



Harrison-AI Medical Pty Ltd
Haylee Bosshard
Regulatory Affairs Manager
24 Campbell St.
Level P
Sydney, NSW 2000
Australia

March 3, 2026

Re: K253818

Trade/Device Name: Annalise Enterprise
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: February 12, 2026
Received: February 12, 2026

Dear Haylee Bosshard:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written over a large, light blue, semi-transparent watermark of the letters "FDA".

Jessica Lamb, PhD
Assistant Director
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.

K253818

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Please provide the device trade name(s).

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Annalise Enterprise

Please provide your Indications for Use below.

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Intended context:

Annalise Enterprise is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings:

- acute infarct*

**See Additional Information, next page.

The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage.

The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings.

Its results are not intended:

- to be used on a standalone basis for clinical decision making
- to rule out specific findings, or otherwise preclude clinical assessment of non-contrast computed tomography brain

Intended modality:

Annalise Enterprise identifies suspected findings in non-contrast brain CT studies.

Intended user:

The device is intended to be used by trained clinicians who are qualified to interpret CTB studies as part of their scope of practice.

Intended patient population:

The intended population is patients who are 22 years or older.

Additional information:

The device includes acute infarct of the cerebral hemispheres or cerebellum, also including early signs of acute middle cerebral artery (MCA) infarct such as insular ribbon sign and disappearing basal ganglia sign. The infarct must be a completed infarct (i.e. include an ischemic core of $\geq 5\text{mL}$). The device also includes hyperdense artery in the anterior circulation but does not include lacunar infarcts, brainstem infarcts or venous infarcts.

The radiological device definition of acute infarct includes the following territories and regions:

- anterior cerebral artery (ACA)
- middle cerebral artery (MCA)
- posterior cerebral artery (PCA)
- cerebellum
- basilar artery occlusions
- watershed regions

Specificity may be reduced in the presence of infarcts of $< 5\text{mL}$.

Caution:

All patients should get adequate care for their symptoms, including advanced imaging (e.g., CTA, CTP, MRI, etc.) and/or other appropriate care per standard clinical practice, irrespective of the device output. The device is not intended to be a rule-out device and for cases that have been processed by the device, an absence of a notification for suspected acute infarct should not be viewed as indicating that acute infarct is excluded.

Limitations:

The device does not replace the need for advanced imaging in the stroke workup. It provides workflow prioritization and notification only.

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](#))

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510(k) Summary

SUBMITTER

Company Name	Harrison-AI Medical Pty Ltd
Address	Level P, 24 Campbell Street Sydney, NSW 2000 Australia
Phone Number	+61 1800-958487
Contact Person	Haylee Bosshard
Date Prepared	February 11, 2026

SUBJECT DEVICE

Manufacturer Name	Harrison-AI Medical Pty Ltd
Device Name	Annalise Enterprise
Classification Name	Radiological computer aided triage and notification software (21 CFR 892.2080)
Regulatory Class	II
Product Code	QAS

PREDICATE DEVICE

Manufacturer Name	iSchemaView, Inc.
Device Name	Rapid NCCT Stroke
510(k) reference	K222884
Classification Name	Radiological computer aided triage and notification software (21 CFR 892.2080)
Regulatory Class	II
Product Code	QAS

This predicate device has not been subject to a design-related recall.

REFERENCE DEVICE

Manufacturer Name	Aidoc Medical, Ltd.
Device Name	BriefCase
510(k) reference	K220709
Classification Name	Radiological computer aided triage and notification software (21 CFR 892.2080)
Regulatory Class	II
Product Code	QAS

This reference device has not been subject to a design-related recall.

DEVICE DESCRIPTION

Annalise Enterprise is a software workflow tool which uses an artificial intelligence (AI) algorithm to identify suspected findings on non-contrast brain CT studies in the medical care environment. The finding identified by the device is acute infarct.

Radiological findings are identified by the device using an AI algorithm – a convolutional neural network trained using deep-learning techniques. Images used to train the algorithm were sourced from datasets that included a range of patient demographics and technical characteristics, including different equipment manufacturers and machines. This dataset, which contained over 200,000 CT brain imaging studies, was labelled by trained radiologists regarding the presence of the findings of interest.

The performance of the device's AI algorithm was validated in a standalone performance evaluation, in which the case-level output from the device was compared with a reference standard ('ground truth'). This was determined by two ground truthers, with a third truther used in the event of disagreement. All truthers were US board-certified neuroradiologists or neurologists.

The device interfaces with image and order management systems (such as PACS/RIS) to obtain non-contrast brain CT studies for processing by the AI algorithm. Following processing, if any of the clinical findings of interest are identified in the study, the device provides a notification to the image and order management system for prioritization of that study in the worklist. This enables users to review the studies containing features suggestive of these clinical findings earlier than in the standard clinical workflow. It is important to note that the device will never decrease a study's existing priority in the worklist. This ensures that worklist items will never have their priorities downgraded based on AI results.

The device workflow is performed parallel to and in conjunction with the standard clinical workflow for interpretation of non-contrast brain CT studies. The device is intended to aid in prioritization and triage of radiological medical images only.

INDICATIONS FOR USE

Intended context *Annalise Enterprise is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings:*

- *acute infarct**

**See Additional Information, below.*

The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage.

The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings.

