February 27, 2020

Medos International SARL
Michael Liao
Senior Regulatory Affairs Program Lead
Chemin-Blanc 38
Le Locle, 2400, Switzerland

Re: K192804
Trade/Device Name: CEREBASE DA Guide Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: January 29, 2020
Received: January 30, 2020

Dear Michael Liao:

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,

Xiaolin Zheng, Ph.D., M.S.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192804

Device Name
CEREBASE DA Guide Sheath

Indications for Use *(Describe)*
The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature.

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.

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I. Submitter

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Date Prepared: January 28, 2020

II. Device

Table 1. Device	
Device Proprietary Name	CEREBASE DA Guide Sheath
Common or Usual Name	Catheter, Percutaneous, Neurovasculature
Classification Name	Catheter, Percutaneous, Class II, 21 C.F.R. 870.1250
Regulatory Classification	II
Product Code	QJP

III. Predicate Device

The predicate device is listed below in Table 2.

Table 2. Prior 510(k) Clearance			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K111380	07/19/2011	Neuron MAX System	Penumbra, Inc.
K140080	04/24/2014	ENVOY DA Guiding Catheter	Medos International SARL
K140307	04/21/2014	ENVOY Guiding Catheter	Codman & Shurtleff, Inc.

IV. Device Description

The CEREBASE DA Guide Sheath is a single lumen, stainless steel braided catheter of variable stiffness with a large non-tapered lumen that facilitates the intravascular passage of interventional devices. The guide sheath is a straight shaped catheter that comes in four lengths; 70 cm, 80 cm, 90 cm, and 95 cm. The lubricious PTFE-lined inner lumen is designed to facilitate delivery of the interventional devices. It has a radiopaque marker band on the distal end and a luer hub at the proximal end. The guide sheath has an outer hydrophilic coating at the distal end that reduces friction during use. A hemostasis valve and a dilator are provided with the CEREBASE DA Guide Sheath within its sterile packaging. The dilator is a single lumen radiopaque catheter with a tapered distal end and a luer hub at the proximal end. The dilator is compatible with the CEREBASE DA Guide Sheath and up to 0.038 inch diagnostic guidewires. The hemostasis valve with side port is an off the shelf component used for flushing and insertion of catheters.

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IV. Device Description, Continued

The CEREBASE DA Guide Sheath's lumen must be flushed and outer body wet with heparinized saline solution prior to use. If using as a primary access sheath with the dilator, the dilator must be soaked and flushed with heparinized saline solution as well prior to use. After being flushed with heparinized saline solution the dilator can then be inserted and advanced until the tapered distal tip is beyond the distal end of the CEREBASE DA Guide Sheath. Then the hemostasis valve is closed around the dilator and primary access can be gained to the vasculature using a standard technique of choice.

V. Indications for Use

The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature.

VI. Comparison of Technological Characteristics with Predicate Device

Table 3 below provides comparison of technological characteristics with the predicate device. Based on design verification and validation testing, the minor differences in characteristics do not raise different questions of safety and effectiveness.

Table 3. Technological Characteristic Comparison

Description	CEREBASE DA Guide Sheath – Subject Device	Neuron MAX (K111380)
Indications	The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature.	The Neuron MAXX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature
Lengths	70 cm 80 cm 90 cm 95cm	-- 80 cm 90 cm --
Shapes	Straight	Straight, MP
Outside Diameter	8F	8F
Inside Diameter	0.090"	0.088"
Tip Length	1 mm	2mm
Hub Material	Polycarbonate (yellow)	Nylon, Polyurethane
Shaft Material	Nylon Segment(s) Pebax (nylon blend) Segment(s) Polyurethane Segment(s)	
Inner Lining	PTFE	PTFE
Outer Coating	Hydrophilic Coating	Hydrophilic Coating
Shaft Braid	304 Stainless Steel	Stainless Steel
Outer Jacket Material Segment	11 outer jacket material segments of different durometer	5 outer jacket material segments of different durometer
Distal Tip Radiopaque Marker	Metal Marker Band	Radiopaque Filler and Metal Marker band
Hemostasis Valve	Yes	Yes
Dilator	Yes	Yes
Dilator Material	Polyethylene	Polyethylene
Packaging	PET/ LDPE Tyvek Pouch Polypropylene Tubing SBS Mounting Card SBS Carton	PET/PE/ Tyvek Pouch HPDE Tubing Mounting Card Carton
Sterilization Method	EtO	EtO
Shelf Life	1 year	3 years

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VII. Non-Clinical Data Performance

The design verification and validation testing activities were conducted on the CEREBASE DA Guide Sheath to ensure that design outputs met design inputs. **Table 4** below provides a description and result of each of these performance tests.

