June 12, 2026

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

Re: K260406
Trade/Device Name: Brainomix 360 Hyperdensity
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: May 15, 2026
Received: May 15, 2026

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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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

Sincerely,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic 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)*
K260406

Device Name
Brainomix 360 Hyperdensity

Indications for Use *(Describe)*
Brainomix 360 Hyperdensity is intended for automatic labeling, visualization, and volumetric quantification of intracranial hyperdensities from a set of Non-Contrast CT (NCCT) head scans acquired at a single time point.

The device output should be reviewed along with patient's original images by a physician.

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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K260406

510(K) Summary
Brainomix 360 Hyperdensity

Date Prepared:	11th June 2026
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) 7949 013914 regulatory@brainomix.com
Device Trade Name:	Brainomix 360 Hyperdensity
Device Common Name:	Automated radiological image processing software
Regulatory Class:	Class II
Product Code:	QIH
Regulation No:	21 C.F.R. §892.2050
Classification Panel:	Radiology Devices

1 Predicate Device

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

Trade Name:	Viz HDS, Viz Volume Plus, Viz ICH+ (subsequently referred to as Viz HDS only)
Manufacturer:	Viz.ai, Inc.
Regulation Number:	21 C.F.R. §892.2050
Regulatory Class:	Class II
Regulation Name:	Medical image management and processing system
Product Code:	QIH
Submission Number:	K232363

2 Device Description

Brainomix 360 Hyperdensity is a software-only device that uses a locked artificial intelligence machine learning (AI/ML) algorithm to process non-contrast head CT (NCCT) scans to outline intracranial hyperdense areas and then quantify the volume of intracranial hyperdensities. Brainomix 360 Hyperdensity analyzes the head NCCT series in DICOM format and produces a summary series and a segmentation series in DICOM format. The segmentation series shows an RGB overlay, on each slice of the input series and hyperdensities segmentation masks.

For slices including hyperdensities, their volume would be mentioned in a color legend that is also overlaid on the slice. The colors are only for visual differentiation between the segmented regions; the colors don't have a meaning on their own.

The following image is an example of the Brainomix 360 Hyperdensity desktop user interface displaying output series generated by the device.

