August 26, 2025

Brainomix Limited
Delanyo Mensah
Regulatory Affairs Specialist
First Floor, Seacourt Tower
West Way
Oxford, OX2 0JJ
United Kingdom

Re: K251983
Trade/Device Name: Brainomix 360 Triage Stroke
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological Computer Aided Triage And Notification Software
Regulatory Class: Class II
Product Code: QAS
Dated: June 25, 2025
Received: June 27, 2025

Dear Delanyo Mensah:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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, PhD
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.	?
Please provide the device trade name(s).	?

Brainomix 360 Triage Stroke

Please provide your Indications for Use below. ?

Brainomix 360 Triage Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT (NCCT) images to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of head NCCT images for large vessel occlusion (LVO) of the intracranial ICA and M1 or intracranial hemorrhage (ICH). Specifically, the device is intended to be used for the triage of images acquired from adult patients in the acute setting, within 24 hours of the onset of the acute symptoms, or where this is unclear, since last known well (LKW) time. It is not intended to detect symmetrical bilateral MCA occlusions.

Brainomix 360 Triage Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected NCCT LVO or ICH on the Brainomix 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 LVO or ICH findings via a web user interface or mobile application. 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 Brainomix 360 Triage 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.

Cautions:

• All patients should get adequate care for their symptoms, including angiography and/or other appropriate care per the standard clinical practice, irrespective of the output of Brainomix 360 Triage Stroke.
• Brainomix 360 Triage Stroke 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 angiography, per the standard stroke workup.

Limitations:

1. Brainomix 360 Triage Stroke is not intended for mobile diagnostic use. Images viewed on a mobile platform are compressed preview images and not for diagnostic interpretation.
2. Brainomix 360 Triage Stroke does not replace the need for angiography in ischemic stroke workup - it provides workflow prioritization and notification only.
3. Brainomix 360 Triage Stroke has been validated and is intended to be used on Siemens, GE and Philips scanners.
4. Brainomix 360 Triage Stroke is not intended to be used on patients with recent (within 6 weeks) neurosurgery or endovascular neurointervention or recent (within 4 weeks) previous diagnosis of stroke.
5. Brainomix 360 Triage Stroke is not intended to detect symmetrical bilateral MCA occlusions.
Contraindications:
Brainomix 360 Triage Stroke is not suitable for use with scan data containing image features associated with:
• tumours or abscesses

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

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K251983

510(K) Summary
Brainomix 360 Triage Stroke

Date Prepared:	27Jun2025
Applicant's name:	Brainomix Limited
Applicant's address:	First Floor, Seacourt Tower, West Way Oxford, OX2 0JJ United Kingdom
Official contact:	Delanyo Mensah +44 (0)1865 582730 regulatory@brainomix.com
Device Trade Name:	Brainomix 360 Triage Stroke
Device Common Name:	Radiological Computer-Assisted Triage and Notification Software
Regulatory Class:	Class II
Product Code:	QAS
Regulation No:	21 C.F.R. §892.2080
Classification Panel:	Radiology Devices

1 Predicate Device

The Brainomix 360 Triage Stroke device is claimed to be substantially equivalent to the following legally marketed device:

Trade Name:	Brainomix 360 Triage Stroke
Manufacturer:	Brainomix Limited
Regulation Number:	21 C.F.R. §892.2080
Regulatory Class:	Class II
Regulation Name:	Radiological computer-assisted triage and notification software
Product Code:	QAS
Submission Number:	K232496

2 Device Description

Brainomix 360 Triage Stroke (also referred to as Triage Stroke in this submission) is a radiological computer aided triage and notification software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server. Triage Stroke is a non-contrast CT processing software-only medical device which operates within the integrated Brainomix 360 Platform to provide triage and notification prioritization of suspected large vessel occlusion (LVO) or intracranial hemorrhage (ICH). The device uses machine learning algorithms such as advanced non adaptive imaging algorithms, artificial intelligence, and large data analytics.

