July 20, 2020

Codman & Shurtleff, Inc.
Kirsten Franco, MS, RAC
Associate Director of Regulatory Affairs
325 Paramount Drive
Raynham, MA 02767

Re: K193380
Trade/Device Name: CERENOVUS Large Bore Catheter; CERENOVUS Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 21, 2020
Received: April 22, 2020

Dear Kirsten Franco:

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 (Acting)
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)*
K193380

Device Name
CERENOVUS Large Bore Catheter; CERENOVUS® Aspiration Tubing Set

Indications for Use *(Describe)*

The CERENOVUS Large Bore Catheter, with the CERENOVUS® Aspiration Tubing Set and NOUVAG Vacuson 60 aspiration pump (or equivalent aspiration pump), is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

The CERENOVUS® Aspiration Tubing Set is intended to connect the CERENOVUS Large Bore Catheter to the canister of the NOUVAG Vacuson 60 Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary K193380

Pursuant to the requirements of 21 CFR Section 807.92(c), this 510(k) summary is provided as part of this Premarket Notification containing sufficient details to understand the basis for a determination of substantial equivalence.

Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact

Kirsten Franco
Phone: (484) 868-7991
Email: kfranco5@its.jnj.com

Date Prepared

July 15, 2020

Device Trade or Proprietary Name

CERENOVUS Large Bore Catheter
CERENOVUS® Aspiration Tubing Set

Device Classification

Regulatory Classification: II
Common or Usual Name: Catheter, Thrombus Retriever
Classification Name: Percutaneous Catheter
Regulation Number: 21 CFR 870.1250
Product Code: NRY
Classification Panel: Neurology

Predicate Device

Primary Predicate Device

510(k) Number	Date Cleared	Device Name	Manufacturer
K161064	June 12, 2016	Penumbra System ACE 68 Reperfusion Catheter	Penumbra, Inc.

Reference Predicate Device

510(k) Number	Date Cleared	Device Name	Manufacturer
K191237	Nov 8, 2019	CERENOVUS Large Bore Catheter	Medos International SARL

Device Description

The CERENOVUS Large Bore Catheter is a variable stiffness, single lumen catheter designed to be introduced over a steerable guide wire or microcatheter into the neuro vasculature. The catheter shaft is composed of a stainless steel variable pitch braid with a PTFE inner liner to facilitate movement of guide wires and other devices. The exterior of the catheter shaft is covered with polymer materials, which encapsulate the stainless steel braid construction. The catheter has a stiff proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. The distal end of the catheter has a radiopaque marker band to facilitate fluoroscopic visualization and has a hydrophilic coating to provide lubricity for navigation of vessels. The proximal end of the catheter has a luer fitting located on the end of the catheter hub which can be used to attach accessories for flushing and aspiration. An ID band is placed at the distal end of the hub over a strain relief. The catheter is packaged with a hemostasis valve with a side port and two peel-away introducers as accessories. The hemostasis valve with side port is used for flushing, insertion of catheters, and connection to an external aspiration system. The peel away introducer sheaths are designed to protect the distal tip of the catheter during insertion into the hemostasis valve.

The CERENOVUS Large Bore Catheter can be connected to the NOUVAG Vacuson 60 aspiration pump (or equivalent aspiration pump) using the CERENOVUS® Aspiration Tubing Set.

Indications for Use

The CERENOVUS Large Bore Catheter, with the CERENOVUS® Aspiration Tubing Set and NOUVAG Vacuson 60 aspiration pump (or equivalent aspiration pump), is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

The CERENOVUS® Aspiration Tubing Set is intended to connect the CERENOVUS Large Bore Catheter to the canister of the NOUVAG Vacuson 60 Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.

Predicate Comparison

A comparison of the similarities and differences of product features between the CERENOVUS Large Bore Catheter and the primary predicate device is presented in **Table 1**.

