Brainomix Limited
℅ Zsolt Szrnka
Regulatory Affairs Manager
First Floor Seacourt Tower
West Way
Oxford, OX2 0JJ
United Kingdom

November 21, 2023

Re: K232496
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: November 6, 2023
Received: November 6, 2023

Dear Zsolt Szrnka:

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

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

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

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

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232496

Device Name
Brainomix 360 Triage Stroke

Indications for Use *(Describe)*
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 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.

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 L VO" should not be viewed as indicating that LVO is excluded. All cases should undergo angiography, per the standard stroke workup.

Limitations:
• 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 CT A in ischemic stroke workup - it provides workflow prioritization and notification only.
• 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.

Contraindications: 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K232496

510(K) Summary
Brainomix 360 Triage Stroke

Date Prepared:	16Aug2023
Applicant's name:	Brainomix Limited
Applicant's address:	First Floor, Seacourt Tower, West Way Oxford, OX2 0JJ United Kingdom
Official contact:	Zsolt Szrnka +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

Predicate Device

The Brainomix 360 Triage Stroke device is claimed to be substantially equivalent to the following legally marketed predicate device: iSchemaView's Rapid NCCT Stroke (K222884).

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 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.

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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:

- 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.
- 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.

Contraindications:

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.

Device Description

Brainomix 360 Triage Stroke 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.

The Triage Stroke module is a non-contrast CT processing module which operates within the integrated Brainomix 360 Platform to provide triage and notification prioritization of suspected large vessel occlusion (LVO) and intracranial hemorrhage (ICH). Brainomix 360 Triage Stroke is a stand-alone software device which uses machine learning algorithms that uses advanced non adaptive imaging algorithms, artificial intelligence, and large data analytics to automatically identify suspected LVO and ICH on non-contrast CT (NCCT) imaging 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. The output of the module is a priority notification to clinicians indicating the suspicion of LVO or ICH based on positive findings. Specifically, Brainomix 360 Triage Stroke's ICH analysis 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. It is not intended to detect isolated subarachnoid hemorrhage and symmetrical bilateral MCA occlusions. The Triage Stroke module uses the basic services supplied by the Brainomix 360 Platform including DICOM processing, job management, imaging module execution and imaging output including the 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.

Comparison of Technological Characteristics

Both subject and predicate device use automatic data identification and transfer to send images from the local hospital network to a remote server for image processing and analysis, i.e., via a DICOM router that automatically identifies relevant images on a local IT Network and transfers them to a Backend Server using a DICOM compliant communication protocol. The Backend Server software for each device has the same additional software functionality that interacts with the image management architecture, including a notifier module.

Both subject and predicate device provide triage and notification of suspected ICH and LVO. In case of both devices, the ICH analysis is optimized to identify findings of hyperdense volume in the parenchyma typically associated with acute ICH; and the NCCT LVO suspicion uses the combined analysis of the ASPECTS and hyperdense vessel sign (HDVS) algorithms. The algorithms do not externalize any internal segmentation, analysis, or intermediate outputs used in determining if an ICH or LVO is present in the NCCT, nor does either algorithm mark the analyzed NCCT image. Both devices support a mobile application that allows a user to receive push notifications, preview related images, and view patient details associated with a series. The mobile application of both devices is subject to non-diagnostic viewing limitations and have a non-diagnostic warning on the image viewing screen.

Where subject device differs from the predicate is that Brainomix 360 Triage Stroke may also notify the user of a suspected LVO or ICH via a web user interface, as an additional output. The unprocessed images are subjected to rotation and resampling (pre-processing and registration) which do not alter the original imaging in relation to aid for diagnostic. Identically to the predicate, the notified clinicians are responsible for viewing non-compressed images on a diagnostic viewer and engaging in appropriate patient evaluation and relevant discussion with a treating physician before making care-related decisions or requests. Therefore, the technical differences in how the notification may be sent to the user between the proposed and predicate devices do not raise different questions of safety and effectiveness. The predicate device offers two additional channels of notification via email and PACS, which the subject device does not, and therefore, the risks associated with these are not applicable to the subject device.