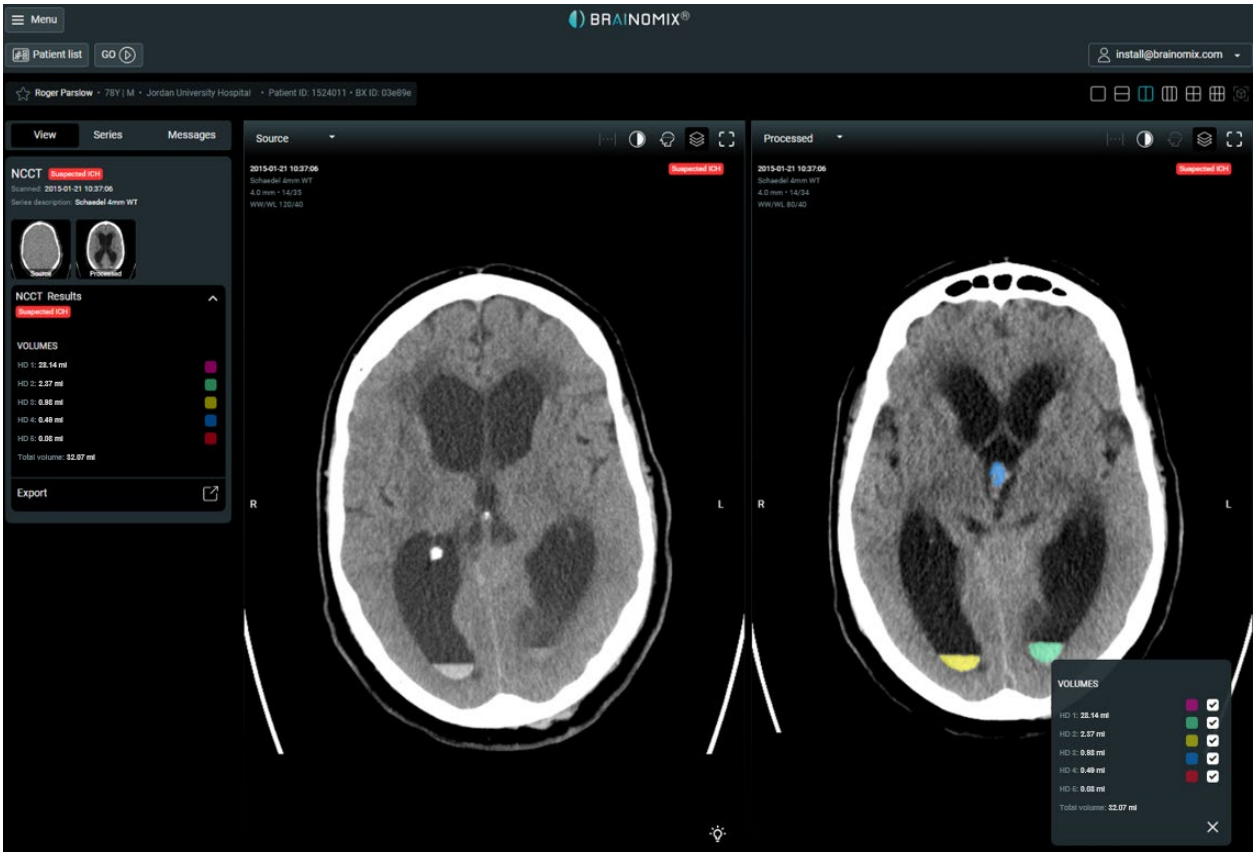

Figure 1: Example NCCT results screen of the Brainomix 360 user interface in case of a scan processed with intracranial hyperdensity detected, segmented and quantified by Brainomix 360 Hyperdensity

The device output is exported in DICOM format, which is sent to a pre-configured PACS destination together with the original NCCT series for review by a physician to aid in the assessment of measuring intracranial hyperdensities.

Users can access the system through a web browser on any machine with a connection to the Brainomix 360 platform, including mobile devices. A user may filter the view in the Brainomix 360 Viewer, to add or remove segmented volumes from the total hyperdense volume; however, the edited results are not sent back to PACS i.e., only viewed at a local level.

The Brainomix 360 Hyperdensity device is made available to the user through the Brainomix 360 platform, which is a central control unit which coordinates the execution image processing modules which support various analysis methods used in clinical practice today.

3 Clinical Characteristics

The primary users of the Brainomix 360 platform are medical imaging professionals. Brainomix 360 Hyperdensity is a parallel workflow tool installed across the neurology network in healthcare facilities to identify and communicate images and provide information of scans from adult populations who have undergone a non-contrast CT head scan in the context of suspected acute intracranial hemorrhage as part of primary diagnostic workup. After a NCCT scan has been performed, a copy of the study is automatically sent and processed by Brainomix 360 Hyperdensity which provides the user with labeling, visualization, and volumetric quantification of intracranial hyperdensities.

4 Indications for Use

Brainomix 360 Hyperdensity is intended for automatic labeling, visualization, and volumetric quantification of intracranial hyperdensities from a set of Non-Contrast CT (NCCT) head scans acquired at a single time point.

The device output should be reviewed along with patient's original images by a physician.

5 Technological Characteristics

Networking and Image Transfer

Brainomix 360 Hyperdensity may be used as a stand-alone tool. However, for streamlined integration in clinical use, the software may communicate with other DICOM-compliant medical devices through the DICOM Network Integration Module. The DICOM network integration module (DNIM) utilizes the Brainomix 360 Platform API to perform transfers of DICOM series using the DICOM network communications protocol. Practical uses of this module include connection to a CT scanner workstation, so long as the connected DICOM device supports the necessary DICOM network protocol features.