Table 4. Performance Testing

Test	Test Method Summary	Results
Visual Inspection	The purpose of this test was to verify that the test samples meet the visual requirements of ISO 10555-1.	Pass. Samples passed established acceptance criteria.
Catheter Internal Diameter (ID)	The purpose of this test was to verify that the catheter internal diameter meets requirements. The inner diameter of each sample was measured.	Pass. Samples passed established acceptance criteria.
Catheter Outer Diameter (OD)	The purpose of this test was to verify that the catheter outer diameter meets requirements. The outer diameter of each sample was measured.	Pass. Samples passed established acceptance criteria.
Catheter Working Length	The purpose of this test was to ensure the working length meets requirements. The length of the catheter was measured.	Pass. Samples passed established acceptance criteria.
Distal Tip Length	The purpose of this test was to ensure the distance of the distal edge of the marker band to the tip of the catheter meets requirements.	Pass. Samples passed established acceptance criteria.
Hub Luer Taper	The purpose of this test was to verify that the catheter hub luer taper fits standard luer fittings using a taper device.	Pass. Samples passed established acceptance criteria.
Air Leak Test	The purpose of this test was to verify that there are no air leaks into the hub subassembly. The samples were inspected to ensure no air bubbles that may indicate a hub air leak.	Pass. Samples passed established acceptance criteria.
Liquid Leak Test	The purpose of this test was to ensure that the catheter joint strength meets the freedom from leakage requirements (liquid during pressurization) requirements of ISO 10555-1.	Pass. Samples passed established acceptance criteria.
Static Burst	The purpose of this test was to verify the maximum hydrostatic pressure meets requirements of ISO 10555-1.	Pass. Samples passed established acceptance criteria.
Hub Pull Testing	The purpose of this test was to verify that the strength of the catheter hub meets the requirements of ISO 10555-1. A tensile tester measured the tensile strength of the joint.	Pass. Samples passed established acceptance criteria.
Shaft Tensile Strength	The purpose of this test was to verify that the strength of the catheter shaft meets the requirements of ISO 10555-1. A tensile tester measured the tensile strength of the distal section of the catheter shaft.	Pass. Samples passed established acceptance criteria.
Particulate Count	The purpose of this test was to quantify the particulate count generated by simulated use of the test samples.	Pass. Samples passed established acceptance criteria.
Coating Lubricity	The purpose of this test was to measure the lubricity of the coating. The test samples were put through a lubricity tester to measure frictional force.	Pass. Samples passed established acceptance criteria.
Coating Durability	The purpose of this test was to measure the durability of the lubricious coating layer.	Pass. Samples passed established acceptance criteria.
Coating Length	The purpose of this test was to verify that the catheter hydrophilic coating length meets the design requirement.	Pass. Samples passed established acceptance criteria.
Kink Resistance	The purpose of this test was to confirm the catheter met requirement for stability and did not kink during use.	Pass. Samples passed established acceptance criteria.
Delamination of PTFE Liner	The purpose of this test was to verify that the PTFE is appropriately adhered to the inner lumen of the catheter with braid reinforcement.	Pass. Samples passed established acceptance criteria.

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VII. Non-Clinical Data Performance, Continued

