October 20, 2026

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

Re: K262062
Trade/Device Name: CINA-Aneurysm
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer-Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QBS, QFM, QIH
Dated: September 10, 2026
Received: September 10, 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. FDA's substantial equivalence determination

also included the review and clearance of your Predetermined Change Control Plan (PCCP): Predetermined Change Control Plan CINA-Aneurysm, AV-DP-CINA-BAT-10-032-PCCP-V02. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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.	K262062

Please provide the device trade name(s).

CINA-Aneurysm

Please provide your Indications for Use below.

CINA-Aneurysm is a computer-assisted detection (CADe) and diagnosis (CADx) software device to be used as a concurrent reading aid to help medical specialists in the detection, assessment, and characterization of saccular brain aneurysm > 3mm in size, from head CTA images. The software identifies images with brain aneurysms to enable triage and provides information about the presence, location, and size of saccular brain aneurysms.

Intended users include medical specialists appropriately trained to assess independently, the presence of brain aneurysms in CTA images and radiologists.

CINA-Aneurysm should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace a qualified physician's review of the raw image. When a radiologist assesses the original CT images, both the CINA-Aneurysm annotated images and the original, unaltered images are used for concurrent reading. CINA-Aneurysm is indicated for adults and Transitional Adolescents (18 to < 22 years old but treated like adults).

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)

510(K) SUMMARY

AVICENNA.AI's CINA-Aneurysm

K262062

Submitter

Applicant:

AVICENNA.AI
Espace Mistral B,
375 avenue du Mistral,
13600 LA CIOTAT France

Contact Person:

Stephane Berger
Regulatory Manager
Phone: +33 6 12 12 28 13
E-mail: stephane.berger@avicenna.ai

Date prepared: October 19, 2026

Device Identification

Name of Device:	CINA-Aneurysm
Classification Name:	Radiological computer-assisted detection and diagnosis software
Regulation No:	21 CFR § 892.2090
Product Code:	QBS, QFM, 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):	K223491
Device Name:	Critical Care Suite with Pneumothorax Detection AI Algorithm, Critical Care Suite 2.1, Critical Care Suite
Manufacturer:	GE Medical Systems, LLC
Classification Name:	Radiological computer-assisted detection/diagnosis software for fracture
Regulation No:	21 CFR § 892.2090

Product Code:	QBS
Regulatory Class:	Class II

Device Description

CINA-Aneurysm is a Radiological Computer Assisted Detection And Diagnosis device (“CADe/x”).

CINA-Aneurysm is a standalone software device for the automated analysis of head CT angiography images to detect the presence of brain aneurysms and provide information about their location and size. Targeted lesions are saccular untreated aneurysm over 3mm in size and located in the following circle of Willis segments: ICA (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.

The device operates as concurrent reading to routine standard-of-care image interpretation, and clinicians are ultimately responsible for making or confirming a diagnosis.

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.

CINA-Aneurysm receives head CT angiography scans identified by compatible medical image communications devices, processes them using algorithmic methods involving execution of multiple computational steps to identify the presence of brain aneurysms and provides information about their location and size. It generates results files to be transferred by medical image communications device for output to a PACS system or workstation.

DICOM images are received, recorded and filtered before processing. The series are processed chronologically by running algorithms on each series to identify the presence of brain aneurysms.

CINA-Aneurysm also assists in the detection / diagnosis of brain aneurysms for medical specialists that have been trained to independently assess the presence of brain aneurysms in head CT angiography images. CINA-Aneurysm provides passive notification to flag images with a suspicious finding and a localization overlay of the suspected brain aneurysms as well as measurements of maximum diameters of brain aneurysms.

For each detected aneurysm, the device provides a vessel territory label (e.g., ICA, ACA, MCA, etc.), including laterality where anatomically applicable (e.g., left MCA, right ICA, etc.). When more than one aneurysm is detected, the device generates individual results for each detected aneurysm, including a separate localization overlay, vessel territory label, laterality where applicable, and maximum diameters measurements.

These outputs can be displayed wherever the reviewing physician normally conducts their reads per their standard of care, including PACS and workstation.