Its results are not intended:

- *to be used on a standalone basis for clinical decision making*
- *to rule out specific findings, or otherwise preclude clinical assessment of non-contrast computed tomography brain*

Intended modality *Annalise Enterprise identifies suspected findings in non-contrast brain CT studies.*

Intended user *The device is intended to be used by trained clinicians who are qualified to interpret CTB studies as part of their scope of practice.*

Intended patient population *The intended population is patients who are 22 years or older.*

Additional information *The device includes acute infarct of the cerebral hemispheres or cerebellum, also including early signs of acute middle cerebral artery (MCA) infarct such as insular ribbon sign and disappearing basal ganglia sign.*

The infarct must be a completed infarct (i.e. include an ischemic core of $\geq 5\text{mL}$). The device also includes hyperdense artery in the anterior circulation but does not include lacunar infarcts, brainstem infarcts or venous infarcts.

The radiological device definition of acute infarct includes the following territories and regions:

- *anterior cerebral artery (ACA)*
- *middle cerebral artery (MCA)*
- *posterior cerebral artery (PCA)*
- *cerebellum*
- *basilar artery occlusions*
- *watershed regions*

Specificity may be reduced in the presence of infarcts of $< 5\text{mL}$.

Caution:

All patients should get adequate care for their symptoms, including advanced imaging (e.g., CTA, CTP, MRI, etc.) and/or other appropriate care per standard clinical practice, irrespective of the device output.

The device is not intended to be a rule-out device and for cases that have been processed by the device, an absence of a notification for suspected acute infarct should not be viewed as indicating that acute infarct is excluded.

Limitations:

The device does not replace the need for advanced imaging in the stroke workup. It provides workflow prioritization and notification only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device was evaluated and compared to the predicate device with respect to the following characteristics:

1. Indications for Use
2. Target population
3. Anatomical site and modality
4. Intended user and clinical use environment
5. Finding of interest
6. Device input and radiological image protocol
7. Device output and means of notification to user
8. System components
9. Prioritization relationship to standard of care workflow
10. AI models and performance of algorithm (performance level, triage effectiveness)

The following characteristics showed a difference between the subject and predicate devices. The different characteristics include:

1. Finding of interest
2. AI models and performance of algorithm (performance level, triage effectiveness)

All differences were technological characteristic differences that do not raise different questions of safety and effectiveness. Furthermore, a standalone performance study has been provided for this submission to evaluate these differences and establish substantial equivalence.

Characteristics	Subject Device (Annalise Enterprise)	Predicate Device (Rapid NCCT Stroke, K222884)	Reference Device (Aidoc BriefCase, K220709)
Indications for use	Intended context Annalise Enterprise is a device designed to be used in the medical care environment to aid in triage and prioritization of studies with features suggestive of the following findings: - acute infarct* <i>*See Additional Information below.</i> The device analyzes studies using an artificial intelligence algorithm to identify findings. It makes study-level output available to an order and imaging management system for worklist prioritization or triage. The device is not intended to direct attention to specific portions of an image and only provides notification for suspected findings. Its results are not intended: - to be used on a standalone basis for clinical decision making - to rule out specific findings, or otherwise preclude clinical assessment of non-contrast computed tomography brain Intended modality Annalise Enterprise identifies suspected findings in non-contrast brain CT studies. Intended user The device is intended to be used by trained clinicians who are qualified to interpret CTB studies as part of their scope of practice. Intended patient population The intended population is patients who are 22 years or older. Additional information The device includes acute infarct of the cerebral hemispheres or cerebellum, also including early signs of acute middle cerebral artery (MCA) infarct such as	Rapid NCCT Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of (1) nonenhanced head CT (NCCT) images. The device is intended to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of (1) head CT images for Intracranial Hemorrhage (ICH) and (2) NCCT large vessel occlusion (LVO) of the ICA and MCA-M1. Rapid NCCT Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected (1) ICH or (2) NCCT LVO on the Rapid server on premise or in the cloud in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected ICH or LVO findings via PACS, email or mobile device. Notifications include compressed preview images that are meant for informational purposes only, and are not intended for diagnostic use beyond notification. The device does not alter the original medical image, and it is not intended to be used as a primary diagnostic device. The results of Rapid NCCT Stroke are intended to be used in conjunction with other patient information and based on professional judgment to assist with triage/prioritization of medical images. Notified clinicians are ultimately responsible for reviewing full images per the standard of care. Rapid NCCT Stroke is for Adults only. <u>Cautions:</u> - All patients should get adequate care for their symptoms including CTA and/or other appropriate care per the standard clinical practice, irrespective of the device output. - The device is not intended to be a rule-out device and for cases that have been processed by the device without notification for "Suspected LVO" should not be viewed as indicating that LVO is excluded. All cases should undergo CTA, per the standard stroke workup.	BriefCase is a radiological computer aided triage and notification software indicated for use in the analysis of head CTA images in adults or transitional adolescents aged 18 and older. The device is intended to assist hospital networks and appropriately trained medical specialists in workflow triage by flagging and communication of suspected positive findings of complete Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4. BriefCase uses an artificial intelligence algorithm to analyze images and highlight cases with detected findings on a standalone desktop application in parallel to the ongoing standard of care image interpretation. The user is presented with notifications for cases with suspected findings. Notifications include compressed preview images that are meant for informational purposes only and not intended for diagnostic use beyond notification. The device does not alter the original medical image and is not intended to be used as a diagnostic device. The results of BriefCase are intended to be used in conjunction with other patient information and based on their professional judgment, to assist with triage/prioritization of medical images. Notified clinicians are responsible for viewing full images per the standard of care.

