Brainomix Limited
% Thais Sala
Regulatory Affairs Manager
First Floor, Seacourt Tower, West Way
Oxford, OX2 0JJ
UNITED KINGDOM

September 28, 2023

Re: K231837
Trade/Device Name: Brainomix 360 Triage LVO
Regulation Number: 21 CFR 892.2080
Regulation Name: Radiological computer aided triage and notification software
Regulatory Class: Class II
Product Code: QAS
Dated: August 29, 2023
Received: August 29, 2023

Dear Thais Sala:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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

Your device is also subject to, among other requirements, the Quality 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.

Submission Number *(if known)*

K231837

Device Name

Brainomix 360 Triage LVO

Indications for Use *(Describe)*

Brainomix Triage LVO 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 Triage LVO 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 analyzes CT angiogram images of the brain acquired in the acute setting, and sends notifications to a neurovascular specialist that a suspected large vessel occlusion (LVO) has been identified and recommends review of those images. Images can be previewed through a mobile application or via email. Brainomix Triage LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.
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 noncompressed 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 Triage LVO 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.

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.

BRAINOMIX

Head office
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510(K) Summary
Brainomix Limited – Brainomix 360 Triage LVO

Date Prepared:	19Jun2023
Applicant's Name:	Brainomix Limited
Applicant's Address:	First Floor, Seacourt Tower, West Way Oxford, OX 0JJ United Kingdom
Official Contact:	Thais Sala +44 (0) 7375 967 695 tsala@brainomix.com
Device Proprietary Name:	Brainomix 360 Triage LVO
Device Common Name:	Radiological Computer-Assisted Triage And Notification Software
Regulatory Class:	Class II
Product Code:	QAS
Regulation:	21 C.F.R. §892.2080
Reference Device:	Rapid LVO 1.0 (K200941)

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

510(k) Number	Trade Name	Manufacturer
K223042	Viz LVO	Viz AI

1 Device Description

Brainomix 360 Triage LVO is a radiological computer aided triage and notification (CADt) software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server.

The Triage LVO module is a CTA processing module which operates within the integrated Brainomix 360 Platform to provide triage and notification prioritization of suspected LVO. Brainomix 360 Triage LVO 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 on CTA imaging in the acute setting. The output of the module is a priority notification to clinicians indicating the suspicion of LVO based on positive findings. Specifically, Brainomix 360 Triage LVO is optimized to evaluate occlusions of the intracranial internal carotid artery (ICA) and proximal middle cerebral artery (M1 segment). The Triage LVO 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.

Images used to train the algorithm were sourced from datasets that included a range of equipment manufacturers including Toshiba, GE, Siemens, Philips and Canon/Toshiba. This dataset, which contained over 1600 CT brain imaging studies, was labelled by trained radiologists regarding the presence of LVO. The performance of the device's AI algorithms were validated in a standalone

performance evaluation, utilizing and independent dataset than the one used for algorithm training, in which the case-level output from the device was compared with a reference standard ('ground truth'). This was determined by two ground truthers, with a third ground truther used in the event of disagreement. All truthers were US board-certified neuroradiologists.

Brainomix 360 Triage LVO notification capabilities enable clinicians to review and preview images via mobile app notification. Alternatively, intended users can also access the notification (a "Suspected LVO" 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.

Brainomix 360 Triage LVO notification capabilities enable clinicians to preview compressed and informational images through via mobile application notification with preview of unprocessed image attachments. Alternatively, the user may review unprocessed images via web user interface on a radiology workstation.

2 Intended Use / Indications for Use

Brainomix Triage LVO 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 Triage LVO 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 analyzes CT angiogram images of the brain acquired in the acute setting, and sends notifications to a neurovascular specialist that a suspected large vessel occlusion (LVO) has been identified and recommends review of those images. Images can be previewed through a mobile application or via email. Brainomix Triage LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs.

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 noncompressed 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 Triage LVO 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.

3 Performance Data

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

Software Verification and Validation Testing

Software verification and validation testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005.

Performance Testing

Brainomix performed standalone performance in accordance with the §892.2080 special controls to show acceptance of the clinical performance of the Brainomix 360 Triage LVO module. The test dataset used during standalone performance evaluation was newly acquired and appropriate steps were taken to ensure it is independent from the training dataset used in model development.

