



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

January 6, 2025

Re: K242123

Trade/Device Name: Brainomix 360 e-CTA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ, QIH
Dated: November 22, 2024
Received: November 27, 2024

Dear Zsolt Sznka:

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

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

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

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

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style and is positioned above the printed name.

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

Indications for Use

Submission Number (if known)

K242123

Device Name

Brainomix 360 e-CTA

Indications for Use (Describe)

Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard "off the-shelf" hardware (physical or virtualized) and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices.

Brainomix 360 e-CTA provides viewing and analysis capabilities for imaging datasets acquired with CTA (CT Angiography).

Brainomix 360 e-CTA is not intended for mobile diagnostic use.

Brainomix 360 e-CTA vessel density asymmetry ratio applies only to the MCA region.

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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510(K) Summary

Brainomix Limited – Brainomix 360 e-CTA

Date Prepared: 26Nov2024
Applicant's Name: Brainomix Limited
Applicant's Address: First Floor, Seacourt Tower, West Way
Oxford, OX2 0JJ
United Kingdom
Official Contact: Zsolt Szrnka
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regulatory@brainomix.com
Device Proprietary Name: Brainomix 360 e-CTA
Device Common Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: Primary: LLZ, Secondary: QIH
Regulation: 21 C.F.R. §892.2050

1. Predicate Devices

Brainomix 360 e-CTA is Substantially Equivalent to the following Legally Marketed devices:

Trade Name: Brainomix 360 e-CTA (*Primary Predicate*)
Manufacturer: Brainomix Ltd.
Regulation Number: 21 C.F.R. §892.2050
Regulatory Class: Class II
Regulation Name: Medical Image Management And Processing System
Product Code: LLZ
Submission Number: K192692

Trade Name: Rapid (*Secondary Predicate*)
Manufacturer: iSchemaView
Regulation Number: 21 C.F.R. §892.2050
Regulatory Class: Class II
Regulation Name: Medical Image Management And Processing System
Product Code: LLZ, QIH
Submission Number: K233582

2. Device Description

Brainomix 360 e-CTA is a medical image visualization and processing software package compliant with the DICOM standard and running on an off-the-shelf physical or virtual server.

Brainomix 360 e-CTA allows for the visualization, analysis and post-processing of DICOM compliant CTA images which, when interpreted by a trained physician or medical technician, may yield information useful in clinical decision making.

Brainomix 360 e-CTA provides a wide range of basic image viewing, processing and manipulation functions, through multiple output formats. Functionality includes image registration and visualization of large cerebral vessels to provide an analysis of hemispheric difference via contralateral comparison (displayed as a relative percentage).

Brainomix 360 e-CTA processes the images using AI/ML algorithms where the input channels will help the software distinguish bone from vessels and reduce image grain.

Brainomix 360 e-CTA automatically provides a colored overlay to provide a visual reference of the MCA hemisphere of the brain with lower vessel density, and corresponding contrast intensity measurements and estimated phase.

Brainomix 360 e-CTA can connect with other DICOM-compliant devices, for example to transfer CTA scans from a Picture Archiving and Communication System (PACS) to Brainomix 360 e-CTA software for processing. Results and images can be sent to a PACS via DICOM transfer and can be viewed on a PACS workstation or via a web user interface on any machine contained and accessed within a hospital network and firewall and with a connection to the Brainomix 360 e-CTA software (e.g. a LAN connection).

Brainomix 360 e-CTA notification capabilities enable clinicians to preview images via e-mail notification with result image attachments. Images that are previewed via e-mail are compressed, are for informational purposes only, and not intended for diagnostic use beyond notification.

Brainomix 360 e-CTA is not intended for mobile diagnostic use. 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.

3. Intended Use / Indications for Use

Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard “off the-shelf” hardware (physical or virtualized) and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices.

Brainomix 360 e-CTA provides viewing and analysis capabilities for imaging datasets acquired with CTA (CT Angiography).

Brainomix 360 e-CTA is not intended for mobile diagnostic use.

Brainomix 360 e-CTA vessel density asymmetry ratio applies only to the MCA region.

4. Performance Data

4.1 Summary of Digital Phantom Validation

Digital phantom evaluation was performed to validate the “vessel density ratio value” output as calculated by Brainomix 360 e-CTA.

The tests have passed and demonstrate that Brainomix 360 e-CTA performs following its requirements and that the algorithm as implemented in Brainomix 360 e-CTA performs by the required performance criteria, which is summarized below in Table 1.