Characteristics	Subject Device (Annalise Enterprise)	Predicate Device (Rapid NCCT Stroke, K222884)	Reference Device (Aidoc BriefCase, K220709)
	insular ribbon sign and disappearing basal ganglia sign. The infarct must be a completed infarct (i.e. include an ischemic core of $\geq 5\text{mL}$). The device also includes hyperdense artery in the anterior circulation but does not include lacunar infarcts, brainstem infarcts or venous infarcts. The radiological device definition of acute infarct includes the following territories and regions: - anterior cerebral artery (ACA) - middle cerebral artery (MCA) - posterior cerebral artery (PCA) - cerebellum - basilar artery occlusions - watershed regions Specificity may be reduced in the presence of infarcts of $< 5\text{mL}$. <u>Caution:</u> - All patients should get adequate care for their symptoms, including advanced imaging (e.g., CTA, CTP, MRI, etc.) and/or other appropriate care per standard clinical practice, irrespective of the device output. - The device is not intended to be a rule-out device and for cases that have been processed by the device, an absence of a notification for suspected acute infarct should not be viewed as indicating that acute infarct is excluded.. <u>Limitations:</u> - The device does not replace the need for advanced imaging in the stroke workup. It provides workflow prioritization and notification only.	<u>Limitations:</u> - Rapid NCCT Stroke does not replace the need for CTA or MRA in ischemic stroke workup, it provides workflow prioritization and notification only. - Rapid ICH has been shown to reliably identify hemorrhages of $\geq 0.4\text{mL}$. <u>Contraindications/Exclusions</u> - Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. - Hemorrhagic Transformation, Hematoma - Very thin or no Ventricles	
Target population	Adults only	Adults only	Adults or transitional adolescents aged 18 and older
Anatomical site and modality	Non-contrast brain CT	Non-contrast brain CT	Head CTA
Intended user and clinical use environment	Trained clinicians who, as part of their scope of practice, are qualified to interpret brain CT scans	Hospital networks and trained clinicians	Hospital networks and appropriately trained medical specialists

Characteristics	Subject Device (Annalise Enterprise)	Predicate Device (Rapid NCCT Stroke, K222884)	Reference Device (Aidoc BriefCase, K220709)
Finding of interest	Acute infarct of the cerebral hemispheres or cerebellum, also including early signs of acute middle cerebral artery (MCA) infarct such as insular ribbon sign and disappearing basal ganglia sign. The infarct must be a completed infarct (i.e., include an ischemic core of $\geq 5\text{mL}$). The device also includes hyperdense artery in the anterior circulation but does not include lacunar infarcts, brainstem infarcts or venous infarcts. The radiological device definition includes the following territories and regions: • Anterior cerebral artery (ACA) • Middle cerebral artery (MCA) • Posterior cerebral artery (PCA) • Cerebellar regions • Basilar artery occlusion • Watershed regions	(Comparison made to only LVO portion of device) Large vessel occlusions within the ICA and MCA-M1, identified by hyperdense vessel sign	Large Vessel Occlusion (LVO) - MCA-M1, PCA-P1, ACA-A1, ICA, Basilar; and Medium Vessel Occlusions (MeVO) - MCA-M2, MCA-proximal M3, PCA-P2, PCA-proximal P3, ACA-A2, ACA-proximal A3, and Vertebral-V4
Device input and radiological image protocol	DICOM-compliant non-contrast brain CT scans Attributes model: Determines which series the algorithm processes based on pixel data to maximize the proportion of series that are appropriately analyzed by AI	DICOM-compliant non-contrast brain CT scans	DICOM-compliant head CTA scans aiOS: Determines which series the algorithm processes based on pixel data to maximize the proportion of studies that are appropriately analyzed by AI
Device output and means of notification to user	Notifications via customizable workflows into existing systems (e.g., PACS, RIS, TigerConnect, Epic, etc.). A non-diagnostic viewer, where users can preview DICOM image series, is provided. This viewer is for informational purposes only.	Notifications via PACS, email, or mobile device A non-diagnostic viewer, where users can preview DICOM image series, is provided. This viewer is for informational purposes only.	Notifications via Aidoc Desktop Application, a dedicated tool requiring new workflows and integrations. A non-diagnostic viewer, where users can preview DICOM image series, is provided. This viewer is for informational purposes only.
System components	Software architecture (Integration Adapter and Backend API services) handles image transmission, storage/security management and output to medical worklist software.	AI/ML SaMD within the Rapid Platform including DICOM processing, job management, imaging module execution and imaging output including the notification and compressed image.	(1) Aidoc Hospital Server (AHS/Orchestrator) for image acquisition; (2) Aidoc Cloud Server (ACS) for image processing; and (3) Aidoc Desktop Application for workflow integration
Prioritization relationship to standard of care workflow	Operates parallel to and independent of the current clinical workflow (No cases are removed from the worklist)	Operates parallel to and independent of the current clinical workflow (No cases are removed from the worklist)	Operates parallel to and independent of the current clinical workflow (No cases are removed from the worklist)
Performance level – Sensitivity and Specificity	Operating point 1 ($\leq 1.5\text{mm}$): Se: 89.2% (95% CI: 85.8, 92.6) Sp: 84.1% (95% CI: 81.5, 86.9) Operating point 2 ($\leq 1.5\text{mm}$): Se: 88.5 (95% CI: 84.8, 92.0) Sp: 87.5 (95% CI: 85.0, 89.8) Operating point 3 ($\leq 1.5\text{mm}$): Se: 87.3 (95% CI: 83.6, 91.0)	Operating point 1: Se: 63.5% (95% CI: 54.4, 71.7) Sp: 95.1% (95% CI: 89.1, 97.9) (For LVO indication only one operating point reported)	Operating point 1: Se: 91.3% (95% CI: 83.6, 96.2) Sp: 85.6% (95% CI: 80.6, 89.7) Operating point 2: Se: 91.3% (95% CI: 83.58, 96.17) Sp: 85.2% (95% CI: 80.18, 89.36).