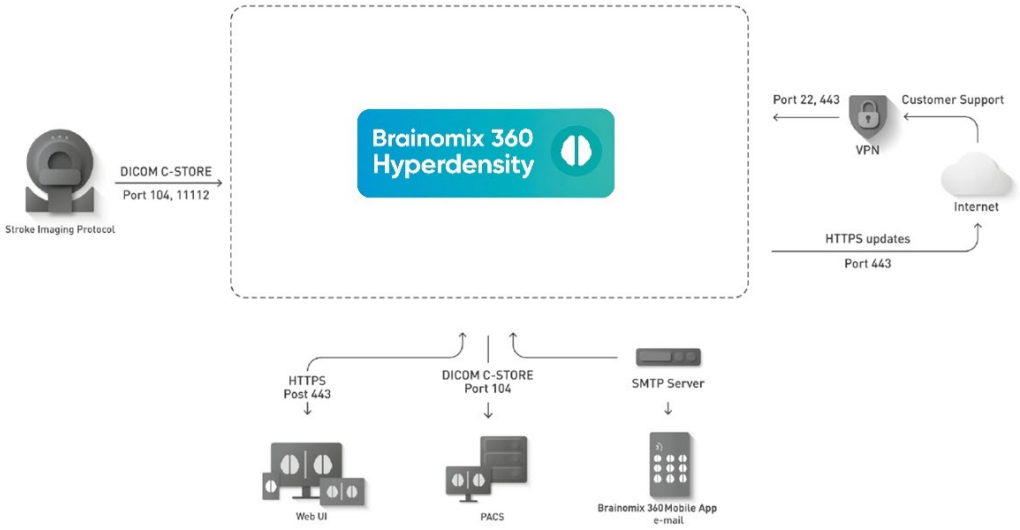

Figure 2: Networking and image transfer workflow

Principal Workflow

Brainomix 360 Hyperdensity principal workflow includes the following key steps:

1. NCCT head image input: Brainomix 360 Hyperdensity provides an automated workflow which will automatically process image data received by the system in accordance with pre-configured user DICOM routing preferences.
2. Image processing function: The algorithm processes NCCT scans searching for segmentable intracranial hyperdensities.
3. Image processing output: Segmentable hyperdense volume displayed on the NCCT results screen of the user interface is considered as the output of the processing function, which prompts user interaction.

6 Performance Data

Clinical testing was performed as a study comparing output of Brainomix 360 Hyperdensity to the ground truth as established by trained radiologists. The study demonstrated that the MAE (Mean absolute error) for hyperdensities total volume, upper 95% CI bounds was less than 7.5 mL between the algorithm and the established ground truth,

which was aligned with the performance goal. Additionally, DICE score was calculated to describe the degree of agreement between the measurements by the Brainomix 360 Hyperdensity algorithm in comparison to the measurements that were obtained manually. The study demonstrated that the DICE score for hyperdenity(ies) lower CI bound was greater than 70%, which was aligned with the performance goal. Stratification of device performance was divided by clinical site, sex, age, race/ethnicity, slice thickness, scanner manufacturer and size of estimated quantity.

7 Prescriptive Statement

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

8 Verification and Validation

Brainomix 360 Hyperdensity has been designed, verified and validated in compliance with 21 CFR, Part 820.30 requirements. The device has been designed to meet the requirements associated with ISO 14971:2019 for risk management and the software development process conforms to IEC 62304:2015 and IEC 82304-1. The performance of Brainomix 360 Hyperdensity has been validated through clinical test data.

9 Cybersecurity

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

10 Substantial Equivalence

Intended Use/Indications for Use

Both the subject and predicate device are software packages that assist the user in the labeling, visualization, and quantification of segmentable brain structures from a set of Non-Contrast CT (NCCT) head scans. They are both intended to automate the current manual process of identifying, labeling, and quantifying the volume of segmentable intracranial hyperdensities identified on NCCT images. Both devices are Software as a Medical Device (SaMD) which are designed to streamline medical image processing tasks that are time consuming and fatiguing in routine patient workup. The device output of both devices should be reviewed along with patient's original images by a physician. Therefore, the subject and the predicate device have the same intended use.

Where the subject device and predicate device differ is that the indications for use of the subject device does not provide two of the outputs that the predicate does, namely lateral ventricles volume and midline shift. This difference does not raise any safety or efficacy question as the clinical value of the software in identifying, labeling, and quantifying the volume of segmentable intracranial hyperdensities is not negatively impacted by the non-display of lateral ventricle volume and midline shift and therefore the risks associated with these types of outputs are not applicable to the subject device. These radiological findings are distinct from the segmentation and volumetry of hyperdensity. Therefore the absence of automated assessment of lateral ventricle volume and midline shift in this device does not pose any additional risk in its clinical use as compared to the predicate device.