Metric Name	Value	Criteria	Pass/Fail
Left-MAE	6.444	<10	Pass
Left-MAE-STD	9.269	<15	Pass
Right-MAE	5.611	<10	Pass
Right-MAE-STD	8.610	<15	Pass

Table 1. Vessel density ratio validation results

4.2 AI/ML Comparison Digital Phantom Validation

The algorithm version of the primary predicate device (K192692) was compared against that of the proposed device having the AI/ML model add-on to increase the quality of the vessel mask. The metrics are summarized in Table 2.

Device	Left MAE (%)	Right MAE (%)
Predicate device with NO-CNN (n=18)	7.333	6.889
Proposed device with CNN (n=18)	3.000	6.278
Difference between devices	4.333 > 0	0.611 > 0

Table 2. Comparison of performance metrics between predicate device and proposed device

The proposed device shows a reduction in the Mean Absolute Error (MAE) for both hemispheres (4.333% left; 0.611% on the right).

These results corroborate that the algorithm approach of the proposed device is safe, effective and does not raise different questions of safety and effectiveness to Brainomix 360 e-CTA while slightly improving its performance.

4.3 Summary of Standalone Performance Study

A retrospective study has been carried out to assess the standalone performance of the processing step of vessel delineation in Brainomix 360 e-CTA in comparison to the predicate (Brainomix 360 e-CTA, K192692).

A sample size of 308 Computed Tomography Angiography (CTA) brain scans (studies) were obtained from clinical sites in the U.S. The majority of studies came from Boston Medical Centre (BMC), or from referring hospitals in the Massachusetts area (N=179). The remaining studies came from Mayo Clinic Rochester (MCR; N=129). The patient cohort was enriched to ensure the distribution of clinical and demographic variables (e.g., age, gender, race) allows generalizability to the patient population for whom use is intended.

The imaging was collected on a variety of different scanner models and manufacturers (Table 8). The dataset included 133 cases from SIEMENS scanners, 96 from GE scanners, 76 from Philips scanners and 4 from Canon/Toshiba scanners.

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 global results are shown below in Table 3, the Dice Similarity Score is 0.955 reaching for the vessel delineation and 0.999 for the parenchyma mask as the desired requirement.

Table 3. Summary performance metrics from full sample of 308 patients, with 95% confidence intervals where appropriate.

Metrics	All Cases (N=308)
Vessels DSC	0.955 (0.953, 0.957)
Parenchyma DSC	0.999 (0.999, 1.000)

In order to assess the generalization of the performance in different patient subgroups, further stratifications were derived from the complete dataset by age (Table 4), by gender (Table 5), by race (Table 6), by clinical site (Table 7), by scanner manufacturer (Table 8), by the presence of stenosis (Table 9).

Table 4. 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
Vessels DSC	0.958 (0.953, 0.962)	0.959 (0.957, 0.962)	0.949 (0.946, 0.953)
Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)

Table 5. Summary performance metrics from patients sub-categorized by gender, with 95% confidence intervals where appropriate.

Metrics	Male	Female
Total N	140	168
Vessels DSC	0.952 (0.949, 0.955)	0.958 (0.955, 0.960)

Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)
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Table 6. Summary 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
Vessels DSC	0.954 (0.951, 0.956)	0.957 (0.953, 0.961)	0.957 (0.949, 0.964)	0.958 (0.948, 0.967)	0.955 (0.951, 0.959)
Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)

Table 7. Summary 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
Vessels DSC	0.952 (0.949, 0.956)	0.957 (0.955, 0.959)
Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)

Table 8. Summary 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
Vessels DSC	0.953 (0.95, 0.956)	0.954 (0.95, 0.957)	0.961 (0.958, 0.964)	0.964 (0.947, 0.981)
Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)

Table 9. Summary performance metrics 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
Vessels DSC	0.957 (0.952, 0.962)	0.955 (0.953, 0.957)
Parenchyma DSC	0.999 (0.999, 1.000)	0.999 (0.999, 1.000)

The standalone performance testing demonstrated that the proposed device provides accurate vessel and parenchyma delineation masks against the predicate device (head-to-head comparison) under a range of clinically relevant variables associated with the intended use of the software. These results corroborate that the algorithm approach of the proposed device adds no risks to Brainomix 360 e-CTA while slightly improving its performance.

5. Prescriptive Statement

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

6. Safety and Effectiveness

Brainomix 360 e-CTA 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).

7. Cybersecurity

Brainomix 360 e-CTA has been designed and validated to the FDA Cybersecurity Guidance and IEC 81001-5-1.