Intended Use / Indications for Use

CINA-Aneurysm is a computer-assisted detection (CADe) and diagnosis (CADx) software device to be used as a concurrent reading aid to help medical specialists in the detection, assessment, and characterization of saccular brain aneurysm > 3mm in size, from head CTA images. The software identifies images with brain aneurysms to enable triage and provides information about the presence, location, and size of saccular brain aneurysms.

Intended users include medical specialists appropriately trained to assess independently, the presence of brain aneurysms in CTA images and radiologists.

CINA-Aneurysm should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace a qualified physician's review of the raw image.

When a radiologist assesses the original CT images, both the CINA-Aneurysm annotated images and the original, unaltered images are used for concurrent reading. CINA-Aneurysm is indicated for adults and Transitional Adolescents (18 to < 22 years old but treated like adults).

Summary of Technological Characteristics

The subject CINA-Aneurysm device and the predicate Critical Care Suite with Pneumothorax Detection AI Algorithm device are software packages with substantially similar technological characteristics and principles of operation. Both devices employ the same fundamental scientific technology, utilizing deep learning artificial intelligence algorithms to process medical images, and both are designed as self-contained software deployable on various computing platforms (such as PACS, On Premise, or On Cloud).

Both the subject and predicate devices operate in parallel to the standard of care workflow and do not alter the original medical images. Instead, both devices produce an output if a suspicious finding is detected, providing an image annotation on a secondary DICOM image and a DICOM message. This output includes a flag for the suspected pathology and a localization overlay of the finding within the image. These outputs can be immediately used to visualize the results on any DICOM destination, such as a user's image storage system (PACS) or workstation.

The primary technological differences between the devices relate to the specific pathology they are trained to detect and the corresponding imaging modality: CINA-Aneurysm uses an AI supervised deep learning algorithm designed to identify and highlight brain aneurysms on head CT angiography images, whereas the predicate device uses AI deep learning algorithms to detect pneumothorax on frontal chest X-ray images. Additionally, regarding the algorithm outputs, CINA-Aneurysm provides measurements of the suspected brain aneurysms, whereas the predicate provides a graphical representation of the algorithm's confidence in its result.

Moreover, standalone performance and effectiveness assessment studies demonstrated that the CINA-Aneurysm device performs as intended, and similar to the predicate Critical Care Suite with Pneumothorax Detection AI Algorithm device. Based upon the foregoing, the CINA-Aneurysm subject device is substantially equivalent to its predicate Critical Care Suite with Pneumothorax Detection AI Algorithm device.

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

Performance Data

Avicenna.AI conducted a retrospective, multicenter, multinational and blinded study with the CINA-Aneurysm application with the primary endpoint to evaluate the software's per-case triage performance (ROC AUC) in detecting targeted brain aneurysms on CT angiography (CTA) images, on 423 clinical anonymized cases. The dataset included 66.9% Female. Mean ± SD age of patients included in the study was 61.3 ± 15.3 years (median: 62; range: 19–90).

Multiple subgroups of interest were considered in the analysis. In fact, the validation data was acquired from 2 different clinical sources with access to multiple clinical sites. Additional imaging parameters considered were scanner manufacturer, slice thickness, and number of detector rows ranges.

The data was provided from multiple U.S. (74.2%) and OUS (25.8%) clinical sites. The independence of the standalone validation dataset from the training data was ensured using data from independent sites. There were 195 (46.1%) positive cases and 228 (53.9%) negative cases included in the analysis. The data was acquired primarily by 4 different scanner makers (GE - 21.7%, Philips - 22.5%, Siemens - 30.5%, and Canon (Formerly TOSHIBA) - 25.3%) and 35 different scanner models.

Device ROC AUC [95%CI], the primary endpoint performance; and Sensitivity [95%CI] and Specificity [95%CI], the secondary endpoint performances, were computed against the ground truth established by consensus of three U.S. board-certified expert neuroradiologists.