Brainomix 360 Triage Stroke is available to users in three configurations, featuring three individual processing modules:

- Triage ICH Module, which can only flag positive findings of suspected ICH;

- Triage Stroke Module, which can flag positive findings of suspected ICH or LVO; And
- NCCT LVO Module, which can flag positive finding of suspected LVO

The Triage ICH Module automatically identifies suspected ICH, the NCCT LVO module automatically identifies suspected LVO, while the Triage Stroke Module automatically identifies suspected ICH or LVO on non-contrast CT (NCCT) imaging acquired from adult patients in the acute setting, within 24 hours of the onset of acute symptoms, or where this is unclear, since last known well (LKW) time. The output of the device is a priority notification to clinicians indicating the suspicion of just ICH for Triage ICH Module, the suspicion of just LVO for the NCCT LVO Module, and suspicion of ICH or LVO for Triage Stroke Module based on positive findings. Specifically, the ICH analysis algorithm is optimized to identify findings of hyperdense volume in the parenchyma typically associated with acute intracranial hemorrhage; and the NCCT LVO suspicion uses the combined analysis of the ASPECTS and hyperdense vessel sign (HDVS) algorithms to identify hyper attenuation in vessels and hypodense regions typically associated with a large vessel occlusion in a non-contrast CT scan.

Brainomix 360 Triage Stroke is not intended to detect symmetrical bilateral MCA occlusions. The device uses the basic services supplied by the Brainomix 360 Platform including DICOM processing, job management, imaging module execution and imaging output including notification and compressed image.

Brainomix 360 Triage Stroke notification capabilities enable clinicians to review and preview images via mobile app notification. Alternatively, intended users can also access the notification (a “Suspected LVO” or “Suspected hemorrhage” flag) and straightened images via the Brainomix 360 web user interface. Images that are previewed via mobile app are compressed, are for preview informational purposes only, and not intended for diagnostic use beyond notification.

The device is intended for use as an additional tool for assisting study triage within existing patient pathways. It does not replace any part of the current standard of care. It is designed to assist in prioritization of studies for reading within a worklist, in addition to any other pre-existing formal or informal methods of study prioritization in place. Specifically, it does not remove cases from a reading queue and operates in parallel to the standard of care. This device is not intended to replace the usual methods of communication and transfer of information in the current standard of care.

The Brainomix 360 Triage Stroke device is made available to the user through the Brainomix 360 Platform The Brainomix 360 Platform is a central control unit which coordinates the execution image processing modules which support various analysis methods used in clinical practice today:

- Brainomix 360 e-ASPECTS (K243294)
- Brainomix 360 e-CTA (K242123)
- Brainomix 360 e-CTP (K223555)
- Brainomix 360 e-MRI (K231656)
- Brainomix 360 Triage ICH (K231195)
- Brainomix 360 Triage LVO (K231837)
- Brainomix 360 Triage Stroke (K232496) (predicate device)

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3 Clinical Characteristics

The primary users of the Brainomix 360 platform are medical imaging professionals. The outputs generated by Brainomix 360 Triage Stroke may be used by clinicians to inform patient triaging decisions as part of a wider set of other imaging to identify signs of ischemic damage.

4 Indications for Use

Brainomix 360 Triage Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT (NCCT) images to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of head NCCT images for large vessel occlusion (LVO) of the intracranial ICA and M1 or intracranial hemorrhage (ICH). Specifically, the device is intended to be used for the triage of images acquired from adult patients in the acute setting, within 24 hours of the onset of the acute symptoms, or where this is unclear, since last known well (LKW) time. It is not intended to detect symmetrical bilateral MCA occlusions.

Brainomix 360 Triage Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected NCCT LVO or ICH on the Brainomix 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 LVO or ICH findings via a web user interface or mobile application. 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 Brainomix 360 Triage 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.

Cautions:

- All patients should get adequate care for their symptoms, including angiography and/or other appropriate care per the standard clinical practice, irrespective of the output of Brainomix 360 Triage Stroke.
- Brainomix 360 Triage Stroke 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 angiography, per the standard stroke workup.

Limitations:

1. Brainomix 360 Triage Stroke is not intended for mobile diagnostic use. Images viewed on a mobile platform are compressed preview images and not for diagnostic interpretation.
2. Brainomix 360 Triage Stroke does not replace the need for angiography in ischemic stroke workup - it provides workflow prioritization and notification only.
3. Brainomix 360 Triage Stroke has been validated and is intended to be used on Siemens, GE and Philips scanners.
4. Brainomix 360 Triage Stroke is not intended to be used on patients with recent (within 6 weeks) neurosurgery or endovascular neurointervention or recent (within 4 weeks) previous diagnosis of stroke.
5. Brainomix 360 Triage Stroke is not intended to detect symmetrical bilateral MCA occlusions.