Characteristics	Subject Device (Annalise Enterprise)	Predicate Device (Rapid NCCT Stroke, K222884)	Reference Device (Aidoc BriefCase, K220709)
	Sp: 89.8 (95% CI: 87.5, 91.9) Operating point 4 ($\leq 1.5\text{mm}$): Se: 86.1 (95% CI: 82.4, 89.8) Sp: 91.4 (95% CI: 89.3, 93.4) Operating point 5 ($\leq 1.5\text{mm}$): Se: 84.5 (95% CI: 80.5, 88.5) Sp: 93.1 (95% CI: 91.1, 95.0) Operating point 6 ($> 1.5\text{mm} \& \leq 5.0\text{mm}$): Se: 85.7 (95% CI: 81.9, 89.2) Sp: 83.2 (95% CI: 80.3, 85.9) Operating point 7 ($> 1.5\text{mm} \& \leq 5.0\text{mm}$): Se: 85.7 (95% CI: 81.9, 89.2) Sp: 84.4 (95% CI: 81.8, 87.0) Operating point 8 ($> 1.5\text{mm} \& \leq 5.0\text{mm}$): Se: 84.8 (95% CI: 81.0, 88.3) Sp: 85.6 (95% CI: 82.9, 88.1) Operating point 9 ($> 1.5\text{mm} \& \leq 5.0\text{mm}$): Se: 83.4 (95% CI: 79.3, 87.2) Sp: 87.0 (95% CI: 84.3, 89.3) Operating point 10 ($> 1.5\text{mm} \& \leq 5.0\text{mm}$): Se: 78.1 (95% CI: 73.8, 82.5) Sp: 91.9 (95% CI: 89.8, 93.9)		
Triage effectiveness performance level – Turn-around time	81.6 (95% CI: 80.3 – 82.9) seconds	2.5 (95% CI: 2.4, 2.6) minutes	2.23 minutes (95% CI: 2.22-2.23)

The key differences between the subject device and predicate and reference devices are described below, following recommendations in the guidance document “Benefit-Risk Factors to Consider When Determining Substantial Equivalence in Premarket Notifications (510(k)) with Different Technological Characteristics - *Guidance for Industry and Food and Drug Administration Staff*”, September 2018.

Benefit/Risk Summary Compared to Predicate and Reference Device

Characteristic	Benefit of difference	Risk of difference and mitigations
Modality: NCCT same as Rapid NCCT Stroke but different from Aidoc (CTA)	In some advanced stroke imaging centers, CTA and CT perfusion may be performed immediately after NCCT, while the patient is still on the scanner table. However, AHA/ASA guidelines recommend interpretation of NCCT and determination of IV-tPA eligibility and, where indicated, immediate administration <i>prior to advanced imaging to determine candidacy for endovascular treatment</i> (Powers, et al., 2019). For facilities following the steps recommended by these guidelines, prioritization and time savings based on the initial NCCT is critical. Furthermore, care coordination is dependent on the acquisition of CTA/CTP images. If notification can be initiated earlier, this could help speed up surgical preparation teams and communication of the impending patient to specialist teams.	NCCT is a less advanced imaging modality than CTA and based on literature it could be expected that infarct detection on NCCT would have much poorer performance. However, the infarct cases of the pivotal study were ground truthed with availability of advanced imaging modality data. There are multiple operating points that exceeded the typical, but not prescriptive, 80% sensitivity/80% specificity bar in triage devices.
Territory coverage: more comprehensive than Rapid NCCT Stroke but similar to Aidoc Briefcase	Territories and regions compared to Rapid (primary predicate): - According to the 2019 Update to the Guidelines for the Early Management of Acute Ischemic Stroke, mechanical thrombectomy may be considered in LVO patients outside of the ICA and M1 segments, including the vessel regions triaged by the subject device, if treatment can be initiated within 6 hours of symptom onset. - Given that MCA infarcts due to LVO account for approximately only 30% of patients with acute ischemic strokes (AIS) (Lakomkin, et al., 2019) (Rennert, et al., 2019) an additional ~70% of AIS patients are currently not triaged on NCCT by the Rapid NCCT Stroke device. Furthermore, the clinical benefit of IV-tPA may be limited in LVO patients (Hassan, 2021), whereas patients with posterior circulation stroke account for up to 36% of acute stroke patients receiving IV-tPA treatment (Keselman, et al., 2020). In comparison to the Aidoc reference device, the territories and regions are similarly comprehensive. (The subject device also includes cerebellum and watershed regions in its Indications for Use.)	The subject device may not be performant in additional territories or regions (especially the rarer locations/regions for infarct), but that risk has been mitigated by subgroup analysis of a sufficient number of test cases across different territories and regions.
Conclusion	- Additional benefit compared to Rapid NCCT LVO because of additional territories and regions, which may result in up to 70% more AIS patients being triaged based on the literature quoted above. - Additional benefit compared to Aidoc BriefCase because triage of patients with potential ischemic stroke can happen earlier in the clinical workflow, at least for a subset of patients that may not receive CTA at the same time as NCCT.	- Lower risk than Rapid because of demonstrated higher sensitivity (while maintaining >80% specificity) at all available operating points. - Similar risk to Aidoc: While the triage is based on NCCT (in comparison to CTA or other advanced imaging which is recognized as more sensitive in identifying ischemic stroke), the ground truthing included availability of an advanced imaging modality. Furthermore, multiple operating points exceeded 80% sensitivity/80% specificity.

