Brainomix Limited
℅ Gwilym Owen
Head of Quality and Regulatory
Suites 11-14 Suffolk House, 263 Banbury Road
Oxford, Oxfordshire OX2 7HN
UNITED KINGDOM

May 28, 2020

Re: K192692
Trade/Device Name: Brainomix 360º e-CTA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 30, 2020
Received: May 7, 2020

Dear Gwilym Owen:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192692

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K192692

510(K) Summary of Safety and Effectiveness

Date of summary:	30th April 2020
Submitter's name:	Brainomix Limited
Submitter's address:	Brainomix Limited, Suites 11-14 Suffolk House, 263 Banbury road, Oxford. OX2 7HN. United Kingdom
Submitter's contact:	Gwilym Owen
Telephone number:	+44 (0)1865 582730
Device Proprietary Name:	Brainomix 360° e-CTA
Device Common Name(s):	PACS - Medical Imaging Software
Classification Name:	Class II: Picture Archiving and Communications System (892.2050) Product Code: LLZ

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

Predicate Devices

510(k) Number	Trade Name	Manufacturer
K172477	**iSchemaView RAPID**	**iSchemaView Inc**

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.

Device Description and Technological Characteristics

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.

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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 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 through 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.

Substantial Equivalence Discussion

Brainomix 360° e-CTA 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-CTA and the predicate device have substantially similar intended use as both perform image processing of CTA data to visualize large cerebral vessels and analyze hemispheric difference via contralateral comparison. Both devices can quantify the presence of the contrast agent within the brain and indicate the difference (ratio) in contrast-agent concentration between the hemispheres.

The primary difference between the proposed device and the predicate device is that Brainomix 360° e-CTA offers a sub-set of the indications for use and functionality of the predicate device.

Where the predicate offers visualisation and analysis capabilities for MRI and CTP data, the proposed device does not and therefore the risks associated with this type of analysis capability for MRI and CTP data are not applicable to the proposed device.

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Brainomix 360° e-CTA includes similar CTA processing features and technological characteristics as compared to the 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.

We therefore conclude that the the proposed device is substantially equivalent to the predicate device.

Characteristic/Parameter	Brainomix 360° e-CTA – Proposed Device	iSchemaView RAPID - Predicate Device (K172477)
Product Code	LLZ	LLZ
Regulation	21 CFR 892.2050	21 CFR 892.2050
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.	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 images. Data and images are acquired through DICOM compliant imaging devices. The iSchemaView RAPID provides both viewing and analysis capabilities for functional and dynamic imaging datasets acquired with CT Perfusion (CT-P), CT Angiography (CTA), and MRI including a Diffusion Weighted MRI (DWI) Module and a Dynamic Analysis Module (dynamic contrast-enhanced imaging data for MRI and CT).

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Characteristic/Parameter	Brainomix 360° e-CTA – Proposed Device	iSchemaView RAPID - Predicate Device (K172477)
		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.
Environment of use	Clinical/Hospital environment	Clinical/Hospital environment
Energy used and/or delivered	None – software only application. The software application does not deliver or depend on energy delivered to or from patients	None – software only application. The software application does not deliver or depend on energy delivered to or from patients
Human Factors	Designed to be used by trained clinicians	Designed to be used by trained clinicians
Design: Supported Modalities for image processing and visualization	CTA	CT, MRI, CTA, CTP
Design: PACS functionality	View process and analyze medical images. performs standard PACS functions with respect to querying and listing	same
Design: DICOM compliance	Yes	Yes
Design: Computer Platform	Standard off-the-shelf server or virtual server	same
Design: Data acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	same
Acquisition and modalities features: MRI	No	Diffusion Weighted Image (DWI) Dynamic Analysis tissue flow (perfusion) and tissue blood volume
Acquisition and modalities features: CTP	No	CTP cerebral blood flow and blood volume

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Characteristic/Parameter	Brainomix 360° e-CTA – Proposed Device	iSchemaView RAPID - Predicate Device (K172477)
Acquisition and modalities features: CTA	CTA large vessel density analysis	CTA large vessel density analysis
Additional tools	Arterial input function (AIF)Venous output function (VOF) – CTA	Arterial input function (AIF)Venous output function (VOF) - MRI
Functional overview	Brainomix 360° e-CTA is a software package that provides for the study of changes of tissue in digital images captured by CT. Brainomix 360° e-CTA provides viewing and quantification for CTA images.	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
Biocompatibility	N/A – Software only device	same
Sterility	N/A – Software only device	same
Electrical Safety	N/A – Software only device	same
Mechanical Safety	N/A – Software only device	same
Chemical Safety	N/A – Software only device	same
Thermal Safety	N/A – Software only device	same
Radiation Safety	N/A – Software only device	same

Testing

Brainomix 360° e-CTA is tested against its user needs and intended use by the successful execution of planned software verification and validation testing included in this submission. Algorithm validation testing has additionally been performed using phantom data with known properties.

The results of software verification and validation and algorithmic testing demonstrate that Brainomix 360° e-CTA has met all design requirements and specifications associated with the intended use of the software.

Design, risk management, verification and Validation for Brainomix 360° e-CTA has been carried out in compliance with the requirements of CFR 21 Part 820 and in adherence to the DICOM standard.

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Performance Data

No clinical testing or non-clinical bench performance testing has been carried out, submitted or referenced for this submission. As Brainomix 360° e-CTA is a stand-alone software device, testing for Brainomix 360° e-CTA is captured within software and algorithm verification and validation.

Conclusion

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