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

July 27, 2023

Re: K231195
Trade/Device Name: Brainomix 360 Triage ICH
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: April 21, 2023
Received: June 22, 2023

Dear Szrnka Zsolt:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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)*
K231195

Device Name
Brainomix 360 Triage ICH

Indications for Use *(Describe)*
Brainomix 360 Triage ICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

Brainomix 360 Triage ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device is intended to be used for the triage of non-contrast CT images of the brain 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. The device sends notifications to a neurovascular specialist that a suspected intracranial hemorrhage has been identified and recommends review of those images. Images can be previewed through a mobile application.

Images that are previewed through the mobile application are compressed and are for informational purposes only and not intended for diagnostic use beyond notification. 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. Brainomix 360 Triage ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Limitations:
• Brainomix 360 Triage ICH is not intended for mobile diagnostic use. Images viewed on a mobile platform are preview images and not for diagnostic interpretation.
• Brainomix 360 Triage ICH has been validated and is intended to be used on GE and Philips scanners.
• Brainomix 360 Triage ICH is not intended to detect isolated subarachnoid hemorrhage.
• Brainomix 360 Triage ICH 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 intracranial hemorrhage.

Contraindications:
Brainomix 360 Triage ICH is not suitable for use with scan data containing image features associated with:
• tumors or abscesses
• coils, shunts, embolization or movement artefacts
Brainomix 360 Triage ICH 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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Brainomix Limited
First Floor, Seacourt Tower, West Way
Oxford OX2 0JJ, United Kingdom

K231195

510(K) Summary
Brainomix Limited's Brainomix 360 Triage ICH

Date Prepared:	June 22, 2023
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 zszrnka@brainomix.com
Device Proprietary Name:	Brainomix 360 Triage ICH
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

Brainomix 360 Triage ICH is Substantially Equivalent to the following Legally Marketed device:

Predicate Device

510(k) Number	Trade Name	Manufacturer
K193658	Viz ICH	Viz.ai, Inc.

Intended Use / Indications for Use

Brainomix 360 Triage ICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.

Brainomix 360 Triage ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device is intended to be used for the triage of non-contrast CT images of the brain 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. The device sends notifications to a neurovascular or neurosurgical specialist that a suspected intracranial hemorrhage has been identified and recommends review of those images. Images can be previewed through a mobile application.

Images that are previewed through the mobile application may be compressed and are for informational purposes only and not intended for diagnostic use beyond notification. 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. Brainomix 360 Triage ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.

Limitations:

- Brainomix 360 Triage ICH is not intended for mobile diagnostic use. Images viewed on a mobile platform are preview images and not for diagnostic interpretation.
- Brainomix 360 Triage ICH has been validated and is intended to be used on GE and Philips scanners.
- Brainomix 360 Triage ICH is not intended to detect isolated subarachnoid hemorrhage.
- Brainomix 360 Triage ICH 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 intracranial hemorrhage

Contraindications:

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

- tumors or abscesses
- coils, shunts, embolization or movement artefacts

Brainomix 360 Triage ICH 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 ICH 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 ICH module is a non-contrast CT processing module which operates within the integrated Brainomix 360 Platform to provide triage and notification prioritization of suspected intracranial hemorrhage (ICH). Brainomix 360 Triage ICH 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 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 ICH based on positive findings. Specifically, Brainomix 360 Triage ICH is optimized to detect and evaluate hyperdense volume in the parenchyma typically associated with acute intracranial hemorrhage (ICH). The Triage ICH 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 ICH notification capabilities enable clinicians to review and preview images via mobile app notification. Alternatively, intended users can also access the notification (a “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.

Summary of Technological Characteristics

Both proposed and predicate device are a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow. Notifications generated from both proposed and predicate devices are shared with clinicians to alert that a suspected intracranial hemorrhage has been identified and recommends review of those images.

The proposed and predicate devices are equally intended for use as an additional tool for assisting study triage within existing patient pathways. They do not replace any part of the current standard of care. Likewise, they are 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.