8. Summary of Technological Characteristics

Brainomix 360 e-CTA includes similar CTA processing features and technological characteristics as compared to the predicate devices. Where the proposed device differs from the predicate devices, is that it provides three new claims listed below:

1. **Algorithm:** The proposed device introduces an AI/ML algorithm which was not present in the primary predicate (Brainomix e-CTA). The input channels are intended to help the software distinguish bone from vessels which leads to improved image quality (less grain) as well as improved vessel detection, which has been extensively validated through digital phantom testing. In summary, the phantom validation results show a reduction in the Mean Absolute Error (MAE) for both hemispheres (4.333% left; 0.611% on the right), which corroborates that the proposed device is safe and effective and does not raise different questions of safety and effectiveness. Furthermore, the use of AI/ML algorithms is similar to the technological characteristics of the secondary predicate (Rapid).
2. **Accessible MIP views:** The proposed device introduces posterior views to be accessed through Brainomix 360 e-CTA which was not present in the primary predicate (Brainomix 360 e-CTA). The current MIP views of the primary predicate device (Brainomix 360 e-CTA) already display posterior vessels where this new added view just enables focused visualization of posterior large vessels. Furthermore, there are no separate density analysis performed on the posterior MIPs and therefore this change does not raise different questions of safety and effectiveness.
3. **3D-colored overlay:** The proposed device introduces a 3-dimensional opacity graded overlay to the primary predicate device (Brainomix 360 e-CTA) that helps to visualize the asymmetry in blood vessel density between MCA hemispheres which is calculated via contralateral comparison. This colored overlay is a similar technological characteristic when compared to the secondary predicate device's (Rapid) 2D-colored overlay. The proposed 3D-colored overlay compares to the secondary predicate in that:
 - a. Both the outputs – 3D-colored overlay in the subject device and the 2D-colored overlay of the secondary predicate device are similar as they are a mathematical quantification of image outputs displayed in percentage that provides a reference for the clinician. Furthermore, the intended user is responsible to follow the standard of care and to engage in appropriate patient evaluation based on relevant clinical background before making care-related decisions when using both the proposed device and secondary predicate

device. Where the features differ is that the proposed overlay (3D-colored overlay) uses a transparency scale instead of a multi-colored scale (secondary predicate device).

- b. The proposed overlay (3D-colored overlay) is defined as such given the user’s ability to view it through different slices of the DICOM image. However, per slice it is presented as a 2D overlay. The presentation of the outputs of the regions of asymmetry in a transparency scale as compared to a multi-colored scale would not change how the user interacts with the device and the intended use of the overlay and therefore, does not raise new questions of safety and effectiveness.

The proposed device (Brainomix 360 e-CTA) and the secondary predicate (Rapid) include similar CTA processing features and technological characteristics as compared to the secondary predicate device. Where technological differences exist, these are predominantly where the predicate device offers more features, functionality and a broader set of imaging indications as compared to the proposed device. The differences in technological characteristics for the proposed device do not raise any new or unanswered questions of safety or effectiveness.

9. Substantial Equivalence

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

Characteristics/ Parameter	Proposed Device Brainomix 360 e-CTA (K242123)	Primary Predicate Device Brainomix 360 e-CTA (K192692)	Secondary Predicate Device iSchemaView Rapid (K233582)
510(k) Number	K242123	K192692	K233582
Product Code	LLZ, QIH	LLZ	LLZ, QIH
Regulation Number	21 CFR §892.2050	21 CFR §892.2050	21 CFR §892.2050
Intended Use/Indications for Use	Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard “off the-shelf” hardware (physical or virtualized) and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Brainomix 360 e-CTA provides viewing and analysis capabilities for imaging datasets acquired with CTA (CT Angiography).	Brainomix 360 e-CTA is an image processing software package to be used by trained professionals, including, but not limited to physicians and medical technicians. The software runs on standard “off the-shelf” hardware (physical or virtualized) and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Brainomix 360 e-CTA provides viewing and analysis capabilities for imaging datasets acquired with CTA (CT Angiography).	Rapid is an image processing software package to be used by trained professionals, including but not limited to physicians (medical analysis and decision making) and medical technicians (administrative case processing). The software runs on a standard off-the-shelf computer or a virtual platform, such as VMware, and can be used to perform image viewing, processing, and analysis of images. Data and images are acquired through DICOM compliant imaging devices. Rapid is indicated for use in Adults only. Rapid provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT, CT Perfusion (CTP), CT Angiography (CTA), C-arm CT