The standalone performance validation study of CINA-Aneurysm demonstrated strong triage performance, with a per-case ROC AUC of 0.954 [95% CI: 0.934–0.974], a sensitivity of 94.4% [95% CI: 90.1%–97.2%], and a specificity of 91.7% [95% CI: 87.3%–94.9%]. In comparison, the predicate device, Critical Care Suite with Pneumothorax Detection AI Algorithm (GE HealthCare), achieved a ROC AUC of 0.961 [95% CI: 0.949–0.972], with a sensitivity of 84.3% [95% CI: 80.6%–88.0%] and a specificity of 93.2% [95% CI: 90.8%–95.6%]. Both systems met the predefined primary and secondary performance endpoints, with lower bounds of the 95% confidence intervals exceeding 90% for ROC AUC and 80% for both sensitivity and specificity. Overall, these results support the substantial equivalence of CINA-Aneurysm to the predicate device.

In addition, CINA-Aneurysm demonstrated rapid prioritization and triage capability, with a mean time-to-notification (TTN) of 1.0 minute [95% CI: 1.0–1.1] across all cases (n = 423). When restricted to true positive cases (n = 184), the mean TTN was 1.2 minutes [95% CI: 1.2–1.2]. Comparable TTN data for the predicate device were not reported.

A retrospective, fully-crossed MRMC crossover study evaluated the clinical benefit of CINA-Aneurysm. Eight U.S. board-certified readers (4 neuroradiologists, 4 general diagnostic radiologists) each interpreted the same 230 CTA cases with and without the device across two sessions separated by a 4-week washout (1,840 CTA cases per arm), against a reference standard set by three independent expert neuroradiologists. Per applicable FDA CADe guidance, clinical value was assessed on the totality of evidence across complementary endpoints.

Primary endpoint (ROC AUC): Reader-averaged AUC was numerically higher in the Aided Arm than the Unaided Arm, increasing from 0.9375 to 0.9497(difference: +0.0123 [95% CI: -0.0014 to +0.0259]; p=0.075). Formal superiority was not established for the primary endpoint, although the result was directionally favorable in the setting of high unaided reader performance.

Supporting Evidence of Benefit:

- Patient-level: Sensitivity increased from 92.2% to 96.2% (+4.0%; 95%CI: 1.9% to 6.2%) with no loss of specificity (87.1% to 88.4%; +1.3%; 95% CI -0.8% to 3.4%). Accuracy (+2.7%; 95%CI: 1.2% to 4.2%)), PPV (+1.5%; 95% CI -0.2% to 3.5%) and NPV (+4.1%; 95%CI: 1.9% to 6.7%) all improved in the Aided arm .
- Lesion-level (wAFROC): Reader-averaged wAFROC improved from 0.904 to 0.927 (difference = +0.022 [95% CI: +0.003 to +0.041]; p=0.025 and per-lesion sensitivity increased by 4.6% (p<0.0001), supporting improved detection and localization.
- Reading time (Secondary endpoint): mean reading time was reduced by 9.9 seconds per case [95% CI: -15.1 to -4.6 s] (p = 0.0002), providing supportive evidence of improved reading efficiency.

Performance Improvements Across Predefined Subgroups: Supportive subgroup analyses showed directionally favorable accuracy improvements across reader expertise groups, including expert neuroradiologists (+2.5%) and non-expert diagnostic radiologists (+2.8%), as well as across all four scanner manufacturers (+1.5% to +3.7%), slice thicknesses, detector configurations, U.S./OUS provenance, and patient demographic subgroups. The largest observed benefit was for small aneurysms (<5 mm), where per-lesion sensitivity improved from 71.0% to 81.6% (+10.7%; p=0.0007), with additional gains observed for medium-sized lesions and preserved high performance for large lesions. Together with the standalone performance results and other supportive MRMC findings, these data support the performance of CINA-Aneurysm for its intended use and its substantial equivalence to the predicate device.

