June 1, 2022

ArteryFlow Technology Co., Ltd.
Jianping Xiang, Ph.D.
General Manager
459 Qianmo Road, Suite C1-501, Binjiang District,
310051 Hangzhou City, Zhejiang Province,
China

Re: K213838
Trade/Device Name: AneuGuide
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: PZO
Dated: April 25, 2022
Received: May 2, 2022

Dear Dr. Xiang:

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,

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
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)*
K213838

Device Name
AneuGuide

Indications for Use *(Describe)*
AneuGuide enables visualization of intracranial vessels for preoperational planning and sizing for neurovascular interventions. AneuGuide also allows for the ability to computationally model the placement of neurointerventional devices. General functionalities are provided such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of X-ray based images for 2D review and 3D reconstruction
- Placing and sizing tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

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.

K213838: 510(k) Summary

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

1. Submitter's Information

Submitter: ArteryFlow Technology Co., Ltd.

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Primary correspondent: Jianping Xiang, PhD, General Manager

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Secondary correspondent: Ashley Fu, RA Specialist

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Date of preparation: April 25, 2022

2. Device Information

Trade/ Device Name: AneuGuide

Common Name: Radiological Image Processing Software

Regulatory Class: Class II

Regulation Description: Medical Image Management and Processing System, Software for Visualization of Vascular Anatomy and Intravascular Devices

Regulation number: 892.2050

Classification Product Code: PZO

3. Predicate Device Information

Manufacturer: Sim&Cure

Device Name: Sim&Size

Regulatory Class: Class II

Regulation Number: 892.2050

Classification Product Code: PZO

510(k) number: K202322

4. Device Description

The AneuGuide software is a medical device intended to provide a 3D view of the final placement of implants. It uses an image of the patient produced by 3D rotational angiography. It offers clinicians the possibility of computationally modeling the flow diverters (FD) in the artery to be treated through endovascular surgery.

AneuGuide is intended to import DICOM images and to provide a 3D reconstruction of the vascular tree in the surgical area. Also, it allows to pre-operationally estimate the size of flow diverter devices.

AneuGuide is composed of the following analysis workflows: image loading, selection of the volume of interest (VOI), segmentation threshold adjustment, reconstruction, selection of the region of interest (ROI), selection of the vessel inlet, generation of centerline, initializing the flow diverter, and sizing the flow diverter.

The flow diverter supported by the software is the Pipeline Flex Embolization Device (Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, PMA: P100018/S015), which is an FDA-approved neurointerventional device. AneuGuide software has a “moderate” level of concern. It is intended only for preoperational planning. It is not intended for diagnosis.

5. Intended Use / Indication for Use

AneuGuide enables visualization of intracranial vessels for preoperational planning and sizing for neurovascular interventions. AneuGuide also allows for the ability to computationally model the placement of neurointerventional devices.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Automatic centerline detection
- Visualization of X-ray based images for 2D review and 3D reconstruction
- Placing and sizing tools
- Reporting tools

Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider’s judgment and analysis of the patient’s condition.

6. Comparison of Technological Characteristics

A comparison of the technological characteristics of the predicate and subject devices is provided in the table below.

Table 1. General Comparison

Characteristic	**Predicate device** **Sim&Size** **K202322**	**Subject device** **AneuGuide** **K213838**
Indications for Use	Sim&Size enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. Sim&Size also allows for the ability to computationally model the placement of neurointerventional devices. General functionalities are provided such as: ● Segmentation of neurovascular structures ● Automatic centerline detection ● Visualization of X-Ray based images for 2D review and 3D reconstruction ● Placing and sizing tools ● Reporting tools Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.	AneuGuide enables visualization of intracranial vessels for preoperational planning and sizing for neurovascular interventions. AneuGuide also allows for the ability to computationally model the placement of neurointerventional devices. General functionalities are provided such as: ● Segmentation of neurovascular structures ● Automatic centerline detection ● Visualization of X-Ray based images for 2D review and 3D reconstruction ● Placing and sizing tools ● Reporting tools Information provided by the software is not intended in any way to eliminate, replace or substitute for, in whole or in part, the healthcare provider’s judgment and analysis of the patient’s condition.
Interface to Image Sources	DICOM Image Data	DICOM Image Data
Import of Patient Data	Manual through keyboard/mouse, automatic import with image file, study creation list	Same
List Image Functionality	Deleting, anonymizing, search	Same
Image Processing	Segmentation by user with clinician review and comment	Same

3D Assessment	3D assessment based on 3D model of the simulated device inside the vessels	Same
Image and 3D Display	Orthogonal, color volume rendering, 2D slide review, active presets, 3D view of assemblies of devices	Same
DICOM Support	Read DICOM images from 3D rotational angiography stations	Same
Computer OS Compatibility	MS Windows and Mac OS	Mac OS
Data Interchange/Transfer Method	Transfer by physical media, i.e. USB memory stick and Scanner Workstations (retrieve function only)	Transfer by physical media, i.e. USB memory stick
Output File Format	Local openGL rendering	Local VTK rendering
Preoperational Planning	Yes	Yes
Patient Contact	No	No
Human Intervention for Interpretation of Images	Yes	Yes
Implantable Medical Device (IMD) Database	- Pipeline™ Flex Embolization Device (Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, PMA number P100018/S015) - Woven EndoBridge (WEB) Aneurysm Embolization System (MicroVention, Inc., PMA number P170032) - Surpass Evolve Flow Diverter System (Stryker Neurovascular, P170024/S003).	- Pipeline™ Flex Embolization Device (Micro Therapeutics, Inc. d/b/a ev3 Neurovascular, PMA number P100018/S015)
Fusion correction	Automatic and manual	Manual

7. Performance Data

The following performance data were performed on AneuGuide in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided

as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

The software for this device was considered as a "moderate" level of concern, since prior to mitigation of hazards, a failure of the software device could result in minor injury to a patient.

The following performance tests were conducted:

- Tests of importation of DICOM images.
- Patient management tests.
- Tests of image display and processing.
- Functioning tests for visualization of anatomic reconstruction.
- Report creation and visualization tests.
- Cybersecurity tests.

All tests have passed and demonstrate that the software is designed to meet the software requirements and functions as intended.

Performance Testing – Bench

The computational modeling of the Pipeline Flex Embolization Device was tested through two tests:

- Using silicone phantoms representative of patients presenting with intracranial aneurysms to compare the *in vitro* and virtual placement of the flow diverter.
- Validation study of the AneuGuide performance comparing the simulated deployed length of the Pipeline Flex Embolization Device with its implanted length in patients with intracranial aneurysms.

These validation tests allow to evaluate the performance (error) of the AneuGuide in calculating the deployed length of the Pipeline Flex Embolization Device after implantation.

8. Conclusion

The AneuGuide has the same intended use and indications for use as the predicate device Sim&Size.

Verification and validation testing have produced results consistent with design input requirements. During the development, potential hazards were controlled by the risk management report, including risk analysis, risk mitigation, verification and validation.

ArteryFlow Technology concludes that the AneuGuide, intended for preoperational planning but not for diagnosis, is as safe and effective as the predicate device. The differences between the subject and predicate devices do not raise new questions of safety and effectiveness.