Characteristics/ Parameter	Proposed Device Brainomix 360 e-CTA (K242123)	Primary Predicate Device Brainomix 360 e-CTA (K192692)	Secondary Predicate Device iSchemaView Rapid (K233582)
	<p>Brainomix 360 e-CTA is not intended for mobile diagnostic use.</p> <p>Brainomix 360 e-CTA vessel density asymmetry ratio applies only to the MCA region.</p>	<p>Brainomix 360 e-CTA is not intended for mobile diagnostic use.</p>	<p>Perfusion and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI, CT, and C-arm CT). Rapid C-arm CT Perfusion can be used to qualitatively assess cerebral hemodynamics in the angiography suite. The CT analysis includes NCCT maps showing areas of hypodense and hyperdense tissue. The DWI Module is used to visualize local water diffusion properties from the analysis of diffusion - weighted MRI data. The Dynamic Analysis Module is used for visualization and analysis of dynamic imaging data, showing properties of changes in contrast over time. This functionality includes calculation of parameters related to tissue flow (perfusion) and tissue blood volume. Rapid CT Perfusion and Rapid MR Perfusion can be used by physicians to aid in the selection of acute stroke patients (with known occlusion of the intracranial internal carotid artery or proximal middle cerebral artery). Instructions for the use of contrast agents for this indication can be found in Appendix A of the User's Manual. Additional information for safe and effective drug use is available in the product-specific iodinated CT and gadolinium-based MR contrast drug labeling. In addition to the Rapid imaging criteria, patients must meet the clinical requirements for thrombectomy, as assessed by the physician, and have none of</p>

Characteristics/ Parameter	Proposed Device Brainomix 360 e-CTA (K242123)	Primary Predicate Device Brainomix 360 e-CTA (K192692)	Secondary Predicate Device iSchemaView Rapid (K233582)
			<p>the following contraindications or exclusions:</p> <ul style="list-style-type: none"> Bolus Quality: absent or inadequate bolus. Patient Motion: excessive motion leading to artifacts that make the scan technically inadequate. Presence of hemorrhage. C-Arm CTP is not to be used in the Rapid Thrombectomy indication for patient selection criteria, other modalities should be consulted. <p>Cautions:</p> <p>C-Arm CTP provides qualitative data only, review other modalities prior to diagnosis. CBV and CBT are not absolute and CBT, CBV, MTT and Tmax are supported for qualitative interpretation of the perfusion maps only.</p>
Environment of use	Clinical/Hospital environment	Same	Same
Energy used and/or delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	Same	Same
Primary Users	Radiologist/Clinician	Same	Same
Design: Supported Modalities for image processing and visualization	CTA only	CTA only	CT [NCCT, CT, CTA, C-arm CT(CBCT)] or MR (MR, MRA)
MIP Views accessible	Maximum intensity projections (MIPs) of the vascular system in axial, coronal, left and right hemisphere sagittal, and posterior views	Maximum intensity projections (MIPs) of the vascular system in axial, coronal and left and right hemisphere sagittal views	Maximum intensity projections (MIPs) of the vascular system in axial, coronal, left and right hemisphere sagittal.
Technical Implementation	Mixed Traditional and AI/ML	Traditional	Mixed Traditional and AI/ML
Image Overlay	Vessel Density with visual representation (3D-colored overlay)	No	Vessel Density with visual representation (2D-colored overlay)

Characteristics/ Parameter	Proposed Device Brainomix 360 e-CTA (K242123)	Primary Predicate Device Brainomix 360 e-CTA (K192692)	Secondary Predicate Device iSchemaView Rapid (K233582)
Design: PACS functionality	View, process and analyze medical images. Performs standard PACS functions with respect to querying and listing	Same	Same
Design: DICOM compliance	Yes	Yes	Yes
Design: Computer Platform	Standard off-the-shelf server or virtual server	Same	Same
Design: Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same	Same
Additional tools	Arterial input function (AIF) Venous output function (VOF) – CTA	Same	Same
Functional overview	Brainomix 360 e-CTA is a software package that provides for the study of changes of tissue in digital images captured by CTA. Brainomix 360 e-CTA provides viewing and quantification for CTA images.	Same	RAPID is a software package that provides for the visualization and study of changes of tissue in digital images captured by CT and MRI. RAPID provides viewing and quantification.
Materials	N/A – Software only device	Same	Same
Biocompatibility	N/A – Software only device	Same	Same
Sterility	N/A – Software only device	Same	Same
Electrical Safety	N/A – Software only device	Same	Same
Mechanical Safety	N/A – Software only device	Same	Same
Chemical Safety	N/A – Software only device	Same	Same
Thermal Safety	N/A – Software only device	Same	Same
Radiation Safety	N/A – Software only device	Same	Same

10. Conclusion

The proposed device has the same intended use as the primary predicate and similar intended use as the secondary predicate. The proposed device and predicate devices utilize similar CTA processing features. The differences in technological characteristics for the proposed device do not raise any new or unanswered questions of safety or effectiveness.

We conclude that the proposed device raises no unanswered questions with regards to safety and efficacy and demonstrates substantial equivalence to the predicates, Brainomix 360 e-CTA (K192692) and Rapid (K233582).