October 19, 2026

Avicenna.Ai
% John J. Smith
Partner
Hogan Lovells US LLP
Columbia Sq., 555 Thirteenth St., NW
Washington, District of Columbia 20004

Re: K262147
Trade/Device Name: CINA-Aneurysm+
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: September 17, 2026
Received: September 17, 2026

Dear John J. 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262147

Please provide the device trade name(s).

CINA-Aneurysm+

Please provide your Indications for Use below.

CINA-Aneurysm+ is a software-only medical device intended for the assessment, characterization, and tracking of known, untreated, saccular brain aneurysms over 3 mm in size on head CT angiography (CTA) images. The software can analyze one exam or two exams from the same patient acquired at different time points, providing measurements and, when two exams are available, an assessment of changes over time.

The device is intended to assist qualified healthcare professionals in the evaluation of known brain aneurysms. The device is intended to be deployed within a clinical workflow that includes a human review step, whereby a qualified clinician reviews, and accepts or rejects the AI-generated results prior to their clinical use or archiving.

It is not a diagnostic device, and the output must be reviewed along with the patient's original images and clinical information by a clinician.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K262147

510(K) SUMMARY

AVICENNA.AI's CINA-Aneurysm+

Submitter

Applicant:

AVICENNA.AI
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Date Prepared: June 25, 2026

Device Identification

Name of Device:	CINA-Aneurysm+
Classification Name:	System, Image Processing, Radiological
Regulation No:	21 CFR 892.2050
Product Code:	QIH
Regulatory Class:	Class II
Classification Panel:	Radiology

Predicate Device

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

510(k):	K210831
Device Name:	OnQ Neuro
Manufacturer:	CorTechs Labs, Inc.
Classification Name:	System, Image Processing, Radiological
Regulation No:	21 CFR § 892.2050
Product Code:	QIH
Regulatory Class:	Class II

Device Description

CINA-Aneurysm+ is a software-only medical device that processes head CT angiography (CTA) images in DICOM format for the purpose of assessment, characterization and tracking of known, untreated saccular brain aneurysms over 3mm in size located in the following circle of Willis segments:

Internal Carotid Arteries (superior to or at the level of the lesser wing of the sphenoid bone), Middle Cerebral Arteries (M1, M2), Anterior Cerebral Arteries (A1,A2), Anterior Communicating Artery, Posterior Communicating Artery, Posterior Cerebral Arteries (P1), Basilar artery and vertebral arteries (V4). It is also intended for the assessment of the saccular lumen of thrombosed aneurysms, provided the lumen is larger than 3 mm.

CINA-Aneurysm+ 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 can analyze one head CTA study or two head CTA studies acquired on the same patient at different time points. When two studies are available, the software performs an automated comparative analysis of aneurysm measurements and provides a summary of changes over time.

The device receives DICOM head CTA series from a user's Picture Archiving and Communication System (PACS) and processes the series through a locked artificial intelligence (AI) based algorithm. The algorithm locates known saccular aneurysms over 3 mm and automatically performs segmentation and quantitative measurements, including maximum diameter, dome height, neck width, aspect ratio, volume, and, when two time points are available, the change between time points.

Following processing, the software generates automated results that includes the measured parameters for each aneurysm and, when applicable, the comparative results between time points. The results also include preview images displaying the aneurysm with overlaid annotations of measurements. It generates results files as pending results, pending clinician review and acceptance to be transferred by a medical image communications device for output to a PACS System or workstation.

The CINA-Aneurysm+ device is composed of:

- The CINA-Aneurysm+ image processing application, which reads the input file and generates automatic results and the application's output.
- The specifications of an UI Agent, to be implemented by the 3rd party platform in accordance with the requirements defined by Avicenna.AI, that provides the results to the clinician to review and accept or reject for final archiving. This Agent may be integrated within the Medical Image Communications Device (MICD).

Clinician acceptance is required before any result is made available for clinical use. The final accepted results 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.

Intended Use / Indications for Use

CINA-Aneurysm+ is a software-only medical device intended for the assessment, characterization, and tracking of known, untreated, saccular brain aneurysms over 3 mm in size on head CT angiography (CTA) images. The software can analyze one exam or two exams from the same patient acquired at different time points, providing measurements and, when two exams are available, an assessment of changes over time.

The device is intended to assist qualified healthcare professionals in the evaluation of known brain aneurysms. The device is intended to be deployed within a clinical workflow that includes a human

review step, whereby a qualified clinician reviews, and accepts or rejects the AI-generated results prior to their clinical use or archiving.

