August 30, 2023

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

Re: K231656
Trade/Device Name: Brainomix 360 e-MRI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 30, 2023
Received: June 7, 2023

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 (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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*

K231656

Device Name

Brainomix 360 e-MRI

Indications for Use *(Describe)*

Brainomix 360 e-MRI 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-MRI provides both viewing and analysis capabilities for imaging datasets acquired with MRI including Perfusion Weighted Imaging (PWI) and Diffusion Weighted Imaging (DWI).

The DWI MRI analysis capabilities are used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

The MRI PWI 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.

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

K231656

510(K) Summary
Brainomix 360 e-MRI

Date Prepared:	June 6, 2023
Applicant's name:	Brainomix Limited
Applicant's address:	First Floor, Seacourt Tower, West Way Oxford, OX2 0JJ United Kingdom
Official contact:	Zsolt Szrnka +44 (0)1865 582730 zszrnka@brainomix.com
Device Trade Name:	Brainomix 360 e-MRI
Device Common Name:	Brainomix 360 e-MRI
Classification:	Device Class: II Primary Product Code: LLZ Regulation No.: 21 § CFR 892.2050
Classification Panel:	Radiology Devices
Predicate Device:	iSchemaView's RAPID (K121447)

Intended Use / Indications for Use

Brainomix 360 e-MRI 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-MRI provides both viewing and analysis capabilities for imaging datasets acquired with MRI including Perfusion Weighted Imaging (PWI) and Diffusion Weighted Imaging (DWI).

The DWI MRI analysis capabilities are used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data.

The MRI PWI 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.

Device Description

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

Brainomix 360 e-MRI software allows for visualization of DICOM compliant MRI (Magnetic Image Resonance) 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 system consists of platform functionality and the e-MRI processing module. It provides both analysis and viewing capabilities for functional and dynamic imaging datasets acquired with MR including Diffusion Weighted Imaging (DWI) and Dynamic Susceptibility Contrast (DSC), which is the term used in the Brainomix 360 e-MRI software for perfusion-weighted imaging technique. The DWI capabilities are for visualization of local water diffusion properties from the analysis of diffusion-weighted MR data. The DSC capabilities are for the characterization of perfusion parameters in the image following the injection of a contrast bolus, and visualization of these parameters.

e-MRI provides a wide range of basic image viewing, processing and manipulation functions, through multiple output formats. The Brainomix 360 platform has been designed to connect with other DICOM-compliant devices. This functionality enables the transfer of MRI scans from a Picture Archiving and Communication System (PACS) to Brainomix 360 e-MRI software for processing.

Technological Characteristics

Brainomix 360 e-MRI is a standalone software application designed to receive MRI 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-MRI software may be used as a standalone 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 MRI scan image storage and transmission, which is used for transmitting MRI scans) may be used, there are two main groups of devices that e-MRI is intended to interact with:

- MRI scanner workstation software
- PACS systems

The software uses image and signal processing software techniques to process a brain perfusion scan captured by a standard MRI scanner. The software applies pre-processing, motion correction, filtering, AIF (Arterial Input Function) / VOF (Venous Output Function) detection, and deconvolution algorithms to process the scans and create an output report and processed images for review.

If a DWI scan is provided, the e-MRI module applies pre-processing, registration, filtering, and computation of an ADC (Apparent Diffusion Coefficient) map, together with the region of restricted diffusion, from the analysis of diffusion-weighted MR data.

Performance Testing Summary

Brainomix 360 e-MRI 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-MRI 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 Brainomix 360 e-MRI met all design requirements and specifications.

Substantial Equivalence

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

Characteristic/ Parameter	**RAPID (K121447) – Predicate Device**	**Brainomix 360 e-MRI – 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-MRI 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-MRI provides both viewing and analysis capabilities for imaging datasets acquired with MRI including Perfusion Weighted Imaging (PWI) and Diffusion Weighted Imaging (DWI). The DWI MRI analysis capabilities are used to visualize local water diffusion properties from the analysis of diffusion-weighted MRI data. The MRI PWI 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 CT capabilities.
Environment of Use	Clinical/Hospital environment	Same
Primary Users	Trained professionals - including but not limited to physicians and medical technicians	Same

PACS Functionality		
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	Magnetic Resonance Image (MRI) Computed Tomography (CT)	Same None
CT	CT Perfusion (CTP)	None
MRI	Diffusion Weighted Image (DWI) Perfusion Weighted Image (PWI)	Same
Computed Parameter Maps		
Perfusion CT and Perfusion MRI	Cerebral blood flow (CBF)	Same
	Cerebral blood volume (CBV)	Same
	Mean Transit Time (MTT)	Same
	Tissue residue function time to peak (Tmax)	Same
		Time to Peak (TTP)
		Perfusion CT: None
Diffusion MRI	Apparent Diffusion Coefficient (ADC)	Same
	Trace of diffusion tensor (Trace)	Same
	Isotropic DWI (isoDWI)	Same
	Fractional Anisotropy (FA) and Color FA	None
Measurement Tools		
MRI and CT Tools	Arterial input function (AIF)/ Venous output function (VOF)	Same
	Time-course	Same
	Motion Correction	Same
	Mask	Same
	Volumetry analysis	Region of Interest (ROI) and Volumetry
	Volumetric comparison between regions *(Mismatch volume/ratio, relative mismatch, hypoperfusion intensity ratio)*	Same
	Export perfusion and diffusion files to PACS and DICOM file systems	Same
	Acquire, transmit, process, and store medical images	Same
		CT Measurement Tools: None

Where the proposed device and the predicate differ in technological characteristics, is that Brainomix 360 e-MRI offers a sub-set of the indications for use and functionality of the predicate device. Where the predicate offers visualisation and analysis capabilities for CT perfusion data, the proposed device does not and therefore the risks associated with this type of analysis capability for CT perfusion data are not applicable to the proposed device.

Conclusion

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

In conclusion, the predicate device has the same technological characteristics and intended use as Brainomix 360 e-MRI. Brainomix 360 e-MRI 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-MRI is safe and effective for use as intended and described in its indications for use.