December 28, 2023

MENTICE SPAIN S.L.
Héctor Fernández
Responsible Technician and PRRC
Rambla de Catalunya 53, 4-H
Barcelona, 08007
Spain

Re: K230006
Trade/Device Name: ANKYRAS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: PZO
Dated: November 27, 2023
Received: November 29, 2023

Dear Héctor Fernández:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230006

Device Name
ANKYRAS

Indications for Use *(Describe)*
ANKYRAS enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery.

ANKYRAS also allows for the ability to computationally model the placement of neurointerventional braided endovascular devices.

General functionalities are provided such as:
• Segmentation of neurovascular structures
• Semi-automatic centerline generation from segmented blood vessels
• Visualization of X-ray based images
• Placing and sizing tools for braided endovascular devices
• Save user data

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.

510(k) Summary K230006

This 510(k) Summary is being submitted in accordance with the requirements detailed in 21 CFR 807.92.

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Date Prepared:	December 26, 2023
DEVICE TRADE NAME:	ANKYRAS
COMMON NAME:	Software for Visualization of Vascular Anatomy and Intravascular Devices
DEVICE CLASS:	Class II
REGULATION NUMBER:	892.2050
REGULATION NAME:	Medical Image Management and Processing System
PRODUCT CODE:	PZO
PREDICATE DEVICE:	Sim&Size (Sim&Cure; K190049)

DEVICE DESCRIPTION

ANKYRAS is a software as a medical device that allows the simulation of neurointerventional braided endovascular devices, such as flow diverters (FDs), and is intended to be used by physicians trained in medical procedures involving percutaneous and intravascular interventions for preoperational planning and sizing for neurovascular interventions and surgery. The software includes a database with FDA-approved FDs: P100018/S015 - Pipeline Flex Embolization Device, Medtronic, Inc.; P170024/S003 - Surpass Evolve Flow Diverter System, Stryker Neurovascular; P180027 - Flow Re-Direction Endoluminal Device (FRED®) System, MicroVention, Inc.

ANKYRAS is intended to be used with 3D Rotational Angiography (3DRA) images. From the 3DRA images the user can extract the target artery vessel model using ANKYRAS segmentation functionality for further analysis and computational modeling (simulation) of the listed above FDs:

- First, using the vessel model and proximal and distal points selected by the user, ANKYRAS calculates the vessel centerline and displays cross-sectional dimensional information in an interactive chart.
- Second, using the vessel model, centerline, and dimensions, ANKYRAS simulates the FD devices selected by the user. The user can compare the results between different simulated FD devices and/or different positions including simulated device length, expansion along the centerline, and local porosity.

The 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.

ANKYRAS software is intended to be installed on a computer with Windows operating systems.

INTENDED USE/INDICATIONS FOR USE

ANKYRAS enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery.

ANKYRAS also allows for the ability to computationally model the placement of neurointerventional braided endovascular devices.

General functionalities are provided such as:

- Segmentation of neurovascular structures
- Semi-automatic centerline generation from segmented blood vessels
- Visualization of X-ray based images
- Placing and sizing tools for braided endovascular devices
- Save user data

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Characteristics and features of ANKYRAS software have been compared to the characteristics and features of the predicate device Sim&Size.

Table 1: Summary of comparison of characteristics and features – proposed and predicate devices.

Characteristic	Proposed Device ANKYRAS (MENTICE SPAIN S.L.)	Predicate Device Sim&Size (Sim&Cure)	Comments
Regulatory Information			
Regulatory Class	Class II	Class II	Same
Classification name	Software for Visualization of Vascular Anatomy and Intravascular Devices	Software for Visualization of Vascular Anatomy and Intravascular Devices	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Product Code	PZO	PZO	Same
510(k) Number	K230006	K190049	-
Indications for Use	ANKYRAS enables visualization of cerebral blood vessels for preoperational planning and sizing for neurovascular interventions and surgery. ANKYRAS also allows for the ability to computationally model the placement of neurointerventional braided endovascular devices. General functionalities are provided such as: ● Segmentation of neurovascular structures ● Semi-automatic centerline generation from segmented blood vessels ● Visualization of X-ray based images ● Placing and sizing tools for	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 and deployment 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	Similar

Characteristic	Proposed Device ANKYRAS (MENTICE SPAIN S.L.)	Predicate Device Sim&Size (Sim&Cure)	Comments
	braided endovascular devices • Save user data 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.	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.	
Technical Characteristics			
Computer OS Compatibility	MS Windows	MS Windows and Mac OS	ANKYRAS is compatible with MS Windows only
Interface to Image Sources	DICOM Image Data	DICOM Image Data	Same
Import of Patient Data	Manual through keyboard/mouse, automatic import with image file or morphological mesh, study creation list.	Manual through keyboard/mouse, automatic import with image file, study creation list.	Similar
Image Processing	Segmentation and use by physician.	Segmentation and use by physician.	Same
3D Assessment	3D assessment based on 3D model of the simulated endovascular braided device inside the vessels.	3D assessment based on 3D model of the simulated neurointerventional device inside the vessels.	Same
Image and 3D Display	Orthogonal, color volume rendering, 2D slide review, active presets, 3D view of assemblies of endovascular braided devices.	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 (3DRA).	DICOM compliance for CT and enhanced CT, read DICOM images from 3D rotational	Similar

Characteristic	Proposed Device ANKYRAS (MENTICE SPAIN S.L.)	Predicate Device Sim&Size (Sim&Cure)	Comments
		angiography stations.	
Data Interchange / Transfer Method	Transfer by physical media; i.e. USB memory stick.	Transfer by physical media; i.e. USB memory stick.	Same
Output File Format	Local openGL rendering	Local openGL rendering	Same
Preoperational Planning	Yes	Yes	Same
Patient Contact	No	No	Same
Human Intervention for Interpretation of Images	Yes	Yes	Same

Performance Testing

The following verification and validation tests were performed on ANKYRAS in support of the substantial equivalence to the predicate.

Software verification and validation tests were conducted and documentation was provided as recommended by FDA, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

The following tests were conducted:

- Tests of importation of DICOM images.
- Patient list management tests.
- Tests of image display and processing.
- Functioning tests for visualization of anatomic reconstruction.
- Save user data and visualization tests.
- Cybersecurity tests.

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

The computational modeling and prediction accuracy/error of deployed length, expansion, and porosity of the selected flow diverters by ANKYRAS was evaluated through the following two tests:

- Using physical phantoms representative of anatomy of patients presenting with intracranial aneurysms to compare the *in vitro* placement and measurement of flow diverters to virtual flow diverter placement and outputs by ANKYRAS.
- Using retrospective clinical images to compare the placement and measurements of actual flow diverters to virtual flow diverter placement and outputs by ANKYRAS.

Conclusions

ANKYRAS (subject device) and Sim&Size (predicate device) have similar indications for use and similar technological characteristics. The differences between the technological characteristics do not raise different questions of safety and effectiveness. The verification, validation, and performance testing of ANKYRAS demonstrate that the device performs as intended.

MENTICE SPAIN S.L. concludes that the ANKYRAS (subject device) is substantially equivalent to the Sim&Size (predicate device).