It is not a diagnostic device, and the output must be reviewed along with the patient's original images and clinical information by a clinician.

Summary of Technological Characteristics

The subject CINA-Aneurysm+ device and the predicate OnQ Neuro (K210831) device are software packages with substantially similar technological characteristics and principles of operation. Both devices are software-only medical devices that process medical images in DICOM format and are designed as self-contained software deployable within a hospital's IT infrastructure or in the cloud. Both devices accept DICOM input, perform automatic segmentation and quantitative measurements of a targeted pathology through a locked algorithm, and generate output in standard DICOM format. Both the subject and predicate devices operate as fully automated post-processing applications that do not require user intervention for image analysis.

Both devices support longitudinal analysis by comparing derived image metrics from two time points acquired on the same patient. Both devices present results in tabular and graphical formats in DICOM Secondary Captures. Both devices require a human review step, whereby a qualified clinician reviews, and accepts or rejects the AI-generated results prior to their clinical use or archiving.

The primary technological differences between the devices relate to the specific pathology they are trained to assess and the corresponding imaging modality. CINA-Aneurysm+ uses a locked AI deep learning algorithm designed to automatically segment, characterize and measure known untreated saccular brain aneurysms over 3mm on head CT angiography (CTA) images, whereas OnQ Neuro is designed to segment and quantify brain tumors on MRI images. The quantitative measurements provided also differ accordingly: CINA-Aneurysm+ reports maximum 3D diameter, dome height, neck width, aspect ratio, and volume of aneurysms, while OnQ Neuro reports ROI volumes and histogram statistics of quantitative maps for brain tumors. Additionally, OnQ Neuro includes automated fusion of segmentation results with parametric maps derived from diffusion-weighted imaging (DWI), a feature that is not applicable to CINA-Aneurysm+ given its CTA-based modality. CINA-Aneurysm+ does not include segmentation editing tools, consistent with OnQ Neuro.

Moreover, standalone performance and effectiveness assessment studies demonstrated that the CINA-Aneurysm+ device performs as intended, and is similar to the predicate OnQ Neuro device. Based upon the foregoing, the CINA-Aneurysm+ subject device is substantially equivalent to its predicate OnQ Neuro device (K210831).

A table comparing the key features of the subject and predicate devices is provided below.

Performance Data

Avicenna.AI conducted a retrospective, multicenter, multinational, blinded validation studies of CINA-Aneurysm+ to evaluate its per-lesion performance for identifying existing and known targeted untreated saccular brain aneurysms (ruptured and/or unruptured) with a maximum diameter greater than 3 mm on CT angiography (CTA) examinations. For the Pivotal Standalone Validation Study, a total of 195 confirmed positive anonymized CTA cases were included. These cases were drawn from a broader dataset of 244 confirmed-positive cases, the remainder being reserved for the Follow-up

Validation Study.

Multiple subgroups of interest were considered in the analysis. In fact, the validation data was acquired from 2 different clinical sources, both representing U.S medical technology companies which have access to a database of medical images from various U.S. and OUS hospitals, to account for race/ethnicity in the intended U.S. patient population. Additional scanner parameters considered were scanner manufacturer, slice thickness, and number of detector rows ranges. Detailed subgroup analysis was reported in the labeling.

The data was provided from 44 clinical sites, including 22 U.S. and 22 OUS institutions. The independence of the standalone validation dataset from the training data was ensured using data from independent sites. The dataset included 75.8% U.S and 24.2% OUS CTA anonymized cases. All 244 cases were confirmed positive (CTA with at least one targeted brain aneurysm). The data was acquired primarily by 4 different scanner makers (GE, Philips, Siemens, and Canon (Formerly TOSHIBA)) and 32 different scanner models.

The Pivotal Standalone Validation Study conducted on 236 brain aneurysms (from 195 CTA cases; 72.8% female; mean age of 63.6 ± 14.2 years; range: 26 - 90 years), demonstrated strong per-lesion performance for the identification of existing and known brain aneurysms. CINA-Aneurysm+ successfully met the primary endpoint, achieving a per-lesion sensitivity of 89.0% [95% CI: 85.0% - 92.9%], with the lower bound of the confidence interval exceeding the prespecified performance threshold.