	CINA-Aneurysm Software	**Critical Care Suite with Pneumothorax Detection AI Algorithm, Critical Care Suite 2.1, Critical Care Suite (K223491)**
Intended Use/ Indications for Use	CINA-Aneurysm is a computer-assisted detection (CADe) and diagnosis (CADx) software device to be used as a concurrent reading aid to help medical specialists in the detection, assessment, and characterization of saccular brain aneurysm > 3mm in size, from head CTA images. The software identifies images with brain aneurysms to enable triage and provides information about the presence, location, and size of saccular brain	Critical Care Suite with Pneumothorax Detection AI Algorithm is a computer-aided triage, notification, and diagnostic device that analyzes frontal chest X-ray images for the presence of a pneumothorax. Critical Care Suite identifies and highlights images with a pneumothorax to enable case prioritization or triage and assist as a concurrent reading aid during interpretation of radiographs. Intended users include qualified independently licensed healthcare professionals (HCPs) trained to

	aneurysms. Intended users include medical specialists appropriately trained to assess independently, the presence of brain aneurysms in CTA images and radiologists. CINA-Aneurysm should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace a qualified physician's review of the raw image. When a radiologist assesses the original CT images, both the CINA-Aneurysm annotated images and the original, unaltered images are used for concurrent reading. CINA-Aneurysm is indicated for adults and Transitional Adolescents (18 to < 22 years old but treated like adults).	independently assess the presence of pneumothoraxes in radiographic images and radiologists. Critical Care Suite should not be used in-lieu of full patient evaluation or solely relied upon to make or confirm a diagnosis. It is not intended to replace the review of the X-ray image by a qualified physician. Critical Care Suite is indicated for adults and Transitional Adolescents (18 to < 22years old but treated like adults).
User Population	Medical specialists and radiologists that have been trained to independently assess the presence of brain aneurysms in head CTA.	Radiologists and HCPs that have been trained to independently assess the presence of pneumothoraxes in radiographic images.
Targeted clinical condition, anatomy, and imaging modality	Brain Aneurysm Head Computerized tomography angiography	Pneumothorax Chest/Lung AP/PA Chest X-Ray Imaging
Technological Characteristics		
Algorithm Inferencing Mechanism	AI supervised deep learning algorithm designed to aide in identifying and highlighting brain aneurysms during the review of CT angiography images.	AI deep learning algorithms designed to detect pneumothorax in frontal chest X-ray images to aide in identifying and highlighting pneumothoraxes during the review of radiographs.
Computational Platform	CINA-Aneurysm is designed as a self-contained software deployable on various computing platforms such as Medical Image and	Critical Care Suite is designed as a self-contained software module deployable on various computational and x-ray imaging system platforms such as Digital Projection

	Communication Devices, On Premise or On Cloud.	Radiographic Systems, PACS, On Premise or On Cloud.
Algorithm Outputs	Image annotations that contain: • Flag if at least a suspected brain aneurysm was detected • Overlay that localizes brain aneurysms within the image • Measurements of maximum diameters of brain aneurysms	1. Configurable DICOM tag that identifies if a suspected pneumothorax was detected. 2. Image annotations that contain: • Flag if a suspected pneumothorax was detected • Graphical representation of the algorithms confidence in the algorithms result • Overlay (color or grayscale) that localizes the pneumothorax within the image
Destination for Viewing Algorithm Results	Image annotation on a secondary DICOM image and a DICOM message that identifies if a suspected brain aneurysm was detected within the study. The output can be immediately used to visualize the results on any DICOM destination such as a user's images storage system (PACS) or the workstation.	Image annotation on a secondary DICOM image and a DICOM message that identifies if a suspected pneumothorax was detected within the study. The output can be immediately used to visualize the results on any DICOM destination such as a user's images storage system (PACS) or the x-ray system.

Predetermined Change Control Plan

AVICENNA.AI will make future algorithm improvements and input parameter expansions under a Predetermined Change Control Plan (PCCP) for CINA-Aneurysm. The PCCP specifies the types of anticipated modifications to the device software and the methods to implement those modifications. The PCCP also specifies the performance requirements and validation activities to ensure the device remains as safe and as effective as the cleared device.

The detailed description of the modifications, testing methods, validation activities, performance requirements, and communication to users are summarized in the table below.