The below table summarizes and compares data on the Brainomix 360 Triage Stroke device, the subject of this filing, with the Rapid NCCT Stroke device (K222884).

Characteristic/Parameter	**Brainomix 360 Triage Stroke** ***Subject Device (K232496)***	**iSchemaView Rapid NCCT Stroke** ***Predicate Device (K222884)***
Product Code	QAS	QAS
Regulation	21 C.F.R. §892.2080	21 C.F.R. §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 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	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 or MRA 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 or MRA, per the standard stroke workup.

	angiography, per the standard stroke workup. Limitations: • 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. • 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. Contraindications: 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.	Limitations: • Rapid NCCT Stroke does not replace the need for CTA in ischemic stroke workup, it provides workflow prioritization and notification only. • Rapid ICH has been shown to reliably identify hemorrhages of ≥ 0.4ml. Contraindications/Exclusions/Cautions: • Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. • Hemorrhagic Transformation, Hematoma Very thin or no Ventricles
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	PACS, email 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.	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.	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
Results of Image Analysis	Internal, no image marking	Internal, no image marking
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	Two cascaded functions (ICH then LVO) using three integrated algorithms
Removal of Cases from SoC review	No	No

Performance Data

A retrospective study was conducted with the primary endpoint of assessing the performance of Brainomix 360 Triage Stroke in identifying NCCT head images containing intracranial hemorrhage (ICH) or large vessel occlusion (LVO) findings in 267 cases (ICH positive: 40 cases; LVO positive: 112 cases; Negative for ICH or LVO: 115; excluded: 3 cases due to technical inadequacy). ICH positive cases were previously truthed using NCCT imaging with additional clinical information as described in the standalone study for our previously cleared device, Brainomix 360 Triage ICH (K231195). The LVO positive and negative cases were truthed using acute CTA imaging and additional clinical information by consensus of three experienced US board certified neuroradiologists.

Sensitivity and specificity exceeded the pre-specified performance goals for ICH and NCCT LVO. Specifically, ICH performance was observed at 92.5% sensitivity (95% CI: 80.97-98.36%) and 87.22% specificity (CI: 82.39-91.18%). These results were consistent with the Triage ICH standalone module performance (K231195). NCCT LVO performance was observed at 68.75% sensitivity (CI: 59.71-76.90%) and 89.57% specificity (CI: 82.92-94.36%).

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%).

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 was assessed and combined to create a range of expected values for the total time-to-notification. The results were a minimum expected time-to-notification of 62 seconds, and a maximum of 134 seconds. This met the acceptability criterion of time-to-notification of under 3.5 minutes.

Performance across subgroups

Subgroup analyses were conducted for the LVO indication (the ICH algorithm is the same as the device cleared under K231195). The analyses assessed performance across age, gender, slice thickness and scanner manufacturer subgroups.

Metrics	21 < Age < 50	50 ≤ Age < 70	Age ≥ 70
Total Positives	13	39	60

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Sensitivity	84.62% (58.59-97.46)	74.36% (59.09-86.41)	61.67% (48.93-73.39)
Specificity	94.74% (77.09-99.67)	89.09% (78.7-95.74)	87.8% (75.07-95.75)

Metrics	Female	Male
Total Positives	48	64
Sensitivity	75.0% (61.4-85.89)	64.06% (51.78-75.19)
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)	76.0% (56.8-90.0)	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)	69.7% (52.68-83.68)	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)

Additional subgroup analysis is reported in the labeling. 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.

Prescriptive Statement

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

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 EN 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.

Substantial Equivalence Discussion

The subject device includes similar features as compared to the predicate device. Both devices have substantially equivalent indications for use, technical approaches 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 not introduce any new risks 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. Compared to the predicate device, the subject device

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offers one additional channel of notification (web user interface), while the predicate offers notification via email and PACS, which the subject device does not.

Conclusion

In conclusion, Brainomix 360 Triage Stroke has the same intended use and is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Rapid NCCT Stroke (K222884).