Background on Standard of Care

Given that the clinical workflow for stroke is complex, in order to substantiate the importance of the benefit of earlier triage of infarct on NCCT as summarized in the table above, the following background discussion on variability within current standard of care has been provided.

Acute infarct is classified by the 2019 model of the Clinical Practice of Emergency Medicine as “a life-threatening illness or injury with a high probability of mortality if immediate intervention is not begun to prevent further airway, respiratory, hemodynamic, and/or neurologic instability.” In 2020, stroke was listed by the CDC as the fifth leading cause of death in the US. When cerebral blood supply is interrupted, if left unchecked, neuronal cell death (infarct) occurs within 5 minutes (Ju, 2018). The burden of stroke lies not only in the high mortality, but up to 50% of survivors are encumbered with chronic disability (Donkor, 2018). The most fundamental aspect of stroke management is “time is brain.” Delayed access to beneficial treatment has been shown to have poorer outcomes. Early intervention is critical for successful outcomes.

Based on guidelines including AHA/ASA and the American College of Emergency Physicians, physical and neurological assessment followed by NCCT is the current standard of care for diagnosis of acute ischemic stroke (AIS), and delineation of mimics. The device is intended to work in parallel with the current workflow but will provide triage and notification (active and passive) to treating clinicians, to ensure high-risk patients are evaluated faster, facilitating expeditious follow up imaging and treatment as needed.

Diagnosis of infarct relies on rapid imaging to enable access to life-saving treatment options that are restricted in therapeutic benefit due to a very narrow therapeutic time-window. The window for administration of the current gold-standard treatment (thrombolysis/ IV-tPA) is ≤ 4.5 hours from the onset of symptoms, *with reduced morbidity and mortality associated with earlier administration*. After 4.5 hours from symptom onset, administration of thrombolytic treatment is contraindicated. To maximize the number of eligible patients, national guidelines have been developed that recommend a *door-to-needle* time of ≤ 60 minutes for at least 50% of patients presenting with symptoms of acute stroke; however, despite these guidelines, a combination of both pre- and in- hospital delays currently precludes approximately 9 out of 10 patients from receiving this treatment (Wijngaarden, et al., 2009). For those that do receive this treatment, every 15-minute reduction in time to initiation is associated with better prognosis such as increased odds of independent mobility and discharge to home, and reduced odds of in-hospital mortality. (Saver, et al., 2013) (Darehed, et al., 2020) (Man, et al., 2020).

Endovascular treatment (EVT) is recommended in patients experiencing infarct due to a large vessel occlusion (LVO), however this treatment is also limited by a narrow therapeutic window (ideally ≤ 6 hours but up to 24 hours) and requires admission to a comprehensive stroke center (CSC) with rapid access to cerebral angiography, qualified neuro-interventionalists, and a comprehensive periprocedural care team. For many patients this necessitates inter-hospital transfer to an appropriate facility, which relies on streamlined coordination of clinical care teams. Patients requiring inter-hospital transfers are subject to delayed access to treatment (Saver, et al., 2016), and poorer clinical outcomes. A prospective, multicenter, observational, single-arm study of real-world thrombectomy patients for acute stroke due to LVO reported that patients that had a shorter median time to treatment (202.0 vs 311.5 minutes) had a significantly greater odds ratio (1.38; 95% CI 1.06 – 1.79; $p = 0.02$) of achieving functional independence (Froehler, 2017), with every 4 minutes delay in EVT associated with increased 90-day disability for 1 in 100 patients.

To maximize the number of patients eligible for thrombolytic therapy, National guidelines have been developed that recommend a door-to-needle time for thrombolysis of ≤ 60 minutes for at least 50% of patients presenting with symptoms of acute stroke. Within a stroke workflow, at comprehensive stroke centers, a code-stroke patient is likely to receive timely NCCT, followed by IV placement, discussion of eligibility and safety of t-PA with patient and lab review, if necessary, before urgently commencing IV-tPA in eligible patients. In potential EVT eligible patients, this is followed by CTA or other advanced imaging and mobilization of the EVT team and resources. In these settings a dedicated team can be ready to evaluate NCCT findings with reported average interpretation times less than 7 minutes (Pearson, 2018).

However, despite these national guidelines, a combination of both pre- and in-hospital delays preclude many stroke patients from receiving the recommended treatment at the recommended time interval. Therefore, in considering the potential benefit of the infarct NCCT triage device, it is important to consider the current state of care for a diverse patient population, as summarized below.

