Yukun (Beijing) Technology Co., Ltd.
℅ Wang Qi
Regulatory Affairs Manager
Room 313/315, Building 3, No.11 Chuangxin Road, Science Park
Beijing, Beijing 102200
CHINA

April 13, 2023

Re: K213986
Trade/Device Name: CerebralGo Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: March 12, 2023
Received: March 13, 2023

Dear Wang Qi:

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 Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: 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)*
K213986

Device Name
CerebralGo Plus

Indications for Use *(Describe)*
CerebralGo Plus 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 and can be used for image viewing and processing. Data and images are acquired through DICOM compliant imaging devices.

CerebralGo Plus provides viewing and processing capabilities for imaging datasets acquired with adult's CTA (CT Angiography).

CerebralGo Plus is not intended for primary 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

A. SUBMITTER

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Date Summary Prepared: Mar. 21, 2023

B. DEVICE

Trade or Proprietary Name:	CerebralGo Plus
Version:	1.0
Common Name:	Picture Archiving and Communications System
Regulation Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Regulatory Class:	Class II
Product Code:	QIH, LLZ

C. LEGALLY MARKETED PREDICATE DEVICE

Table 1 Predicate device information

510(k) Number	Product Code	Trade Name	Manufacturer
K192692	LLZ	Brainomix 360° e-CTA	Brainomix Limited

This predicate device has not been subject to a design-related recall.

There are no reference devices in this submission.

D. DEVICE DESCRIPTION

CerebralGo Plus is a medical image management and 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 and can be used for image viewing, and processing images of DICOM compliant CTA imaging which, when interpreted by a trained clinician, may yield information useful in clinical decision making.

CerebralGo Plus system provides a wide range of basic image viewing, processing, and manipulation functions, through multiple output formats. The software is used to visualize large vessels from head and neck CTA *imaging*.

CerebralGo Plus can connect with other DICOM-compliant devices (e.g., Picture Archiving and Communication System (PACS), Workstations, CT Scanners) to receive CTA scans. After 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 contained and accessed within a hospital network and firewall.

Algorithm training of *CerebralGo Plus* has been conducted on images collected from China as training dataset. Algorithm verification has been conducted on US images.

E. INDICATIONS FOR USE

The proposed indications for use for *CerebralGo Plus* are as follows:

CerebralGo Plus 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 and can be used for image viewing, and processing. Data and images are acquired through DICOM compliant imaging devices.

CerebralGo Plus provides viewing and processing capabilities for imaging datasets acquired with adult's CTA (CT Angiography).

CerebralGo Plus is not intended for primary diagnostic use.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological design features of *CerebralGo Plus* have been compared to the predicate in intended use, indications for use, design, function, and technology and it is demonstrated that they are substantially equivalent.

Table 2 Technological Characteristics Comparison Table

Characteristics	**Predicate Device**	**Subject Device**
	Brainomix 360° e-CTA (K192692)	**CerebralGo Plus (K213986)**
	Brainomix Limited	Yukun (Beijing) Technology Co., Ltd
Regulatory Class	Class II	Class II
Product Code	LLZ	QIH, LLZ
Regulation	21 CFR 892.2050	21 CFR 892.2050

Device Description	*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.	*CerebralGo Plus* is a software package that provides for the visualization digital images capture by CTA.
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.	*CerebralGo Plus* 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 and can be used for image viewing and processing. Data and images are acquired through DICOM compliant imaging devices. *CerebralGo Plus* provides viewing and processing capabilities for imaging datasets acquired with adult's CTA (CT Angiography). *CerebralGo Plus* is not intended for primary diagnostic use.
Environment of Use	Clinical/Hospital Environment	Clinical/Hospital Environment
Energy used an/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
End User	Trained clinicians	Trained clinicians

Supported Modalities for image processing and visualization	CTA	CTA
PACS Functionality	View process and analyze medical images. Performs standard PACS functions with respect to querying and listing	View process and analyze medical images. Performs standard PACS functions with respect to querying and listing
DICOM Compliance	Yes	Yes
Computer Platform	Standard Physical and Virtual off-the shelf Server	Standard off-the shelf server
Data Acquisition	Acquires medical image data from DICOM compliant imaging devices and modalities	Acquires medical image data from DICOM compliant imaging devices and modalities
CTA modality	CTA large vessel	CTA large vessel
Performance Data	Stand-alone software performance testing	Stand-alone software performance testing

G. PERFORMANCE DATA

The results of software performance testing demonstrate that *CerebralGo Plus* has met all design requirements and specifications associated with the intended use of the software. All testing has been carried out in compliance with the requirements of 21 CFR 820 and in adherence to the DICOM standard.

Regarding the validation of the algorithm, the test data was used independently from training dataset.

The algorithm testing of CerebralGo Plus has been performed using 141 images collected from US, which covered different gender, age, ethnicity, equipment and CT protocol used to collect images. The information of demographic and equipment distribution was as follows:

Demographic information		Quantity
Gender	Male	68
	Female	73
Age	＜40	6
	40~70	58
	＞70	54

	Unknown	23
Ethnicity	Black or African American	1
	Hispanic/Latino	2
	Non-Hispanic/Latino	82
	White	5
	Unknown	51

Equipment information		Quantity
Equipment	GE	4
	Siemens	6
	Philips	101
	Toshiba	30

The reference standard of 141 images was created by 3 radiologists from US. When the two radiologists conflicted, the third radiologist would arbitrate and generate the reference standard. The results output by algorithm were compared with the reference standard, the value of Dice coefficient was 0.942, the value of 95% Hausdorff Distance was 3.692. The subgroups analysis was conducted based on scanning equipment, gender and age, and the results were shown in the table below:

Parameter		Dice	HD95
Equipment	TOSHIBA	0.936	3.979
	Philips	0.945	3.494
	SIEMENS	0.942	1.328
	GE	0.924	10.098
Gender	Female	0.941	3.702
	Male	0.944	3.682
Age	<40	0.955	1.000
	40-70	0.946	2.426

	>=70	0.940	4.846

Clinical Information

Not applicable; determination of substantial equivalence is not based on assessment of clinical performance data.

H. CONCLUSION

Based upon the information provided in this 510(k) submission, it has been determined that the subject device is substantially equivalent to the predicate device in regards to indications for use, intended use, design, technology, and performance.