A retrospective study has been carried out to assess the standalone performance of the image analysis algorithm and notification functionality of Triage LVO. The study evaluated the Triage LVO image analysis in terms of sensitivity and specificity with respect to a ground truth, as established by US board certified neuroradiologists, in the detection of large vessel occlusion (LVO) in the brain.

A sample size of 308 CTA scans (studies) were obtained 14 different hospitals and clinics in the U.S. The majority of patients were scanned at Mayo Clinic Rochester (N= 129) and Boston Medical Centre (N= 179) of which 56 scans were transferred from a total of 11 hospitals in the Massachusetts area. The patient cohort was enriched to ensure an approximately equal balance of LVO positive and negative studies and to ensure the distribution of clinical and demographic variables (e.g., age and gender) allows generalizability to the patient population for whom use is intended. To determine the ground truth, each case was reviewed by two ABR-certified neuroradiologists (ground truthers), with a consensus determined by a third ground truther in the event of disagreement.

In the CTA image dataset, the slice thickness distribution was median 0.75mm [IQR: 0.625 – 0.8] with a minimum of 0.5mm (n=2) and a maximum of 1mm (n=42). In-plane (axial) resolution showed a range of 0.381mm to 0.72mm with a median of 0.49mm. Four different tube voltage (KvP, peak kilovoltage) values were encountered in the dataset (90KvP n=6, 100KvP, n=64; 120KvP n=137 and 140KvP, n=99). Tube current was median of 526mA [IQR: 445mA - 645mA]. With respect to contrast phase during acquisition, 62 studies were Early Arterial (EA), 130 Peak Arterial (PA), 110 in Equilibrium phase (EQ), 3 in Peak Venous (PV), and 3 in Late Venous (LV). All the images used a standard or a soft (low-pass filter) convolution kernel for reconstruction (e.g., STANDARD in GE MEDICAL SYSTEMS).

The cases (n=308) were all successfully processed with the algorithm. The confusion matrix was as follows: True Positives (TP): 126, True Negatives (TN): 156, False Positives (FP): 12, False Negatives (FN): 14. The standalone performance exceeded the 80% goal using the lower bound of the 95% Confidence Interval (CI) for Sensitivity (or positive percentage agreement, defined as TP/[TP+FN]) and Specificity (or negative percentage agreement, defined as TN/[TN+FP). The observed results are Sensitivity of 90% (95% CI: 84.2-94.3) and Specificity 92.9% (95% CI: 88.0-94.3) with a receiver operating curve (ROC) AUC of 91.4% (95% CI: 88.2-94.5), as shown in Figure 1.

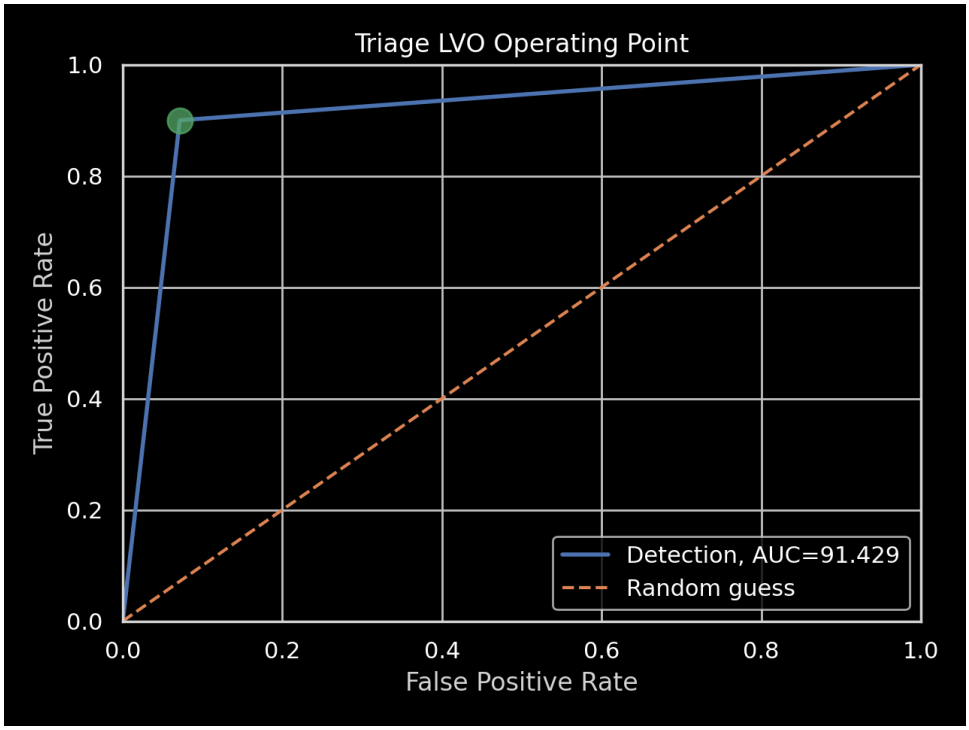

Figure 1. Receiver Operating Curve for the device, with the operating point (sensitivity 90%, specificity 92.9%) shown in the red triangle.