Environments and Users

Both the subject and predicate device are designed to be used by trained clinicians in a hospital/clinical environment.

User Interface

Both the subject and predicate device provide the results and images via a web user interface (desktop and mobile) or PACS viewer that allow the user to preview images and patients identified, labelled and quantified with segmentable intracranial hyperdensities to automate the manual process of measurement.

Technological Characteristics

Both the subject and predicate device use a deep-learning algorithm that analyzes NCCT images for identifying, labeling and quantifying the volume of segmentable intracranial hyperdensities. Both the devices have DICOM annotated series image and summary report as an output which is sent to pre-configured PACS destinations together with the original NCCT series for review by a physician. They both provide RGB overlay as the output for intracranial hyperdensities where the colors are only for visual differentiation between the segmented regions and the colors don't have a meaning on their own.

Where the subject and predicate device differ in technological characteristics is in relation to the functions which are present in the predicate but not in the subject device (display of lateral ventricle volume and midline shift). The differences in technological characteristics of the devices do not raise different questions of safety and effectiveness as the risks associated with these outputs (display of lateral ventricle volume and midline shift) do not apply to the subject device.

Performance data has been collected through clinical study to support that the technical characteristics of the algorithm meet the clinical performance criteria of the predicate device. In order to sufficiently characterize the clinical performance of the subject device, Brainomix 360 Hyperdensity used the same approach to characterize clinical performance as the predicate device. The two primary outcome measures used in the validation were mean absolute error and Dice similarity coefficients – the same outcome measures reported by the predicate. As the performance of the subject device met the performance reported by the predicate device and, therefore, the data demonstrates equivalence.

11 Substantial Equivalence Comparison

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

Characteristics/ Parameter	Subject Device Brainomix 360 Hyperdensity	Predicate Device Viz HDS
Application No.	K260406	K232363
Product Code	QIH	QIH
Regulation No.	21 C.F.R. §892.2050	21 C.F.R. §892.2050
Intended Use / Indications for Use	Brainomix 360 Hyperdensity is intended for automatic labeling, visualization, and volumetric quantification of intracranial hyperdensities from a set of Non-Contrast CT (NCCT) head scans acquired at a single time point. The device output should be reviewed along with patient's original images by a physician.	The Viz HDS device is intended for automatic labeling, visualization, and quantification of segmentable brain structures from a set of Non-Contrast CT (NCCT) head scans. The software is intended to automate the current manual process of identifying, labeling, and quantifying the volume of segmentable brain structures identified on NCCT images. Viz HDS provides volumes from NCCT scans acquired at a single time point. The Viz HDS software is indicated for use in the analysis of the following structures: Intracranial Hyperdensities, Lateral Ventricles and Midline Shift. The device output should be reviewed along with patient's original images by a physician.
Anatomical Region	Head	Head
Independent Standard of Care Workflow	Yes	Yes

Characteristics/ Parameter	Subject Device Brainomix 360 Hyperdensity	Predicate Device Viz HDS
Input Images	Non-contrast CT from a single time point	Non-contrast CT from a single time point
Clinical Condition	Intracranial hyperdensities	Intracranial hyperdensities, lateral ventricles and midline shift
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities
Supported Imaging Modality	Non-contrast CT (NCCT)	Non-contrast CT (NCCT)
Alteration of Original Image	No	No
Algorithm Type	Locked AI/ML	Locked AI/ML
Output	Multiple electronic reports with volumetric information of brain structures indicative of intracranial hyperdensities and annotated DICOM Images	Multiple electronic reports with volumetric information of brain structures and midline shift and annotated DICOM Images
Inclusion of a PCCP	Included	None

12 Predetermined Change Control Plan (PCCP)

Brainomix 360 Hyperdensity contains a Predetermined Change Control Plan (PCCP), which complies with Section 3308 of the Food and Drug Omnibus Reform Act (FDORA) of 2022, enacted on December 29, 2022. Modifications to the device will be made in accordance with the PCCP.