Table 1. Subject and Predicate Device Comparison Summary

Description	Subject Device: CERENOVUS Large Bore Catheter	Primary Predicate Device: ACE 68 Reperfusion Catheter (K161064)
Product Code	NRY	Same
Regulatory Name	Catheter, Percutaneous	Same
Classification	Class II - 21 CFR 870.1250	Same
Basic Design	Variable stiffness single lumen catheter	Same

Description	Subject Device: CERENOVUS Large Bore Catheter	Primary Predicate Device: ACE 68 Reperfusion Catheter (K161064)
Indications For Use	The CERENOVUS Large Bore Catheter, with the CERENOVUS® Aspiration Tubing Set and NOUVAG Vacuson 60 aspiration pump (or equivalent aspiration pump), is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment. The CERENOVUS® Aspiration Tubing Set is intended to connect the CERENOVUS Large Bore Catheter to the canister of the NOUVAG Vacuson 60 Aspiration Pump (or equivalent vacuum pump) and to allow the user to control the fluid flow.	The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.
Dimensions:		
Length	125 - 135 cm	115 – 132 cm
ID	0.071”	0.068”
Distal OD	0.081"	0.084"
Proximal OD	0.0825"	0.084"
Catheter Coating	Hydrophilic	Hydrophilic
Coating Length	30 cm	Same
Materials:		
Marker Band	Metal Platinum (90%) / Iridium (10%)	Same
Braid	Stainless Steel	Stainless Steel, Nitinol
Liner	PTFE Liner	Same
Hub	Polyamide	Polyamide
Strain Relief		Polyamide, Stainless Steel
Outer Jacket	Pebax, Urethane, Nylon	Same
Tip Configuration	Non-shapeable tip	Steam shapeable by user
Accessories Included:		
Hemostasis valve	Hemostasis Valve with Side Port Extension Tubing	Rotating Hemostasis Valve
Introducer Sheath	Peel-Away Sheath Introducer (2)	Peelable Sheath
Shaping	N/A	Shaping Mandrel 0.038" SST
Sterilization Method	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	Same
Packaging	Polyethylene Hoop and Mounting Card, Pouch, Carton	Same
Shelf Life	1 year	8 months
Required Additional Accessories	CERENOVUS Aspiration Tubing NOUVAG Vacuson 60 Pump	Penumbra Hi-Flow Tubing Penumbra Pump MAX
Aspiration Pump Requirements		
Minimum Aspiration Pressure	-20 inHg (-68 kPa)	Same
Maximum Aspiration Pressure	-29 inHg (-98 kPa)	Same
Flowrate (Air)	0 to 60LPM	0 to 23 LPM
Aspiration Tubing Requirements		
Tubing ID	0.110 in minimum	Same
Tubing Length	112 in	Same
Flow Control Mechanism	Flow Control Switch	Same

Non-Clinical Testing Summary

Performance Testing - Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the CERENOVUS Large Bore Catheter to demonstrate that it is substantially equivalent to the legally marketed Predicate device. The following performance data has been provided in support of the substantial equivalence determination. All testing was conducted using sampling methods as required by Codman & Shurtleff, Inc. Design Control procedures. The bench testing included the following tests:

Test	Test Summary	Result
Visual Inspection	Confirm that the CERENOVUS Large Bore Catheter meets the visual requirement described in ISO 10555-1 Section 4.4	PASS: Samples met the established acceptance criteria
Catheter ID	Verify that the catheter internal diameters meet the requirements	PASS: Samples met the established acceptance criteria
Introducer ID	Verify that the introducer internal diameters meet the requirements	PASS: Samples met the established acceptance criteria
Catheter OD	Verify that the catheter outer diameters meet the requirements	PASS: Samples met the established acceptance criteria
Introducer OD	Verify that the introducer outer diameters meet the requirements	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working length of a catheter as defined in ISO10555-1 Section 3.6.	PASS: Samples met the established acceptance criteria
Introducer Working Length	Confirm the working length of the introducer	PASS: Samples met the established acceptance criteria
Distal Tip Length	Verify the distal tip length of the catheter	PASS: Samples met the established acceptance criteria
Hub Luer Taper	Verify that the catheter hub luer taper fit standard luer fittings using a taper device	PASS: Samples met the established acceptance criteria
Air Leak testing	Verify that there is no air leak into the hub subassembly	PASS: Samples met the established acceptance criteria
System Liquid Leakage	Verify that the catheter joint strength meets the freedom from leakage (liquid during pressurization) requirements of ISO 10555-1:2013, section 4.7	PASS: Samples met the established acceptance criteria
Delamination of PTFE Liner	Verify that the PTFE has appropriately adhered to the inner lumen of the catheter with braid reinforcement	PASS: Samples met the established acceptance criteria
Kink (Distal & Proximal)	Confirm that the CERENOVUS Large Bore Catheter meets the requirement for the catheter to remain stable and not kink during use	PASS: Samples met the established acceptance criteria
Tip Movement	Confirm that the CERENOVUS Large Bore Catheter meets the tip column stiffness requirement	PASS: Samples met the established acceptance criteria
Tip Linear Stiffness	Test the tip flexibility of the CERENOVUS Large Bore catheter, relative to other devices of similar design	PASS: Samples met the established acceptance criteria
Coating Lubricity & Durability	Verify the lubriciousness and durability of the catheter hydrophilic coating	PASS: Samples met the established acceptance criteria