Both proposed and predicate devices are designed to be used by trained clinicians in a hospital/clinical environment.

Both proposed and predicate devices run on standard physical and/or virtual servers which are installed within a hospital network and within the protection of hospital firewalls.

The predicate device notifies the user via mobile and provides compressed original images which are used for informational purposes only. Likewise, the images which are shared on notifications by the proposed device are compressed and for informational purposes only. As the predicate, a persistent warning is displayed to alert users that the images are compressed and not intended for diagnostic purposes.

Where Brainomix 360 Triage ICH differs from the predicate is that the proposed device may also notify the user of a suspected ICH via the web user interface, as an additional channel of 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.

Characteristic/Parameter	**Brainomix 360 Triage ICH – Subject Device**	**Viz.ai Viz ICH – Predicate Device (K193658)**
Product Code	QAS	QAS
Regulation	21 C.F.R. §892.2080	21 C.F.R. §892.2080
Indications for Use	Brainomix 360 Triage ICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.	Viz ICH is a notification-only, parallel workflow tool for use by hospital networks and trained clinicians to identify and communicate images of specific patients to a specialist, independent of standard of care workflow.
	Brainomix 360 Triage ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate medical	Viz ICH uses an artificial intelligence algorithm to analyze images for findings suggestive of a prespecified clinical condition and to notify an appropriate

	specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device is intended to be used for the triage of non-contrast CT images of the brain 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. The device sends notifications to a neurovascular or neurosurgical specialist that a suspected intracranial hemorrhage has been identified and recommends review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application may be compressed and are for informational purposes only and not intended for diagnostic use beyond notification. 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. Brainomix 360 Triage ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Limitations: • Brainomix 360 Triage ICH is not intended for mobile diagnostic use. Images viewed on a mobile platform are preview images and not for diagnostic interpretation. • Brainomix 360 Triage ICH has been validated and is intended to be used on GE and Philips scanners. • Brainomix 360 Triage ICH is not intended to detect isolated subarachnoid hemorrhage. • Brainomix 360 Triage ICH 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 intracranial hemorrhage Contraindications:	medical specialist of these findings in parallel to standard of care image interpretation. Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes non-contrast CT images of the brain acquired in the acute setting, and sends notifications to a neurovascular or neurosurgical specialist that a suspected intracranial hemorrhage has been identified and recommends review of those images. Images can be previewed through a mobile application. Images that are previewed through the mobile application may be compressed and are for informational purposes only and not intended for diagnostic use beyond notification. 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. Viz ICH is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis. Viz ICH is contraindicated for analyzing non-contrast CT scans that are acquired on scanners from manufacturers other than General Electric (GE) or its subsidiaries (i.e. GE Healthcare). This contraindication applies to NCCT scans that conform to all applicable Patient Inclusion Criteria, are of adequate technical image quality, and would otherwise be expected to be analyzed by the device for a suspected ICH.

	Brainomix 360 Triage ICH is not suitable for use with scan data containing image features associated with: • tumors or abscesses • coils, shunts, embolization or movement artefacts Brainomix 360 Triage ICH is not intended to be used for analyzing CT images in intracranial vascular pathologies such as arterial aneurysms, arteriovenous malformations or venous thrombosis.	
Environment of use	Clinical/Hospital environment	Clinical/Hospital environment
Energy used and/or delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients
Primary Users	Neurovascular Specialist	Neurovascular Specialist
Anatomical Region	Head	Head
Technical Implementation	Artificial intelligence algorithm with database of images	Artificial intelligence algorithm with database of images
Diagnostic application	Notification-only	Notification-only
Results of image analysis	Internal, no image marking	Internal, no image marking
Alteration of original image	No	No
Preview Images	Initial assessment; non-diagnostic purposes	Initial assessment; non-diagnostic purposes
Image viewing and manipulation	Yes – window, pan, level, zoom	Yes – window, pan, level, zoom
Results of Image Analysis	Internal, no image marking	Internal, no image marking
Interference with standard workflow	No. Cases are not removed from worklist or deprioritized	No. Cases are not removed from worklist or deprioritized
Notification	Mobile application and web user interface	Mobile
Design: DICOM compliance	Yes	Yes
Design: Computer Platform	Standard off-the-shelf server or virtual server	Standard off-the-shelf server or virtual server
Design: Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities
Materials	N/A – Software only device	N/A – Software only device
Biocompatibility	N/A – Software only device	N/A – Software only device
Sterility	N/A – Software only device	N/A – Software only device
Electrical Safety	N/A – Software only device	N/A – Software only device
Mechanical Safety	N/A – Software only device	N/A – Software only device
Chemical Safety	N/A – Software only device	N/A – Software only device
Thermal Safety	N/A – Software only device	N/A – Software only device
Radiation Safety	N/A – Software only device	N/A – Software only device