Patient group	Current state
Not immediately allocated to a stroke workflow due to an initial missed or delayed diagnosis	Unsuspected infarct prior to NCCT: A retrospective study within the US that reviewed patient charts over a one-year period at two separate hospitals, found ~20% of ischemic stroke patients were missed in the emergency department despite presenting within the appropriate time window for thrombolytic treatment (Arch, et al., 2016). Suspected infarct prior to NCCT: Even for patients suspected of acute infarct prior to NCCT, not all are immediately placed on a stroke workflow. For example, a clinician may consider multiple diagnoses when a patient presents with stroke-like symptoms. The presence of negative and positive neurologic symptoms may lead a clinician to suspect stroke and multiple other stroke mimics (Boushra & Lui., 2025). The positive predictive value for infarct is lower in patients who are more stable, for example those who can ambulate and arrive at an emergency department by personal vehicle. These patients are less likely to be immediately put on a stroke workflow, even if they present with signs of stroke.
Hospital inpatients	Up to 17% of strokes occur in patients already hospitalized (Cumbler E. , 2015). Inpatients experiencing stroke have worse outcomes than those who have stroke in the community (Cumbler E. , 2015) (Cumbler, et al., 2014). In many cases in-hospital strokes are silent and only detected on routine post- operative imaging; symptomatic presentation is often non-specific and difficult to identify as patients are impacted by anesthesia, other medications or are intubated (Benesch, et al., 2021). The median time to treatment for in-patient strokes averaged 100 minutes (vs 76 minutes for community onset) (Zachrisson, et al., 2022), and only one in five patients within-hospital stroke were treated within the recommended 60-minute target, despite already being in a hospital setting (Cumbler, et al., 2014).
Regional, rural, or low-income patients	Regional patients also have poorer outcomes and higher in-hospital mortality associated with longer time to treatment. (Hammond, Luke, Elson, Towfighi, & Maddox, 2020). An analysis of data from 2009 to 2019 found that hospitals located in low-income and rural communities had a lower likelihood of receiving stroke certification than hospitals in general communities. When adjusting the model for population size, it was also discovered that patients in Black, racially segregated communities had the lowest likelihood of access to stroke-certified hospitals (Shen, Sarkar, & Hsia, 2022). Another study that looked at data of 5055 US hospitals from 2009 to 2022 found that hospitals in communities with the greatest level of disadvantage had the lowest likelihood of adopting specialized stroke care services while those in the most advantaged communities had the highest likelihood. In fact, these were 20% to 42% less likely to become stroke-certified compared with hospitals near mixed-advantage communities (Shen, Sarkar, & Hsia, 2022).
Patients treated at hospitals without well-established stroke protocols	Of the 5533 hospital emergency departments on record in the United States, 56% do not include recognized stroke centers, with services that can range from comprehensive stroke management to initiation of care before transferring to a larger hospital (Boggs, et al., 2022). A 2020-2021 survey of emergency departments participating in the ACEP Emergency Quality Network (E-QUAL) Stroke Collaborative found that only 67% of respondents had a written acute stroke protocol (Zachrisson, et al., 2022). A hospital without a stroke protocol may not have a well-established process for ensuring appropriate members of the care team are available, specifically a neuroradiologist is available to read the case as soon as the image is acquired.
Patients admitted outside normal hours	Patients may also experience disparities in stroke care based on the day or time of day of admission. For example, in a recent US study at an institution with a comprehensive stroke center and over 80,000 patient visits per year,

Patient group	Current state
	the median door to needle time was 22 minutes longer during night shift vs during day shift (59 min vs 37 min). When a dedicated stroke team was present, the median door to needle time was 36 min, compared to 51 min when they were not present (Ganti, et al., 2023). Similar delays may be encountered at some facilities over weekends when staff are reduced.
Patients even in stroke centers	There's evidence that many stroke centers do not meet timeline goals for treatment of patients who are identified as suspected stroke. A recent retrospective cohort study involving AHA "Get With the Guidelines-Stroke" participating hospitals, reported a median door to DTN time of 65 minutes (IQR, 49-88 minutes) (Man, Xian, & Holmes, 2020), indicating that the ≤ 60 -minute target is unattainable even for those institutions committed to achieving this goal. Using the American Heart Association Get With The Guidelines-Stroke registry, one study evaluated 108 913 patients with acute stroke requiring inter-hospital transfer from 1925 hospitals and determined that the median door-in to door-out time was 174 minutes, despite the current guidelines recommending no more than 120 minutes at the transferring emergency department. Longer times were associated with groups of patients such as those over 80 years of age, women, Black, and Hispanic patients (Stamm, et al., 2023).

How the subject device integrates into current standard of care clinical workflow

Decision making process for IV-tPA:

Per AHA/ASA guidelines, the treatment window for IV-tPA is a maximum of 4.5 hours from time of symptom onset making early identification of acute ischemic stroke patients critical. The active notification which the subject device can send to the attending clinician and neurologist allows expedited assessment of the patient to determine eligibility for IV-tPA. The AHA/ASA guideline includes a comprehensive list of recommendations for assessment of IV-tPA eligibility including but not limited to patient age, symptom onset time, stroke severity, blood pressure, blood glucose, concomitant disease/disability, concomitant medications, early improvement status, recent surgical and trauma status and contraindications (which include ICH, or Intracerebral Hemorrhage, detected on an NCCT). It is therefore vital that patients are identified as early as possible to maximize the chance that eligible patients can receive IV-tPA within the very short therapeutic window. The device contributes to the decision-making process for IV-tPA through triage of the intended population and active notification that can facilitate earlier assessment for eligibility, including prioritized read of the NCCT exam.

