Brainomix Limited
℅ Thais Sala
First Floor, Seacourt Tower
West way
Oxford, Oxfordshire OX2 0JJ
UNITED KINGDOM

June 1, 2023

Re: K223555
Trade/Device Name: Brainomix 360 e-CTP
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 3, 2023
Received: May 3, 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 (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 S. 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)*
K223555

Device Name
Brainomix 360 e-CTP

Indications for Use *(Describe)*
Brainomix 360 e-CTP 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 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. This includes DICOM files uploaded through a web browser interface.

Brainomix 360 e-CTP provides viewing and analysis capabilities for imaging datasets acquired with CT Perfusion. The CT Perfusion analysis capabilities are 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.

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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K223555

Brainomix 360 e-CTP 510(K) Summary

Manufacturer:	Brainomix Limited First Floor, Seacourt Tower West Way Oxford OX2 7HN United Kingdom
Contact:	Thais Sala Regulatory Affairs Manager +44 (0) 1865 582730
Prepared by:	MCRA, LLC 803 7th St., NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Submitted:	May 03rd, 2023
Device Trade Name:	Brainomix 360 e-CTP
Device Common Name(s):	Brainomix 360 e-CTP
Classification:	Device Class: II Primary Product Code: LLZ Regulation No.: 21 § CFR 892.2050
Classification Panel:	Radiology
Predicate Device:	Primary: RAPID (K121447)
Reference Device:	Viz CTP (K180161)

Device Description

Brainomix 360 e-CTP software allows for visualization of DICOM compliant CT (Computed Tomography) digital images. The software has been designed to run with off-the-shelf physical or virtual servers and provides for viewing, quantification, analysis, and reporting, as an aid to physician diagnosis.

The software consists of one processing module:

1. e-CTP Module- provides both analysis and viewing capabilities for brain CT Perfusion datasets for characterization of perfusion parameters in the image following the injection of a contrast bolus, and visualization of these parameters.

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Indications For Use

Brainomix 360 e-CTP 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 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. This includes DICOM files uploaded through a web browser interface.

Brainomix 360 e-CTP provides viewing and analysis capabilities for imaging datasets acquired with CT Perfusion.

The CT Perfusion analysis capabilities are 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.

Technological Characteristics

Brainomix 360 e-CTP is designed to receive CT perfusion scans and apply algorithms to automatically produce several outputs which the user can then review and assess as part of a broader diagnostic and treatment decision making process.

Brainomix 360 e-CTP software medical device 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. While any DICOM-compliant medical device supporting the appropriate DICOM functionality (particularly CT scan image storage and transmission, which is used for transmitting CT scans) may be used, there are two main groups of devices that e-CTP is intended to interact with:

- CT scanner workstation software
- PACS systems

The analysis consists of AIF and VOF selection, bolus arrival time definition and block-circulant deconvolution. Finally, post-processing parametric maps and volumetric results are generated. Thresholds are user-defined via a configuration/settings file.

Performance Testing Summary

Brainomix 360 e-CTP complies with DICOM (Digital Imaging and Communications in Medicine) - Developed by the American College of Radiology and the National Electrical Manufacturers Association. NEMA PS 3.1 - 3.20.

Additionally, extensive performance validation testing and software verification and validation testing was conducted for the Brainomix 360 e-CTP module. This performance validation testing demonstrated that the module provides accurate representation of key processing parameters under a range of clinically relevant parameters and perturbations associated with the intended use of the software. Software performance, validation and verification testing demonstrated that the Brainomix 360 e-CTP met all design requirements and specifications.

Substantial Equivalence

Brainomix 360 e-CTP and the predicate have substantially similar technological characteristics in that both devices are software packages used for image processing and run on standard physical and/or

virtual servers. Both are intended to be used by trained physicians and provide image viewing, processing and analysis of DICOM compliant images from DICOM compliant imaging devices.

Both Brainomix 360 e-CTP and the predicate device have substantially similar intended use as both perform image processing of CT data.

Parameter	RAPID (K121447) – Predicate Device	Brainomix 360 e-CTP– Proposed Device
Product Code	LLZ	LLZ
Regulation	21 CFR 892.2050	21 CFR 892.2050
Indications for Use	iSchemaView's RAPID 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 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 brain images. Data and images are acquired through DICOM compliant imaging devices. iSchemaView's RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast enhanced imaging data for MRI and CT). 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.	Brainomix 360 e-CTP 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 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. This includes DICOM files uploaded through a web browser interface. Brainomix 360 e-CTP provides viewing and analysis capabilities for imaging datasets acquired with CT Perfusion. The CT Perfusion analysis capabilities are 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.
Functional overview	The software package that provides for the visualization and study of changes of tissue in digital images captured by CT and MRI. The software provides viewing and quantification.	Same but with no MRI capabilities.
Environment of use	Clinical/Hospital environment	Same
Human Factors	Designed to be used by trained clinicians	Same
PACS Functionality		

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Parameter	RAPID (K121447) – Predicate Device	Brainomix 360 e-CTP– Proposed Device
Basic PACS Functions	View process and analyze medical images. performs standard PACS functions with respect to querying and listing	Same
Computer Platform	Standard off-the-shelf server or virtual server	Same
DICOM compliance	Yes	Same
Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Same
Data/Image Types	Computed Tomography (CT) via DICOM format Magnetic Resonance Image (MRI)	Same None
Acquisition and Modalities Features		
CT	CT Perfusion (CTP)	Yes
MRI	Diffusion Weighted Image (DWI) Perfusion Weighted Image (PWI)	None
Computed Parameter Maps		
Perfusion CT and Perfusion MRI	• Cerebral blood flow (CBF) • Cerebral blood volume (CBV) • Mean Transit Time (MTT) • Tissue residue function time to peak (Tmax)	• relative Cerebral blood flow (rCBF) • relative Cerebral blood volume (rCBV) • Mean Transit Time (MTT) • Tissue residue function time to peak (Tmax) • Time to Peak (TTP) • Perfusion MRI: None
Diffusion MRI	• ADC • Trace of diffusion tensor (Trace) • Isotropic DWI (isoDWI) • Fractional Anisotropy (FA) and color FA	• None
Measurement Tools		
Additional tools	• Arterial input function (AIF)/ Venous output function (VOF) • Time-course • Motion Correction • Mask • Region of interest (ROI) and Volumetry • Volumetric comparison between regions • Export perfusion and diffusion files to PACS and DICOM file systems • Acquire, transmit, process, and store medical images	• Arterial input function (AIF)/ Venous output function (VOF) • Time-course • Motion Correction • Mask • Volumetry analysis • Volumetric comparison between regions • Export perfusion and diffusion files to PACS and DICOM file systems • Acquire, transmit, process, and store medical images

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Conclusion:
In conclusion, the predicate device has the same technological characteristics and intended use as Brainomix 360 e-CTP. Brainomix 360 e-CTP is therefore substantially equivalent to the selected predicate device and does not raise any questions of safety or effectiveness.

Software verification and validation and algorithmic testing and risk management demonstrates that Brainomix 360 e-CTP is safe and effective for use as intended and described in its indications for use.