Planned Modifications	Test Methods and Validation Activities	Communication to Users
Modification A : Algorithm Performance Improvement (Re-training). Re-training of CNN model weights (aneurysm detection and/or vessel segmentation steps) on new or expanded annotated CTA datasets to improve sensitivity, specificity, or robustness, without changes to model architecture or intended use. Initiated by pre-specified trigger criteria (accumulated edge-case data, post-market performance signal, or planned scanner expansion).	Evaluation on BRT-Set and expanded validation dataset: (1) Primary: Case-level ROC AUC ≥ 0.90 (lower bound 95% CI, DeLong); (2) Secondary: Case-level Sensitivity and Specificity ≥ 0.80 (lower bound 95% Clopper-Pearson CI); (3) Longitudinal drift: ΔAUC lower bound 95% CI ≥ 0 (DeLong test); McNemar one-sided p > 0.05 for Sensitivity and Specificity degradation vs. previously released version; (4) Supportive: Lesion-level mean DICE ≥ 0.72 (lower bound 95% CI); MAE ≤ 1.0 mm (axial, sagittal, coronal); overall vascular-label PPA ≥ 87.0% (lower bound 95% CI); mean time-to-notification < 5 min; (5) Per-anatomical-location subgroup McNemar non-degradation test (one-sided, p > 0.05) at ICA, MCA, ACA, and PC location groups on BRT-Set.	Updated User Guide with new software version number; release notes describing the modification and any updated sensitivity/specificity/AUC performance claims; updated IFU reflecting current version performance characteristics; direct communication to site administrators.
Modification B : Input Parameter Envelope Expansion. Extension of validated acquisition parameters to new CT scanner manufacturers (from a pre-specified list of seven families) or relaxation of Recommended Protocol Checker thresholds (FOV, overlap, reconstruction kernel) within pre-defined numeric limits. Mandatory criteria are immutable and out of scope of this PCCP.	Dedicated validation dataset for each new scanner category/image acquisition parameter (minimum 137 positive and 137 negative CTA cases, per a priori power calculation) with scanner/image acquisition parameter-stratified subgroup analysis. Same performance acceptance criteria as Modification A, except per-anatomical-location subgroup analysis (ROC AUC, Sensitivity, Specificity, Longitudinal ΔAUC (DeLong test) and Sensitivity, Specificity changes (McNemar test, one sided), DICE, MAE, PPA, TTN) evaluated on both BRT-Set and expanded dataset.	Updated IFU appendix listing newly supported scanner families and acquisition parameters; release notes; direct communication to site administrators.

Modification C : Operating Point Adjustment. Post-deployment selection of up to three alternative detection thresholds applied to the fixed CNN output, to adjust the sensitivity/specificity trade-off. Justified exclusively by: post-market performance signal (Condition 2 per §4.2), peer-reviewed clinical evidence, or formal clinical review. Model weights and architecture are unchanged.	Evaluation on BRT-Set at the new operating point(s): ROC AUC ≥ 0.90 (lower bound 95% CI); Sensitivity and Specificity ≥ 0.80 (lower bound 95% CI); DICE ≥ 0.72 (lower bound 95% CI); MAE ≤ 1.0 mm; PPA ≥ 87.0% (lower bound 95% CI); TTN < 5 min. Longitudinal drift metrics (ΔAUC, McNemar) not applicable (model unchanged). Documented clinical rationale mandatory.	IFU update mandatory prior to deployment, stating ROC AUC, sensitivity, and specificity at each new operating point; release notes.
Modification D : Output Display Format Refinement. Cosmetic changes to DICOM Secondary Capture layout, annotation styling, or language localization that convey the same clinical information as the cleared outputs. No new clinical data, measurements, or output formats are added.	Full regression test suite mandatory; usability/human-factors review per IEC 62366-1 confirming no new use error; confirmation that detection results, localizations, and measurements are identical before and after the change.	Release notes; User Guide update if applicable.

Conclusions

CINA-Aneurysm is as safe and effective as the Critical Care Suite with Pneumothorax Detection AI Algorithm. 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.