Decision making process for thrombectomy:

Per AHA/ASA guidelines, the treatment window for mechanical thrombectomy has recently been increased to a maximum of 24 hours from time of symptom onset; however, this relies on the patient being present at an appropriately qualified facility, making early identification acute ischemic stroke patients critical. The device contributes to decision making process for thrombectomy in the same manner as for IV-tPA, however determining thrombectomy eligibility has greater complexity. Per AHA/ASA guidelines, mechanical thrombectomy requires the patient to be at an experienced stroke center with rapid access to cerebral angiography, qualified neurointerventionalists, and a comprehensive periprocedural care team. Sites that do not meet these criteria must arrange urgent transfer of patients meeting initial eligibility criteria related to symptom onset time, prestroke mRS score and NIHSS stroke severity score. Eligible patients require urgent advanced imaging (CTA with CTP or MRA with DW-MRI with or without MR perfusion) for determination of eligibility requirements relating to the causative occlusion location, ASPECTS score and to rule out the contraindication of infarction involving one-third or more of the MCA territory. For eligible patients, the optimal anesthetic technique must also be determined based on patient risk factors. The comprehensive assessment and complex workflow mean it is vital that imaging exams associated with potential ischemic stroke patients are triaged *as early as possible in the clinical workflow*.

PERFORMANCE DATA

The following performance data have been provided to support evaluation of substantial equivalence.

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions - *Guidance for Industry and Food and Drug Administration Staff*", June 2023.

Performance Testing

Performance of the subject device was assessed in four performance studies to satisfy requirements set forth in the special controls per 21 CFR 892.2080. These included standalone performance and triage effectiveness evaluations.

Standalone performance was assessed via a retrospective, anonymized study of adult patient, DICOM-compliant non-contrast brain CT cases. The test dataset used during the standalone performance evaluation was newly acquired and independent from the training dataset used in model development. The standalone performance study was conducted on a dataset collected consecutively from five US hospital network sites.

The $\leq 1.5\text{mm}$ cohort of the performance testing dataset included 977 cases, with representation across subgroups for patient demographics (gender [female: 52.0%, male: 48%], age [mean: 67.4 years, min: 22, max: 102], ethnicity [Hispanic: 7.1%, Unavailable: 4.6%], race [White/Caucasian: 79.5%, All other groups: 12.1%, Unknown: 7.5%]), co-existing findings or abnormalities and technical parameters (imaging equipment make, model). The dataset included GE Healthcare, NeuroLogica, Siemens and Toshiba CT scanners.

The $>1.5\text{mm}$ & $\leq 5.0\text{mm}$ cohort of the performance testing dataset included 1050 cases, with representation across subgroups for patient demographics (gender [female: 52.5%, male: 47.5%], age [mean: 67.4 years, min: 22, max: 102], ethnicity [Hispanic: 6.8%, Unavailable: 4.5%], race [White/Caucasian: 80.4%, All other groups: 12.1%, Unknown: 7.8%]), co-existing findings or abnormalities and technical parameters (imaging equipment make, model). The dataset included GE Healthcare, NeuroLogica, Siemens and Toshiba CT scanners.

To determine the ground truth, each deidentified case with advanced imaging was annotated in a blinded fashion by at least two ABR-certified and protocol-trained neuroradiologists (ground truthers), with consensus determined by two ground truthers and adjudicated by a third ground truther in the event of disagreement. Some negative cases with chart-based interpretations as reference were reviewed by two ABR-certified, protocol-trained neuroradiologists and/or neurologists with a third adjudicator in the case of disagreement. The key results of the study are summarized in the table below.

Finding	Product Code	Slice Thickness	AUC (95% CI)
Acute Infarct	QAS	$\leq 1.5\text{mm}$	0.952 (0.937, 0.965)
	QAS	> 1.5 & $\leq 5.0\text{mm}$	0.933 (0.917, 0.949)

Finding	Slice Thickness	Operating Point	Sensitivity % (95% CI)	Specificity % (95% CI)
Acute Infarct	≤1.5mm	0.063800	89.2 (85.8,92.6)	84.1 (81.5,86.9)
		0.076008	88.5 (84.8,92.0)	87.5 (85.0,89.8)
		0.083412	87.3 (83.6,91.0)	89.8 (87.5,91.9)
		0.091176	86.1 (82.4,89.8)	91.4 (89.3,93.4)
		0.100900	84.5 (80.5,88.5)	93.1 (91.1,95.0)
	>1.5mm & ≤5.0mm	0.087158	85.7 (81.9,89.2)	83.2 (80.3,85.9)
		0.091176	85.7 (81.9,89.2)	84.4 (81.8,87.0)
		0.095598	84.8 (81.0,88.3)	85.6 (82.9,88.1)
		0.100900	83.4 (79.3,87.2)	87.0 (84.3,89.3)
		0.119914	78.1 (73.8,82.5)	91.9 (89.8,93.9)

The results demonstrate the subject device establishes effective triage within a clinician's queue based on high sensitivity and specificity. Further, these results are substantially equivalent to those of the predicate device.