As part of a secondary analysis, the company stratified the device performance by various confounding variables: age (Table 1); by gender (Table 2); by race (Table 3); by scanner manufacturer (Table 4); by clinical site (Table 5); by vessel affected (Table 6) and by presence of stenosis as noted by the truthers (Table 7).

In addition, the performance for LVO detection in the left and right hemispheres was explored. This showed very similar performance for left hemisphere (sensitivity = 88.6%, CI: 79.4-94.8%) and right hemisphere (91.4%, CI: 83.0-96.7%) LVOs.

Table 1. Summary performance metrics from patients sub-categorized by age, with 95% confidence intervals where appropriate

Metrics	Age 22-50	Age 50-70	Age 70+
Total N	57	132	119
TP	12	44	70
TN	39	75	42
FN	3	8	3
FP	3	5	4
Sensitivity	80.0 (55.2-95.3)	84.6 (72.9-92.8)	95.9 (89.2-99.1)
Specificity	92.9 (79.4-95.9)	93.8 (84.1-94.5)	91.3 (88.7-97.5)
AUC	86.4 (74.0-96.7)	89.2 (83.4-94.2)	94.0 (89.3-98.2)

Table 2. Summary performance matrix from patients sub-categorized by gender, with 95% confidence intervals where appropriate

Metrics	Male	Female
Total N	140	168
TP	57	69
TN	72	84
FN	4	10
FP	7	5
Sensitivity	93.4 (84.9-98.2)	87.3 (78.6-93.6)
Specificity	91.1 (86.7-95.9)	94.4 (86.0-94.6)
AUC	92.3 (87.7-96.5)	91.3 (87.0-95.3)

*Table 3. Summary of performance metrics from patients sub-categorized by race-ethnicity, with 95% confidence intervals where appropriate. *CI could not be calculated due to lack of evidence (low N).*

Metrics	White	Black/African American	Hispanic/ Latino	Asian/Asian American	Unknown/ Refused
Total N	148	85	27	7	40
TP	74	19	10	4	19
TN	58	61	14	3	19
FN	11	2	0	0	1
FP	5	3	3	0	1
Sensitivity	87.1 (78.6-93.2)	90.5 (72.3-98.5)	100.0 (77.5-100.0)	100.0 (58.3-100.0)	95.0 (84.5-99.3)
Specificity	92.1 (83.4-93.6)	95.3 (87.4-98.0)	82.4 (72.8-97.5)	100.0 (70.8-100.0)	95.0 (84.5-99.3)
AUC	88.9 (83.3-93.5)	92.9 (85.8-98.6)	88.5 (75.0-100.0)	100.0 (NA*)	95.0 (87.5-100.0)

Table 4. Summary of performance metrics from patients sub-categorized by scanner manufacturer, with 95% confidence intervals where appropriate

Metrics	SIEMENS	GE Medical Systems	Philips	Canon/ Toshiba
Total N	133	96	75	4
TP	51	38	33	4
TN	72	48	36	0
FN	5	4	5	0
FP	5	6	1	0
Sensitivity	91.1 (81.3-97.0)	90.5 (78.6-97.3)	86.6 (73.3-95.4)	NA
Specificity	93.5 (87.0-96.2)	88.9 (82.2-94.8)	97.3 (84.1-96.9)	NA
AUC	92.3 (87.8-97.2)	89.7 (83.3-95.6)	92.4 (86.1-97.6)	NA

Table 5. Summary of performance metrics from patients sub-categorized by clinical site, with 95% confidence intervals where appropriate. MCR = Mayo Clinic Rochester, BMC = Boston Medical Center.