Contraindications:

Brainomix 360 Triage Stroke is not suitable for use with scan data containing image features associated with:

- tumours or abscesses
- coils, shunts, embolization or movement artifacts

- intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.

5 Technological Characteristics

Brainomix 360 Triage Stroke principal workflow for NCCT includes the following key steps:

1. NCCT image loading. Brainomix 360 Triage Stroke provides an automated workflow which will automatically process image data received by the system in accordance with pre-configured user DICOM routing preferences.
2. Image Processing function. The workflow in this step will depend on the module configured for the user's healthcare facility (Triage ICH Module, Triage Stroke Module or NCCT LVO Module).
3. Notification of 'Suspected hemorrhage' or 'Suspected LVO' sent to the user and image viewing. This is a non-diagnostic DICOM viewing application through mobile app, allowing a trained clinician to preview unprocessed CT studies with basic viewing functions (scroll through a cine, adjust window level and window width, pan, and zoom) prior to definitive review of images on a diagnostic workstation. Alternatively, the straightened images can be visualized in the Brainomix 360 web user interface on a radiologist workstation.

All functions listed here are performed automatically by the software. Notifications and alerts for users (when processing has completed) is the step that includes user interaction and present information to users. This is considered to be the output of the processing functions.

6 Performance Data

The performance of Brainomix 360 Triage Stroke has been validated in three clinical studies:

- A standalone study of ICH detection performance
- A standalone study of LVO and ICH detection performance
- A reader study to compare the sensitivity of LVO detection to that of radiologists.

6.1 Summary of ICH Standalone Performance

A retrospective study was conducted with the primary endpoint of assessing the performance of Brainomix 360 Triage Stroke in identifying ICH findings in NCCT head images. The dataset comprised 341 cases (167 ICH positive; 174 ICH negative). Truthing was conducted by consensus of three experienced US board certified neuroradiologists.

Sensitivity and specificity of ICH detection exceeded the pre-specified performance goal of 80%: sensitivity was 96.41% (95% CI: 92.65-98.65%) and specificity was 96.55% (CI: 92.94-98.70%).

As a secondary outcome measure, performance for detection of subarachnoid hemorrhages (SAHs) was assessed against a pre-defined performance goal: sensitivity was 85.71% (CI: 60.99-97.67%) and specificity was 96.55% (CI: 80.60-98.87%).

6.2 ICH Performance Over Subgroups

ICH detection performance was stratified over a range of relevant clinical variables, including age, gender, slice thickness and scanner manufacturer subgroups. Additional subgroup analysis is reported in the labelling.

Metrics	21 < Age < 50	50 ≤ Age < 70	Age ≥ 70
Total Positives	36	69	62
Sensitivity	94.44% (82.88-99.20)	98.55% (93.01-99.91)	95.16% (87.37-98.97)
Specificity	95.77% (88.90-99.10)	96.25% (90.10-99.21)	100% (88.74-100.00)

Metrics	Female	Male

Total Positives	79	88
Sensitivity	96.20% (89.98-99.20)	96.59% (90.97-99-28)
Specificity	98.78% (94.08-99.92)	94.57% (88.34-98.18)

Metrics	Slice Thickness < 1.5 mm	1.5mm ≤ Slice Thickness < 3 mm	Slice Thickness ≥ 3 mm
Total Positives	112	23	32
Sensitivity	97.32% (92.84-99.44)	95.65% (80.63-99.73)	93.75% (80.94-99.09)
Specificity	99.17% (95.94-99.95)	100.00% (86.70-100.00%)	85.29% (70.47-94.80)

Metrics	GE MEDICAL SYSTEM	Philips	SIEMENS
Total Positives	87	72	7
Sensitivity	98.85% (94.41-99.92)	94.44% (87.12-98.47)	85.71% (49.44-98.90)
Specificity	95.70% (89.92-98.83)	96.88% (90.02-99.58)	100.00% (84.61-100.00)

6.3 Summary of LVO and ICH Standalone Performance

A retrospective study was conducted with the primary endpoint of assessing the performance of Brainomix 360 Triage Stroke in identifying NCCT head images containing large vessel occlusion (LVO) or intracranial hemorrhage (ICH) in 267 cases (LVO positive: 112 cases; ICH positive: 40 cases; Negative for ICH or LVO: 115; excluded: 3 cases due to technical inadequacy). Truthing was conducted by consensus of three experienced US board certified neuroradiologists.