Table 4. Performance Testing, Continued

Test	Test Method Summary	Results
Backup Support	The purpose of this test was to measure the stability of the test sample while advancing other interventional devices through its lumen. A wire was pushed through the lumen of each test sample and the force at which catheter support failed was measured.	Pass. Samples passed established acceptance criteria.
Tip Linear Stiffness	The purpose of this test was to evaluate the flexibility of the catheter relative to other devices of similar design.	Pass. Samples passed established acceptance criteria.
Dilator Visual Inspection	The purpose of this test was to verify that the dilator was free of extraneous matter per ISO 11070.	Pass. Samples passed established acceptance criteria.
Dilator Inner Diameter (ID)	The purpose of this test was to verify that the dilator internal diameter meets requirements.	Pass. Samples passed established acceptance criteria.
Dilator Hub Luer Taper	The purpose of this test was to verify that the dilator fits standard luer fittings using a tapered device.	Pass. Samples passed established acceptance criteria.
Insertion Forces	The purpose of this test was to measure the forces required to insert the dilator and catheter into a simulated model.	Pass. Samples passed established acceptance criteria.
Dilator Outer Diameter (OD)	The purpose of this test was to verify that the dilator outer diameter meets requirements.	Pass. Samples passed established acceptance criteria.
Dilator Working Length (WL)	The purpose of this test is to verify the working length of the dilator to ensure compatibility with the catheter.	Pass. Samples passed established acceptance criteria.
Dilator Tensile Strength	The purpose of this test was to verify that the dilator joint strength meets the requirements of ISO 11070.	Pass. Samples passed established acceptance criteria.
Torque (Turns to Failure)	The purpose of this test is to count the number of turns the catheter can withstand without separating.	Pass. Samples passed established acceptance criteria.
Trackability	The purpose of this test is the measure of the force required to advance the catheter through a simulated vascular model.	Pass. Samples passed established acceptance criteria.
In Vitro Modeling and In Vivo Testing	The purpose of In Vitro modeling and In Vivo testing in a porcine model were to ensure that design outputs meet the customer requirements.	Pass. Samples passed established acceptance criteria.

VII. Non-Clinical Data Performance, Continued

Shelf Life

One year accelerated aging was successfully performed on the CEREBASE DA Guide Sheath. Additionally, through review of package integrity testing and previous testing with a sterile pouch made of the same material combination, the sterile pouch is confirmed to have a shelf life of at least one year. The shelf life of the CEREBASE DA Guide Sheath is established as one year.

Packaging Qualification

The CEREBASE DA Guide Sheath was sterilized, packaged and subjected to conditioning and simulation testing for worst case conditions per ISTA 3A: 2018, *Packaged-Products for parcel Delivery System Shipment 70Kg (150 lb) or less*. The samples were used to validate the package integrity of the CEREBASE DA Guide Sheath per EN ISO 11607-1:2009, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*.

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VII. Non-Clinical Data Performance, Continued

The following packaging qualification testing was completed as part of this evaluation:

Table 5. Packaging Qualification	
Test	**Result**
Visual Inspection	PASS
Dye Leak Penetration	PASS
Seal Strength	PASS
Shelf Life	PASS
Biocompatibility	PASS

Performance Testing – Clinical

No clinical studies were required as appropriate verification and validation of the catheter and packaging modifications were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Biocompatibility Testing

The CEREBASE DA Guide Sheath was assessed for biocompatibility in accordance with International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process.*" and FDA Guidance for Industry and FDA Staff: *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* (Issued June 16, 2016). The subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours. The following Biocompatibility Testing was completed as part of this evaluation:

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VII. Non-Clinical Data Performance, Continued