Metrics	MCR	BMC
Total N	129	179
TP	51	75
TN	70	86
FN	3	11
FP	5	7
Sensitivity	94.4 (85.6-98.8)	87.2 (78.9-93.3)
Specificity	93.3 (88.5-97.2)	92.5 (84.9-93.8)
AUC	93.5 (89.0-97.7)	89.8 (85.2-93.8)

Table 6. Summary performance metrics from patients sub-categorized by affected vessel, with 95% confidence intervals where appropriate. ICA = intracranial carotid artery. MCA M1 = proximal segment of the middle cerebral artery.

Metrics	ICA	MCA M1
TP	29	98
TN	156	156
FN	1	13
FP	14	12
Sensitivity	96.6 (84.3-99.8)	88.7 (81.3-93.5)
Specificity	91.8 (86.9-95.3)	92.9 (88.2-96.2)
AUC	83.0 (75.0-90.3)	90.6 (86.9-93.8)

Table 7. Summary performance from patients with or without stenosis as noted by the truthers, with 95% confidence intervals where appropriate.

Metrics	With Stenosis	Without Stenosis
Total N	30	278
TP	7	119
TN	19	137
FN	3	11
FP	1	11
Sensitivity	70.0 (38.9-92.3)	91.5 (85.8-95.6)
Specificity	95.0 (71.0-96.1)	92.6 (88.4-94.9)
AUC	82.5 (66.3-96.7)	92.1 (88.6-95.0)

In addition, the device time-to-notification was assessed, which includes: (1) transferring data from PACS (picture archiving and communication system) or scanner to the Brainomix 360 server; (2) processing the case and producing and output; (3) sending results to the Brainomix 360 cloud service; and (4) delivering the notification to the user's mobile device through push notification services. The total time-to-notification ranged from 86.3 to 178.2 seconds, meeting the goal of time-to-notification of ≤3.5minutes, as the reference device Rapid LVO 1.0 (K200941).

4 Prescriptive Statement

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

5 Safety and Effectiveness

Brainomix 360 Triage LVO 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 (risk management).

6 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 large vessel occlusion 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 LVO differs from the predicate is that the proposed device may also notify the user of a suspected LVO 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.

7 Substantial Equivalence

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

Characteristic/Parameter	**Brainomix 360 Triage LVO Proposed Device**	**Viz.AI Viz LVO Predicate Device (K223042)**
Application Number	K231837	K223042
Product Code	QAS	QAS
Regulation	21 C.F.R. §892.2080	21 C.F.R. §892.2080
Indications for Use	Brainomix Triage LVO 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 Triage LVO 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.	Viz LVO 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 LVO 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

	Identification of suspected findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting, and sends notifications to a neurovascular specialist that a suspected large vessel occlusion LVO has been identified and recommends review of those images. Images can be previewed through a mobile application. Brainomix Triage LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs. 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 noncompressed 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 Triage LVO 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.	findings is not for diagnostic use beyond notification. Specifically, the device analyzes CT angiogram images of the brain acquired in the acute setting, and sends notifications to a neurovascular specialist that a suspected large vessel occlusion has been identified and recommends review of those images. Images can be previewed through a mobile application. Viz LVO is intended to analyze terminal ICA and MCA-M1 vessels for LVOs. 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 noncompressed 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 LVO 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.
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	Same
Diagnostic application	Notification-only	Notification-only
Segmentation of region of interest	No; the device does not mark, highlight, or direct users' attention to a specific location in the original image	Internal, no image marking
Alteration of original image	No	No
Preview Images	Presentation of a preview of the study for initial informational purposes	Same
Interference with standard workflow	No. Cases are not removed from worklist or deprioritized	Same
Notification	Mobile application and web user interface	Mobile
Design: DICOM compliance	Yes	Yes
Design: Computer Platform	Standard off-the-shelf server or virtual server	Same
Design: Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Materials	N/A – Software only device	Same
Biocompatibility	N/A – Software only device	Same
Sterility	N/A – Software only device	Same
Electrical Safety	N/A – Software only device	Same
Mechanical Safety	N/A – Software only device	Same
Chemical Safety	N/A – Software only device	Same
Thermal Safety	N/A – Software only device	Same
Radiation Safety	N/A – Software only device	Same

8 Conclusion

In conclusion, Brainomix 360 Triage LVO has the same intended use and is substantially equivalent in technological characteristics, safety, and performance characteristics to the legally marketed predicate device, Viz LVO (K223042). Brainomix 360 Triage LVO is therefore substantially equivalent to the selected legally marketed predicate device and does not raise any questions of safety or effectiveness.