Sensitivity and specificity exceeded the pre-specified performance goals for NCCT LVO and ICH. NCCT LVO performance was observed at 69.64% sensitivity (CI: 60.65-77.70%) and 89.57% specificity (CI: 82.92-94.36%). NCCT ICH performance in this smaller subset of cases was consistent with that of the ICH standalone study, as reported above (sensitivity: 95.00% [84.47-99.29%]; specificity: 88.11% [83.39-91.92%]).

The Triage Stroke time-to-notification analysis includes three steps: (1) the time taken to transfer the image for DICOM transfer, (2) the device processing time, and (3) the time taken to deliver a notification after processing. The combined time-to-notification was compared to an acceptability criterion of 3.5 minutes. The minimum and maximum estimates for each of the three steps were assessed and combined to create a range of expected values for the total time-to-notification. The minimum time-to-notification was 58.3 seconds, and the maximum was 150.7 seconds. This met the acceptability criterion of time-to-notification of under 3.5 minutes.

6.4 Summary of Reader LVO Performance

In addition, a reader study was conducted to compare NCCT LVO sensitivity of the device to that of radiologists. Secondary endpoints of expert non-inferiority and non-expert superiority were used. Triage Stroke passed both conditions, with a sensitivity for all readers (experts and non-experts) of 47.94% (CI: 37.91-57.97%). The difference between the device's sensitivity and that of all readers was 20.52% (CI: 8.26-32.78%). The general radiologists (non-experts) performed with a sensitivity of 47.18% (CI: 33.62-60.75%). The difference between the device and non-expert sensitivity was 21.28% (CI: 5.84-36.72%).

6.5 LVO Performance Across Subgroups

Subgroup analyses were conducted for the LVO indication. The analyses assessed performance across age, gender, slice thickness and scanner manufacturer subgroups. Additional subgroup analysis is reported in the labelling.

Metrics	21 < Age < 50	50 ≤ Age < 70	Age ≥ 70

Total Positives	13	39	60
Sensitivity	84.62% (58.59-97.46)	74.36% (59.09-86.41)	63.33% (50.62-74.88)
Specificity	94.74% (77.09-99.67)	89.09% (78.7-95.74)	87.80% (75.07-95.75)

Metrics	Female	Male
Total Positives	48	64
Sensitivity	75.0% (61.4-85.89)	65.62% (53.39-76.57)
Specificity	88.14% (77.94-94.92)	91.07% (81.32-96.95)

Metrics	Slice Thickness < 1 mm	1 mm ≤ Slice Thickness < 3 mm	Slice Thickness ≥ 3 mm
Total Positives	44	25	42
Sensitivity	61.36% (46.46-74.93)	80.00% (61.30-92.70)	71.43% (56.52-83.7)
Specificity	87.76% (76.29-95.19)	96.67% (84.74-99.79)	86.11% (71.95-95.11)

Metrics	SIEMENS	GE MEDICAL SYSTEMS	Philips
Total Positives	48	33	27
Sensitivity	62.5% (48.25-75.4)	72.73% (55.90-86.04)	77.78% (59.56-90.82)
Specificity	88.24% (77.15-95.39)	83.87% (67.93-94.24)	96.97% (86.02-99.81)

In summary, the performance validation data demonstrated that the proposed device provides accurate detection of acute ICH and LVO under a range of clinically relevant variables associated with the intended use of the software. The notification functionality of the device also met the acceptability criterion.

7 Prescriptive Statement

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

8 Safety and Effectiveness

Brainomix 360 Triage Stroke has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 for risk management and the software development process conforms to IEC 62304:2015. The performance of Brainomix 360 Triage Stroke has been validated through retrospective case data based on expert reader truthing of the data and reader testing.

9 Cybersecurity

Brainomix 360 Triage Stroke has been designed to follow the FDA Cybersecurity Guidance and IEC 81001-5-1.