Regarding segmentation quality (secondary endpoint), the median DICE between CINA-Aneurysm+ and the ground truth exceeded inter-reader agreement, with a paired Wilcoxon signed-rank test showing a statistically significant difference favoring CINA-Aneurysm+ ($p = 0.0005$), with a Hodges - Lehmann paired median difference of 0.01965 [95% CI: 0.0093 - 0.0291]. As the lower bound of the two-sided 95% CI of the Hodges - Lehmann difference was greater than 0, the prespecified success criterion was met. A strong volumetric Pearson correlation with $R = 0.93$ [95% CI: 0.90-0.94; $p < 0.0001$] ($R^2 = 0.86$) was observed. Finally, the vascular territory labeling analysis demonstrated a high level of anatomical concordance between CINA-Aneurysm+ and the expert reference standard, with an overall Positive Percent Agreement (PPA) of 91.3%.

The Follow-up Validation Study, conducted on 56 longitudinally matched lesions (from 49 paired CTA examinations; 77.6% female; mean age of 66.9 ± 12.2 years and range: 27 - 90 years at Time Point 1: mean age of 68.8 ± 12.7 and range: 27 - 90 years at Time Point 2), showed a strong longitudinal matching rate of 87.5% exceeding the predefined performance target and meeting the success criterion established for this supportive endpoint. The primary endpoint, agreement between AI-derived and ground-truth lesion-wise longitudinal volume changes, yielded an ICC of 0.94 [95% CI: 0.89–0.96], meeting the prespecified performance criterion.

Based on the clinical performance as documented in the pivotal clinical study, CINA-Aneurysm+ has a safety and effectiveness profile that is similar to the predicate device.

	CINA-Aneurysm+ Software	OnQ Neuro (K210831)
Device Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Regulation Description	Medical image management and processing system	Medical image management and processing system
Product Code	QIH	QIH
Device Class	Class II	Class II
Classification Panel	Radiology	Radiology
Intended Use/ Indications for Use	CINA-Aneurysm+ is a software-only medical device intended for the assessment, characterization, and tracking of known, untreated, saccular brain aneurysms over 3 mm in size on head CT angiography (CTA) images. The software can analyze one exam or two exams from the same patient acquired at different time points, providing measurements and, when two exams are available, an assessment of changes over time. The device is intended to assist qualified healthcare professionals in the evaluation of known brain aneurysms. The device is intended to be deployed within a clinical workflow that includes a human review step, whereby a qualified clinician reviews, and accepts or rejects the AI-generated results prior to their clinical use or archiving. It is not a diagnostic device, and the output must be reviewed along with the patient's original images and clinical information by a clinician.	OnQ Neuro is a fully automated post-processing medical device software intended for analyzing and evaluating neurological MR image data. OnQ Neuro is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. OnQ Neuro is additionally intended to provide automatic fusion of derived parametric maps with anatomical MRI data. OnQ Neuro is intended for use on brain tumors, which are known/confirmed to be pathologically diagnosed cancer. OnQ Neuro is intended for comparison of derived image metrics from multiple time-points. The physician retains the ultimate responsibility for making the final diagnosis and treatment decision.
Intended Users	Medical specialists and radiologists that have been trained to independently assess the presence of brain aneurysms in head CTA.	Radiologists, oncologists

	CINA-Aneurysm+ Software	OnQ Neuro (K210831)
Targeted Clinical Condition, Anatomy, and Imaging Modality	Brain Aneurysm Head Computerized tomography angiography	Brain tumors Head Magnetic Resonance Imaging
Support Longitudinal Analysis	Yes - performs comparison of derived image metrics from multiple time point	Yes - performs comparison of derived image metrics from multiple time point
Segmentation Editing Tools	No	No
Lesion Segmentation Type	Fully-automated, AI-generated.	Fully-automated
Quantitative Analysis	Yes. Including Volumes, maximal 3D diameter, dome height, neck size and aspect ratio.	Yes. Including ROI Volumes, and histogram statistics of optional quantitative maps.
Reporting	Results displayed in tabular and graphical formats in DICOM Secondary Captures.	Results displayed in tabular and graphical formats.
DICOM Communication	Yes	Yes
Image Fusion	No	Automated fusion of segmentation results and parametric maps.
Safety	Results can be viewed, accepted, or rejected by a physician.	Display/measurement data can be viewed, accepted, or rejected by a physician.

Conclusions

CINA-Aneurysm+ is as safe and effective as the OnQ Neuro device. CINA-Aneurysm+ has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between CINA-Aneurysm+ and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that CINA-Aneurysm+ is as safe and effective as the predicate device.

Thus, Avicenna.AI believes that FDA can find the CINA-Aneurysm+ to be substantially equivalent.