May 6, 2025

Mentice Spain S.L.
Héctor Fernández
Technical Manager
Rambla de Catalunya, 53-55, 4-H
Barcelona, 08007
Spain

Re: K250160
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: April 7, 2025
Received: April 7, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Sara S. Thompson -S

Sara S. Thompson, D.V.M.
Assistant Director
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Neurointerventional, and
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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)*
K250160

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
• Download** and share simulation***
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 is available in different platforms: Standalone, WebGL and Mobile App.
*Available for Standalone and WebGL platforms
**Available for WebGL platform
***Available for WebGL and Mobile App platforms

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 – K250160

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

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Date Prepared:	May 5, 2025
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:	ANKYRAS (Mentice Spain S.L.; K230006)

Device Description/ Intended Use

ANKYRAS is a medical device software application that allows the simulation of neurointerventional endovascular braided 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 braided endovascular FD devices: P100018/S015 - Pipeline Flex Embolization Device and P100018/S026 - Pipeline Flex Embolization Device with Shield Technology, Medtronic, Inc.; P170024/S003 - Surpass Evolve Flow Diverter System, Stryker Neurovascular; P180027 - Flow Re-Direction Endoluminal Device (FRED®) System and P180027/S002 - Flow Re-Direction Endoluminal Device (FRED®) X System, MicroVention, Inc. This database can be customized (among FDA cleared braided endovascular devices previously mentioned) according to the user's institution or needs.

ANKYRAS is intended to be used with 3D Rotational Angiography (3DRA) images or with VTK surface models from the target artery. From the 3DRA images, the user can extract the target artery vessel model using ANKYRAS segmentation functionality for further anatomical 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 morphology measurements, ANKYRAS simulates the FD devices selected by the user. The user can compare the results between different simulated FD devices and/or different FD 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 user with a user license and can be installed on a computer with Windows operating systems or installed on an iOS/Android mobile device.

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
- Download** and share simulation***

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 is available in different platforms: Standalone, WebGL and Mobile App.

*Available for Standalone and WebGL platforms

**Available for WebGL platform

***Available for WebGL and Mobile App platforms

Comparison of Intended Use and Technological Characteristics

Characteristics and features of ANKYRAS software have been compared to the features of the predicate device, Ankyras (K230006).

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

Characteristic	Subject Device ANKYRAS v4.0-US (Mentice Spain S.L.)	Predicate Device ANKYRAS v3.0-US (Mentice Spain S.L.)	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	K250160	K230006	-
Intended Use and Indications for Use			
Intended Use	Visualization and measurement of blood vessels and intravascular devices for preoperational planning.	Visualization and measurement of blood vessels and intravascular devices for preoperational planning.	Same
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 • Download** and share	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	Similar to predicate device

Characteristic	Subject Device ANKYRAS v4.0-US (Mentice Spain S.L.)	Predicate Device ANKYRAS v3.0-US (Mentice Spain S.L.)	Comments
	simulation*** 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 is available in different platforms: Standalone, WebGL and Mobile App. *Available for Standalone and WebGL platforms **Available for WebGL platform ***Available for WebGL and Mobile App platforms	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			
Software Version	V4.0 – US	V3.0 – US	
Mode of action	Standalone + WebGL + MobileApp Software Solution	Standalone Software Solution	Similar to predicate device
Computer OS compatibility	MS Windows + Android + iOS	MS Windows	Similar to predicate device
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. Accepts image import from Hospital Workstations	Manual through keyboard/mouse, automatic import with image file or morphological mesh, study creation list.	Similar to predicate device
Target Population	Patients with intracranial aneurysms	Patients with intracranial aneurysms	Same
Image processing	Segmentation by user with clinician review and comment	Segmentation by user with clinician review and comment	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 endovascular braided 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 endovascular braided devices	Same
DICOM Support	Read DICOM images from 3D rotational angiography (3DRA).	Read DICOM images from 3D rotational angiography (3DRA).	Same
Measurements outputs	Length, expansion and porosity of the device simulated. Diameter to perimeter, inscribed diameter and circularity of the vessel.	Length, expansion and porosity of the device simulated. Diameter to perimeter, inscribed diameter and area of the vessel.	Similar to predicate device
Data Interchange / Transfer Method	Transfer by physical media, i.e. USB memory stick	Transfer by physical media, i.e. USB memory stick	Same

Characteristic	Subject Device ANKYRAS v4.0-US (Mentice Spain S.L.)	Predicate Device ANKYRAS v3.0-US (Mentice Spain S.L.)	Comments
Output File Format	Local openGL rendering + share simulation + download simulation	Local openGL rendering	Similar to predicate device
Preoperational Planning	Yes	Yes	Same
Patient Contact	No	No	Same
Human Intervention for Interpretation of Images	Yes	Yes	Same
FD Database	P100018/S015: Medtronic Pipeline Flex Embolization Device P100018/S026: Medtronic Pipeline Flex Embolization Device with Shield Technology P170024/S003: Stryker Surpass Evolve Flow Diverter System P180027: Microvention Flow Re-Direction Endoluminal Device (FRED®) System P180027/S002: Microvention Flow Re-Direction Endoluminal Device (FRED®) X System	P100018/S015: Medtronic Pipeline Flex Embolization Device P100018/S026: Medtronic Pipeline Flex Embolization Device with Shield Technology P170024/S003: Stryker Surpass Evolve Flow Diverter System P180027: Microvention Flow Re-Direction Endoluminal Device (FRED®) System P180027/S002: Microvention Flow Re-Direction Endoluminal Device (FRED®) X System	Same

Performance Testing

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

Software Verification Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's "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.
- Report creation and visualization tests.
- Cybersecurity tests.

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

Software Validation Testing

The computational modeling and prediction accuracy/error deployed length, expansion, and porosity of the selected flow diverters 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.

The criteria used in software validation testing to validate ANKYRAS is based on the accuracy -defined by the difference in % between the estimation and the gold standard- of each ANKYRAS parameter:

- The accuracy of ANKYRAS length estimations against the true length of FD after intervention has to be equal or better than the accuracy of the length calculated from the FD manufacturer specifications, considered as the reference length.
- The accuracy of ANKYRAS expansion estimations against the true expansion of FD after intervention has to be equal or better than the accuracy of the expansion calculated from the mean vessel diameter, considered as the reference expansion.
- The accuracy of ANKYRAS porosity estimations against the true porosity of FD after intervention must be equal or better than:
    - The accuracy of the nominal porosity obtained from the nominal FD diameter and the FD manufacturer specifications, and
    - The accuracy of the reference porosity obtained from the patient's mean vessel diameter and the FD manufacturer specifications.

These validation tests were used to evaluate the performance (error) of the ANKYRAS in calculating the deployed length, expansion, and porosity of the selected flow diverters after implantation.

Cybersecurity Testing

Cybersecurity testing was performed and included penetration testing, cybersecurity requirements testing, threat mitigation testing, and vulnerability testing. Cybersecurity documentation was provided as recommended in FDA Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Conclusions

ANKYRAS software v4.0-US (subject device) and ANKYRAS software v3.0-US (predicate device) have similar indications for use and similar technological characteristics. The differences in technological characteristics between the devices do not raise different questions of safety and effectiveness. The verification, validation, and performance testing demonstrated that the device performs as intended.

Mentice Spain SL concludes that the ANKYRAS software v4.0-US (subject device) is substantially equivalent to the ANKYRAS software v3.0-US (predicate device).