10 Substantial Equivalence

The subject device includes similar features as compared to the predicate device. Both devices have substantially equivalent indications for use, technological characteristics and roles within a clinical workflow relative to triage and notification. Both devices are intended to automatically process and analyze non-contrast CT scans to provide a notification to users in case of a suspected LVO or ICH being identified. The subject device does raise different

questions of safety and effectiveness when compared to the predicate and both include similar mitigation strategies for reducing the risk of off label use of preview images which are shared via mobile.

Where the proposed device differs from the predicate device are:

- Improved ICH algorithm: The proposed device features an updated ICH algorithm using a different deep learning framework, CNN architecture, training data and post-processing capabilities of the algorithm. The improved algorithm resulted in improved sensitivity in detecting SAH and SDH subtypes. Furthermore, the algorithm improvements have also resulted in increased sensitivity and specificity of the software in detecting ICH. The performance of the updated algorithm has been validated in clinical studies, which provides evidence of effective triaging of all ICH subtypes with an increased sensitivity and specificity.
- Indications for use extended to SAH patients: Following the improvements made to the ICH algorithm the proposed device removes a previous SAH limitation and extends the indications of use for Triage Stroke to include subarachnoid hemorrhages (SAH) sub types. The change in the algorithm and the subsequent removal of the limitation has been validated through a clinical study and showed improvements on the performance of Triage Stroke in relation to different ICH subtypes.
- Configurable workflows: The proposed device offers three configurations with three workflows. The Triage ICH Module features a workflow to detect ICH in NCCT scans, the NCCT LVO Module features a workflow to detect LVO in NCCT scans, while the Triage Stroke Module's workflow allows the detection of either ICH or LVO in NCCT scans. The workflow of the Triage ICH Module remains the same as cleared under Brainomix 360 Triage ICH (K231195) and the workflow of the Triage Stroke Module remains the same as cleared under Brainomix 360 Triage Stroke (K232496). The NCCT LVO module utilizes the workflow like that of the Triage Stroke Module but with the device output limited to LVO notification only. The proposed device differs from the predicate in that it offers a choice of these three workflows within a single device and as such, this technological characteristic does not raise different questions of safety or effectiveness compared to the predicate device.

11 Substantial Equivalence Comparison

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

Characteristic/ Parameter	**Brainomix 360 Triage Stroke** ***Predicate Device (K232496)***	**Brainomix 360 Triage Stroke** ***Subject Device***
Product Code	QAS	QAS
Regulation	21 CFR. §892.2080	21 CFR. §892.2080
Indications for Use	Brainomix 360 Triage Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT (NCCT) images to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of head NCCT images for large vessel occlusion (LVO) of the intracranial ICA and M1 and intracranial hemorrhage (ICH). Specifically, the device is intended to be used for the triage of images acquired from adult patients in the acute setting, within 24 hours of the onset of the acute symptoms, or where this is unclear, since last known well (LKW) time. It is not intended to detect isolated	Brainomix 360 Triage Stroke is a radiological computer aided triage and notification software indicated for use in the analysis of non-contrast head CT (NCCT) images to assist hospital networks and trained clinicians in workflow triage by flagging and communicating suspected positive findings of head NCCT images for large vessel occlusion (LVO) of the intracranial ICA and M1 or intracranial hemorrhage (ICH). Specifically, the device is intended to be used for the triage of images acquired from adult patients in the acute setting, within 24 hours of the onset of the acute symptoms, or where this is unclear, since last known well (LKW) time. It is not intended to detect