Performance Data

A retrospective study has been carried out to assess the standalone performance of the image analysis algorithm and notification functionality of Triage ICH. The study evaluated the Triage ICH image analysis algorithm in terms

Brainomix Limited
First Floor, Seacourt Tower, West Way
Oxford OX2 0JJ, United Kingdom

of sensitivity and specificity with respect to a ground truth, as established by experienced US board certified neuroradiologists, in the detection of intracranial hemorrhage (ICH) in the brain. In addition, the study reported and compared the time to notification for the Triage ICH device with respect to the time to notification for the standard of care as established by the predicate device.

A sample size of 341 non-contrast Computed Tomography (NCCT) scans (studies) were obtained from 30 different hospitals and clinics in the U.S. The majority of patients were scanned at Boston Medical Centre (N=237) and the remainder came from 29 different referral hospitals in Massachusetts State. The patient cohort was enriched to ensure an approximately equal balance of ICH positive and negative studies and to ensure the distribution of clinical and demographic variables (e.g., age, gender, ICH subtype, traumatic vs non traumatic etiology) allows generalizability to the patient population for whom use is intended.

The cases (n=341) were all successfully processed with the algorithm. The confusion matrix was as follows: True Positives (TP): 149, True Negatives (TN): 159, False Positives (FP): 15, False Negatives (FN): 18. The overall performance can also be summarized with the following metrics: sensitivity (or positive percentage agreement, defined as TP/[TP+FN]) was 89.22%, specificity (or negative percentage agreement, defined as TN/[TN+FP]) was 91.37%. The receiver operating curve (ROC) for the device is shown in Figure 1.

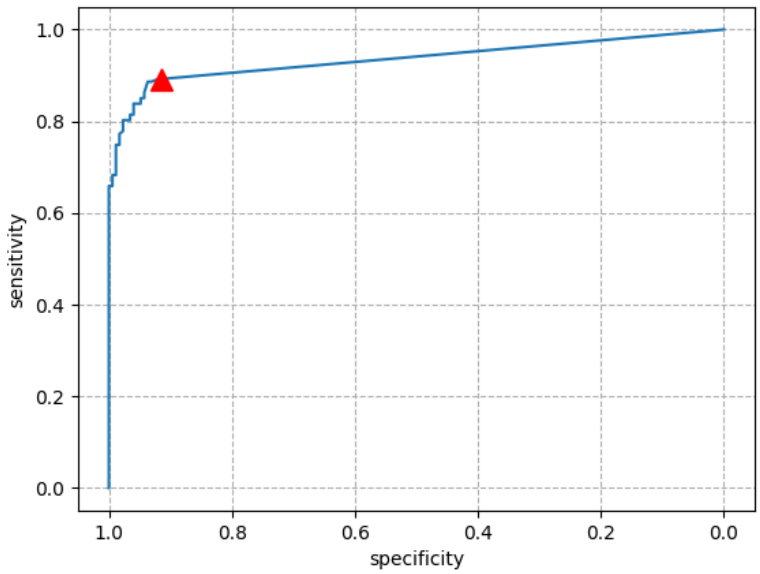

Figure 1. Receiver Operating Curve for the device, with the operating point (sensitivity 89.2%, specificity 91.4%) shown with the red triangle.