The PCCP provides a description of the device's planned modifications, a modification protocol to test, verify, validate, and implement the modifications in a manner that ensures the continued safety and effectiveness of the device. This protocol also includes control measures that mitigate risks associated with changes to the AI/ML algorithm, including an impact assessment of the planned modifications, to ensure modifications conducted in line with the modification protocol will not adversely impact the device's performance, safety, or effectiveness associated with its indications for use. Updates implemented under the PCCP do not change the device's clinical role, user workflow, or interpretation of results. In accordance with the PCCP, all algorithm modifications will be trained, tuned, and locked prior to release of the software to the end user. The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field.

Brainomix 360 is provided as a complete software appliance that can be deployed on virtual machines (VMs) or a dedicated physical server. Any software updates resulting from a modification implemented in accordance with the authorized PCCP will be deployed by Brainomix and will not require action by the end user. Any changes will be communicated through release notes provided to the user prior to deployment of the updated software version. This information is provided to ensure users remain informed of applicable changes and are able to continue to use the device safely and effectively within the cleared indications for use. The PCCP specifies a list of potential modifications to the device software as well as specific verification and validation activities in place to implement these modifications in a controlled manner such that the modified device remains safe and effective.

Modification	Rationale	Testing methods	Impact assessment
Retraining the model weights using expanded	The modification is intended to address underrepresentation and	Testing method will follow the same software verification and validation framework applied	Benefits: improved segmentation accuracy and volumetric precision

Modification	Rationale	Testing methods	Impact assessment
datasets enriched for specific subtypes	morphological variability observed in real-world use. This approach supports more consistent segmentation and volumetric quantification across the full range of segmentable hemorrhage presentations within the authorized scope.	to the originally cleared device. Model performance will be assessed using predefined acceptance criteria, including segmentation accuracy and volumetric precision metrics. Testing activities will be used to support that the modified device continues to meet its intended use and does not raise new questions of safety or effectiveness compared to the predicate device.	Risks: reduction in clinical performance due to overfitting and unintended bias Risk mitigation: verification and validation activities continue to reasonably ensure safety and effectiveness by applying the same rigor used for the originally cleared device. Acceptance criteria require that retraining does not introduce unacceptable degradation in segmentation accuracy or volumetric precision for the intended use population.
Adjustment of probability thresholds for specific subtype classes to optimize performance	The modification enables optimized segmentation behavior and volumetric accuracy for targeted subtypes, while preserving the underlying learned representations. This enables fine-grained performance optimization without introducing new autonomous behavior or expanding clinical claims.	Testing method will follow the same software verification and validation framework applied to the originally cleared device. Model performance will be assessed using predefined acceptance criteria, including segmentation accuracy and volumetric precision metrics. Testing activities will be used to support that the modified device continues to meet its intended use and does not raise new questions of safety or effectiveness compared to the predicate device.	Benefits: improved segmentation accuracy and volumetric precision Risks: reduction in clinical performance due to over- or under-segmentation, volumetric distortion and unintended bias Risk mitigation: verification and validation activities continue to reasonably ensure safety and effectiveness by applying the same rigor used for the originally cleared device. Acceptance criteria require that threshold tuning does not introduce unacceptable degradation in segmentation accuracy or volumetric precision for the intended use population.

Modifications implemented under the PCCP are limited to performance optimization and do not introduce new indications for use, alter user workflow, or change the fundamental algorithmic approach. As such, the inclusion of the PCCP does not affect the determination of substantial equivalence between the subject device and the predicate device.

13 Conclusion

The subject device has a subset of indications for use and technological characteristics of the predicate device. Both devices are intended to be used as aid to physicians for identifying, labeling and quantifying segmentable brain structures on NCCT images. Because of the similarities regarding the type of algorithms, the type of imaging data processed by the devices, the intended use of the devices, and the outputs of the image analysis, the difference in the number of outputs types in the subject device (no lateral ventricle volume and midline shift) does not raise new or unanswered questions regarding safety or efficacy.

We conclude that the subject device is safe and effective, raises no unanswered questions with regards to safety and efficacy and is substantially equivalent to the predicate device, Viz HDS (K232363).