	subarachnoid hemorrhage and symmetrical bilateral MCA occlusions. Brainomix 360 Triage Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected NCCT LVO or ICH on the Brainomix 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 LVO or ICH findings via a web user interface or mobile application. 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 Brainomix 360 Triage 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. <u>Cautions:</u> • All patients should get adequate care for their symptoms, including angiography and/or other appropriate care per the standard clinical practice, irrespective of the output of Brainomix 360 Triage Stroke. • Brainomix 360 Triage Stroke 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 angiography, per the standard stroke workup. <u>Limitations:</u> • Brainomix 360 Triage Stroke is not intended for mobile diagnostic use. Images viewed on a mobile platform are compressed preview images and not for diagnostic interpretation. • Brainomix 360 Triage Stroke does not replace the need for CTA in ischemic stroke workup - it provides workflow prioritization and notification only.	symmetrical bilateral MCA occlusions. Brainomix 360 Triage Stroke uses an artificial intelligence algorithm to analyze images and highlight cases with detected NCCT LVO or ICH on the Brainomix 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 LVO or ICH findings via a web user interface or mobile application. 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 Brainomix 360 Triage 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. <u>Cautions:</u> • All patients should get adequate care for their symptoms, including angiography and/or other appropriate care per the standard clinical practice, irrespective of the output of Brainomix 360 Triage Stroke. • Brainomix 360 Triage Stroke 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 angiography, per the standard stroke workup. <u>Limitations:</u> 1. Brainomix 360 Triage Stroke is not intended for mobile diagnostic use. Images viewed on a mobile platform are compressed preview images and not for diagnostic interpretation. 2. Brainomix 360 Triage Stroke does not replace the need for angiography in ischemic stroke

	• Brainomix 360 Triage Stroke has been validated and is intended to be used on Siemens, GE and Philips scanners. • Brainomix 360 Triage Stroke is not intended to be used on patients with recent (within 6 weeks) neurosurgery or endovascular neurointervention or recent (within 4 weeks) previous diagnosis of stroke. • Brainomix 360 Triage Stroke is not intended to detect isolated subarachnoid hemorrhage and symmetrical bilateral MCA occlusions. <u>Contraindications:</u> Brainomix 360 Triage Stroke is not suitable for use with scan data containing image features associated with: • tumors or abscesses • coils, shunts, embolization or movement artifacts • Brainomix 360 Triage Stroke is not intended to be used for analyzing CT images in intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.	workup - it provides workflow prioritization and notification only. 3. Brainomix 360 Triage Stroke has been validated and is intended to be used on Siemens, GE and Philips scanners. 4. Brainomix 360 Triage Stroke is not intended to be used on patients with recent (within 6 weeks) neurosurgery or endovascular neurointervention or recent (within 4 weeks) previous diagnosis of stroke. 5. Brainomix 360 Triage Stroke is not intended to detect symmetrical bilateral MCA occlusions. <u>Contraindications:</u> Brainomix 360 Triage Stroke is not suitable for use with scan data containing image features associated with: • tumours or abscesses • coils, shunts, embolization or movement artifacts • intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.
Environment of Use	Clinical/Hospital environment	Clinical/Hospital environment
User	Clinician	Clinician
Anatomical Region	Head	Head
Input Data	NCCT (ICH and LVO)	NCCT (ICH and LVO)
Technical Implementation	AI/ML/Neural Network	AI/ML/Neural Network
Diagnostic application	Notification-only	Notification-only
Results of image analysis	Internal no image marking	Internal no image marking
Segmentation of ROI	The device does not highlight or direct user's attention to a specific location in the image file	The device does not highlight or direct user's attention to a specific location in the image file
Notification Display	Web user interface and mobile device	Web user interface and mobile device
Preview Images	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care.	Presentation of a preview of the study for initial assessment not meant for diagnostic purposes. The device operates in parallel with the standard of care.
Annotation / Localization	Device does not mark, highlight, or direct users' attention to a specific location in the original image	Device does not mark, highlight, or direct users' attention to a specific location in the original image
Prioritization Notification	Yes	Yes
Clinical SoC Workflow	In parallel to	In parallel to

Technical Pipeline	Two cascaded functions (ICH then LVO) using three integrated algorithms	Triage Stroke Configuration: two cascaded functions (ICH then LVO) using three integrated algorithms Triage ICH Configuration: ICH analysis function using one algorithm NCCT LVO Configuration: LVO analysis function using three integrated algorithms
Removal of Cases from SoC review	No	No

12 Conclusion

Brainomix 360 Triage Stroke includes similar features as compared to the predicate device. Both devices have similar indications for use, technological approaches and roles within a clinical workflow. The differences in indications for use and technological characteristics for the proposed device do not raise different questions of safety or effectiveness.

The proposed device therefore does not raise different questions with regards to safety and efficacy and demonstrates substantial equivalence to the predicate, Brainomix 360 Triage Stroke (K232496).