Because the lower bound of each confidence interval for sensitivity and specificity exceeded 80%, the study met the pre-specified performance goals.

As part of a secondary analysis, the company stratified the device performance by various confounding variables: ICH subtype (Table 1); by gender (Table 2); by age (Table 3); by slice thickness (Table 4); by clinical site (Table 5); and by ICH Volume (Table 6).

ICH Subtype	Sensitivity (95% CI)
Intraparenchymal Hemorrhage (IPH)	96.61% (88.29-99.59)
Intraventricular Hemorrhage (IVH)	100.00% (59.04-100.00)
Subarachnoid Hemorrhage (SAH)	35.71% (12.76-64.86)

Subdural Hemorrhage (SDH)	66.67% (40.99-86.66)
Multiple Types	98.55% (92.19-99.96)

Table 1. Summary of the performance metrics for the subsets of scans stratified by ICH Subtype.

Gender	Sensitivity (95% CI)	Specificity (95% CI)
Male	93.18% (85.75-97.46)	91.30% (83.58-96.17)
Female	84.81% (74.97-91.90)	91.46% (83.20-96.50)

Table 2. Summary of the performance metrics for the subsets of scans stratified by gender.

Age	Sensitivity (95% CI)	Specificity (95% CI)
21 < Age < 50	83.33% (67.19-93.63)	88.73% (79.00-95.01)
50 ≤ Age < 70	92.75% (83.89-97.61)	91.25% (82.80-96.41)
Age ≥ 70	88.71% (78.11-95.34)	100.00% (85.18-100.00)

Table 3. Summary of the performance metrics for the subsets of scans stratified by age group.

Slice Thickness	Sensitivity (95% CI)	Specificity (95% CI)
Slice Thickness < 1.5 mm	87.50% (79.92-92.99)	94.21% (88.44-97.64)
1.5mm ≤ Slice Thickness < 3 mm	95.65% (78.05-99.89)	100.00% (82.35-100.00)
Slice Thickness ≥ 3 mm	90.62% (74.98-98.02)	76.47% (58.83-89.25)

Table 4. Summary of the performance metrics for the subsets of scans stratified by slice thickness

Clinical Site	Sensitivity (95% CI)	Specificity (95% CI)
Boston Medical Centre	89.38% (82.18-94.39)	94.35% (88.71-97.70)
Other	88.89% (77.37-95.81)	84.00% (70.89-92.83)

Table 5. Summary of the performance metrics for the subsets of scans stratified by referring hospital

Minimal Volume Threshold (ml)	Sensitivity above Threshold (95% CI)
vol ≥ 0 ml	89.22% (83.50-93.49)
vol ≥ 0.4ml	94.59% (89.63-97.64)
vol ≥ 1ml	97.04% (92.59-99.19)
vol ≥ 5ml	99.04% (94.76-99.98)

Table 6. Summary of the sensitivity for the subsets of scans stratified by ICH volume

To assess the secondary outcome measure, the device's time to notification was recorded for a sample of cases. This ranged from 50 seconds to 126 seconds, and is substantially lower than the average time to notification seen in the Standard of Care reported by the predicate device (38.2 minutes).

In summary, the clinical tests demonstrate that the device performs with good sensitivity and specificity to detect acute ICH from non-contrast CT imaging, and met the primary study endpoint of 80% sensitivity and specificity. This acceptability criterion was the same as used for the predicate device (Viz ICH, K193658), supporting the equivalent performance to the predicate. Furthermore, the device's time to notification ranged from 50-126 seconds which

Brainomix Limited
First Floor, Seacourt Tower, West Way
Oxford OX2 0JJ, United Kingdom

was significantly shorter than the average time to notification seen in the Standard of Care of 38.2 minutes reported by the predicate device.

Prescriptive Statement

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

Conclusion

In conclusion, Brainomix 360 Triage ICH has the same intended use and is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Viz ICH (K193658).