Triage effectiveness (turn-around time) was assessed by an internal bench study using a dataset of n=277 cases positive for any of the findings eligible for prioritization. These cases were collected from multiple data sources spanning a variety of geographical locations, patient demographics and technical characteristics. The results demonstrated a triage turn-around time of 81.6 (95% CI: 80.3 – 82.9) seconds, which is substantially equivalent to the total performance time published for the predicate device. A comparison to the predicate is as important as a comparison to standard of care, which is known to be variable across different institutions. To appropriately assess the potential benefit of the subject device, the table below attempts to capture part of that variability leveraging published literature.

Parameter	Target or reported value and range
Time to image interpretation after CT acquired	<u>Patients on Code Stroke workflow</u> - Per AHA/ASA guidelines target value: ≤ 20 minutes (≤ 45 minutes if interpretation time measured from ED arrival, but ≤ 20 minutes is the relevant parameter for comparison to the subject device time to notification) - Even highly experienced hospitals are reported to exceed the above time goal by 50 minutes (Honig, et al., 2014). - The predicate device 510(k) summary K222884 (also on NCCT) makes a comparison to “time to exam open” for data collected for CTA LVO exams in DEN170073: 58.7 (95% CI: 51.5, 71.2) minutes. Just as in K222884, it is reasonable to assume that such CTA exams were collected in the context of a code stroke workflow, and so the elapsed time on the image worklist is a relevant standard of care comparison. <u>Patients not on Code Stroke workflow</u> - Target example hospital guideline expectation for STAT workflow: < 2 hours - Combined data for STAT and Routine workflows: National Radiology Data Registry GRID report for Jan-Sept 2022, generated from data stored in a Qualified Clinical Data Registry (QCDR) for participating hospitals, reported the following aggregated time: Median (IQR) report TAT*** of 4.7 (2.1-11) hours (the time when exam was completed until the time the final report was signed) (National Radiology Data Registry).
Time to Notification of subject device	81.6 (95% CI: 80.3 – 82.9) seconds
Time savings comparison conclusion	The subject device can reduce the time to notification by up to ~1 hour or more, even for patients allocated to a code stroke workflow. Time savings will vary greatly dependent on the institution, procedures, presenting condition of the patient.

Therefore, the subject device has been shown to satisfy the performance requirements per 21 CFR 892.2080, for ‘Radiological computer aided triage and notification software’, by providing clinically effective triage for non-contrast brain CT studies containing features suggestive of acute infarct. This data demonstrates that the subject device is safe and effective for its intended use and thereby supports substantial equivalence.

STANDARDS AND GUIDANCE

Software design, development, testing, deployment, and maintenance approaches utilized for the subject device reflect a comprehensive approach to management of risk through the total product life-cycle. Harrison.ai has also utilized recommendations to address bias and transparency, including a thorough analysis of how the subject device fits into the clinical workflow as documented in this summary and test data across different patient demographics, existing findings or abnormalities and technical parameters (imaging equipment make, model) as documented in this 510(k) summary. As a further transparency-by-design measure, the device user interface provides a link to an electronic version of the instructions for use where users can have ready access to important information including but not limited to a detailed device description, operating instructions including all safety information and troubleshooting, and extensive performance data.

Standards, Guidance, and Best Practices

Description	Title	Year
QMS (also in compliance with 21 CFR 820)	ISO 13485/ EN ISO 13485 – medical device – Quality Management System (Compliance also help ensured through routine audits as part of the Medical Device Single Audit Program)	2016
Risk management	ISO 14971/ EN ISO 14971 - Medical devices — Application of risk management to medical devices	2019
Software best practices and submission content	FDA Guidance: <u>Content of Premarket Submissions for Device Software Functions</u>	2023
Software design & development	IEC 62304 - MEDICAL DEVICE SOFTWARE — SOFTWARE LIFE CYCLE PROCESSES	2006/A1:2015
Usability	IEC 62366-1 - medical devices - Application of usability engineering to medical devices	2015/A1:2020
Cybersecurity	AAMI TIR 57 - Principles for medical device security—risk management	2016/(R) 2019
	FDA Guidance: <u>Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions</u>	2025
Information Security Management	ISO/IEC 27001 - Information technology — Security techniques — Information security management systems — Requirements	2022
Health Software	IEC 82304-1 – Health software - Part 1: General requirements for product safety	2016
Information Management	DICOM - Digital Imaging and Communications in Medicine	Current
Standalone testing methodology, bias, and generalizability considerations specific to certain radiological imaging software devices	FDA Guidance: <u>Computer-Assisted Detection Devices Applied to Radiology Images and Radiology Device Data - Premarket Notification [510(k)] Submissions</u> (utilized for recommendations relevant to CADt including standalone testing)	2022
Multidisciplinary expertise through product lifecycle, good software engineering and security, test set representativeness, data set independence, reference standards, risk mitigations tailored to intended use, human-AI team, clinically relevant testing, user information, and deployment controls	<u>Good Machine Learning Practice for Medical Device Development: Guiding Principles</u> (U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA))	2021

CONCLUSIONS

The subject device and the predicate device are both software only packages, devices intended to assist with worklist triage by providing notification of findings. The subject and predicate devices utilize the same principles of operation and work in parallel to the current standard of care workflow.

Both the subject and predicate devices use an artificial intelligence algorithm to identify findings in images and require the same inputs (DICOM image data) and provide the same outputs (prioritization for a medical worklist).

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness.

Standalone performance testing and the comparison of technological characteristics with the predicate devices shows that the subject device:

- performs as intended,
- is safe and effective for its intended use, and
- is therefore substantially equivalent to the predicate device.

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