Table 6. Biocompatibility Test Results

Test		Test Summary	Conclusion
CEREBASE DA Guide Sheath			
Cytotoxicity – ISO Elution Method		Test articles exhibited no discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth, resulting in a reactivity grade = 0 per ISO 10993-5.	PASS: Non-cytotoxic
Sensitization – ISO Guinea Pig Maximization Sensitization		No abnormal dermal reactions and no sensitization was observed.	PASS: Non-sensitizing
ISO Intracutaneous Reactivity Study		Injection sites appeared normal and no difference in erythema and edema scores from control.	PASS: Non-irritating
ISO Acute Systemic Toxicity in Mice		Animals appeared clinically normal throughout the study upon observation. No deaths and no significant changes in body weight.	PASS: Non-toxic
USP Rabbit Material-Mediated Pyrogenicity		Out of 3 animals, no single animal showed a total temperature rise of ≥ 0.5 °C, within USP requirements.	PASS: Non-pyrogenic
Hemocompatibility	ASTM Hemolysis	Hemolysis % was not higher than control in samples either in direct contact with the catheter or in samples extracted after contact with the catheter.	PASS: Non-hemolytic
	SC5b-9 Complement Activation Assay	SC5b-9 concentration of test article samples were not statistically higher than both negative control and activated normal human serum (NHS) controls.	PASS: Not a potential activator of the complement system
	In Vivo Thromboresistance Study	Thrombus formation on the catheter was comparable to that on control article in similar animal vasculature.	PASS: Acceptable Thromboresistance
Hemostatic Valve			
Cytotoxicity – ISO Elution Method		Test articles exhibited no discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth, resulting in a reactivity grade = 0 per ISO 10993-5.	PASS: Non-cytotoxic
Sensitization – ISO Guinea Pig Maximization Sensitization		No abnormal dermal reactions and no sensitization was observed.	PASS: Non-sensitizing
Irritation or Intracutaneous Reactivity		Injection sites appeared normal. Mean erythema and edema scores of test articles had differences of <1 from control.	PASS: Non-irritating
ISO Acute Systemic Toxicity in Mice		Animals appeared clinically normal throughout the study upon observation. No deaths and no significant changes in body weight.	PASS: Non-toxic
USP Rabbit Material-Mediated Pyrogenicity		Out of 3 animals, no single animal showed a total temperature rise of ≥ 0.5 °C, within USP requirements.	PASS: Non-pyrogenic
Hemocompatibility: ASTM Hemolysis		Hemolysis % was not higher than control in samples either in direct contact with the catheter or in samples extracted after contact with the valve.	PASS: Non-hemolytic

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VII. Non-Clinical Data Performance, Continued

Table 6. Biocompatibility Test Results, Continued

Test		Test Summary	Conclusion
Dilator			
Cytotoxicity – ISO Elution Method		Test articles exhibited no discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth, resulting in a reactivity grade = 0 per ISO 10993-5.	PASS: Non-cytotoxic
Sensitization – ISO Guinea Pig Maximization Sensitization		No abnormal dermal reactions and no sensitization was observed.	PASS: Non-sensitizing
ISO Intracutaneous Reactivity Study		Injection sites appeared normal. Mean erythema and edema scores of test articles had differences of <1 from control.	PASS: Non-irritating
ISO Acute Systemic Toxicity in Mice		Animals appeared clinically normal throughout the study upon observation. No deaths and no significant changes in body weight.	PASS: Non-toxic
USP Rabbit Material-Mediated Pyrogenicity		Out of 3 animals, no single animal showed a total temperature rise of ≥ 0.5 °C, within USP requirements.	PASS: Non-pyrogenic
Hemocompatibility	ASTM Hemolysis	Hemolysis % was not higher than control in samples either in direct contact with the dilator or in samples extracted after contact with the dilator.	PASS: Non-hemolytic
	SC5b-9 Complement Activation Assay	SC5b-9 concentration of test article samples were not statistically higher than both negative control and activated normal human serum (NHS) controls.	PASS: Not a potential activator of the complement system
	In Vivo Thromboresistance Study	Thrombus formation on the dilator was comparable to that on control article in similar animal vasculature.	PASS: Acceptable Thromboresistance
Packaging			
Cytotoxicity – ISO Elution Method		Test articles exhibited no discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth, resulting in a reactivity grade = 0 per ISO 10993-5.	PASS: Non-cytotoxic

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VII. Non-Clinical Data Performance, Continued

Sterilization

The CEREBASE DA Guide Sheath, as packaged with included accessories, is sterilized using a validated 100% Ethylene Oxide sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1: 2014, *Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices*. The CEREBASE DA Guide Sheath and all accessories meet EO residuals per EN ISO 10993-7: 2009 *Biological evaluation of medical devices. Ethylene oxide sterilization residuals* for a limited contact delivery system – externally communicating. The CEREBASE DA Guide Sheath and all accessories are for single use only.

VIII. Conclusion

Based upon the intended use, design, materials, function, side-by-side in-vitro testing and animal testing, and passing biocompatibility test results, it is concluded that the subject device, CEREBASE DA Guide Sheath is substantially equivalent to the predicate device, Neuron MAX System (K111380, cleared 19 July 2011). The fundamental scientific technology is the same as the predicate device. The differences in verbiage in the Indications for Use statement only limits the locations that the subject device can be used and do not raise any questions regarding the safety and effectiveness of the device. Risk assessment of the CEREBASE DA and verification/validation testing confirmed the device is as safe and effective as the predicate device.