhagic Transformation, Hematoma.	
Environment of use	Clinical/Hospital environment	Clinical/Hospital environment
Primary Users	Neuroradiologist/Clinician	Neuroradiologist/Clinician
Anatomical region of interest	Stroke/Head	Stroke/Head
Standard of Care *Representation*	ASPECTS Scoring	ASPECTS Scoring
Data acquisition protocol	Non-contrast head CT scans	Non-contrast head CT scans
Technical *Implementation*	AI/Deep Learning	ML/AI/Random Forest
Segmentation of region of interest	No; device does not mark, highlight, or direct users' attention to a specific location in the original image	No; device does not mark, highlight, or direct users' attention to a specific location in the original image
Image Overlay	ASPECTS regions, highlighted by algorithms.	ASPECTS regions, highlighted by algorithms.
Gating Conditions	Users must confirm ICA or MCA occlusion prior to accessing CINA-ASPECTS results	Users must confirm LVO prior to accessing Rapid ASPECTS results
Alteration of original image data base	No	No

Key Feature	Subject device: CINA-ASPECTS Software	Predicate device: ISchemaView Inc. Rapid ASPECTS Software (K200760)
Alters Standard of Care Workflow	In parallel to	In parallel to

Conclusion

In conclusion, the predicate device has the same intended use and substantially similar indications for use and technological characteristics as CINA-ASPECTS. Performance data demonstrates that CINA-ASPECTS performs as intended within the same clinically relevant parameters for the intended use as the predicate device. The clinical data demonstrates that CINA-ASPECTS shows a significant improvement in the agreement between the readers and a reference standard when using the CINA-ASPECTS software compared to routine clinical practice. CINA-ASPECTS is intended to improve reader performance in estimating an overall ASPECTS score. However, some imaging and anatomical factors, such as important streak and motion artifacts, beam-hardening artifacts, noisy images, presence of tumors, etc., may impede the NCCT interpretation by the device. Therefore, a particular attention must be paid to these confounding factors. The risk/benefit profile of CINA-ASPECTS remains favorable based on the favorable impact on readers' overall aided performance in calculating an ASPECT score (as measured in the reader study), and the inherent inter-reader variability in identifying individual affected ASPECTS regions.

The company believes that CINA-ASPECTS is substantially equivalent to the Rapid ASPECTS predicate.