Coating Length	Verify that the catheter hydrophilic coating length meets the design requirements	PASS: Samples met the established acceptance criteria
Catheter Tensile Strength	Verify that the catheter joint strength meets the requirements of Section 4.5 of ISO 10555-1	PASS: Samples met the established acceptance criteria
Introducer Separation Force	Confirm the force required to separate the peel-away introducer accessory	PASS: Samples met the established acceptance criteria
Particle Count	Verify that the coating integrity of the catheter's outer surface meets the requirements for content of Particle Matter in alignment with USP<788>.	PASS: Samples met the established acceptance criteria
Burst Pressure (static)	Confirm the maximum hydrostatic pressure a catheter can withstand using a Crescent Hydraulic Burst-leak Tester	PASS: Samples met the established acceptance criteria
Static Flow Rate	Determine the flow rate through a catheter	PASS: Samples met the established acceptance criteria
Aspiration Flow Rate	Determine the aspiration flow rate through a catheter when the catheter is connected to a constant vacuum source.	PASS: Samples met the established acceptance criteria
In-vitro Usability Studies	Evaluate catheter trackability, tip stability and visibility under fluoroscopy, aspiration integrity, ability to aspirate emboli/clot to restore flow and the durability, Subject and Predicate devices were tracked to the target site with the provided accessories to perform simulated neurothrombectomy procedure in the neurovascular model that replicates the tortuosity, diameter and location of the arteries in the neurovasculature.	PASS: Samples met the established acceptance criteria

Codman also confirmed that the CERENOVUS Aspiration Tubing Set meets all design and performance requirements through the following bench testing:

Test	Test Summary	Result
Dimensional/ Visual Inspection	Confirm that the Cerenovus Aspiration Tubing meets all dimensional and visual inspection specifications.	PASS: Samples met the established acceptance criteria
Tensile Strength	Confirm that the Cerenovus Aspiration Tubing meets the existing tensile strength specifications.	PASS: Samples met the established acceptance criteria
Connection to Vacuum Pump	Suction Connector of Aspiration Tubing Assembly securely attaches to Pump Canister lid via press fit.	PASS: Samples met the established acceptance criteria
Connection to Catheter	Rotating Luer of Aspiration Tubing Assembly securely connects to the female luer of the catheter hemostasis valve.	PASS: Samples met the established acceptance criteria
Resist ovalization / Lumen Patency	Aspiration Tubing Assembly maintains functionality and maintains an open lumen, with no signs of ovalization, at vacuum pressure per product specification.	PASS: Samples met the established acceptance criteria
Resist Leak	Aspiration Tubing Assembly maintains functionality with no leaks at vacuum pressure per product specification.	PASS: Samples met the established acceptance criteria
Component Connections	Aspiration Tubing Assembly maintains functionality with no detachments of any bonded components during use.	PASS: Samples met the established acceptance criteria
Flow Switch Function	Flow Control Switch arrests fluid flow in the OFF position and restores fluid flow in the ON position.	PASS: Samples met the established acceptance criteria

Performance Testing - Animal

Non-clinical animal testing was conducted to evaluate the safety, efficacy, and usability of the CERENOVUS Large Bore Catheter in comparison to the Penumbra ACE 68 Reperfusion Catheter at acute and chronic time points in a porcine model, both in the presence and absence of simulated clot. Non-clinical animal testing was conducted in accordance with 21 CFR Part 58 for Good Laboratory Practice (GLP) for Non-Clinical Laboratory Studies.

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.

Sterilization

The CERENOVUS Large Bore Catheter, as packaged with included accessories, and the CERENOVUS Aspiration Tubing are sterilized using a validated 100% Ethylene Oxide sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135-1. The CERENOVUS Large Bore Catheter and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CERENOVUS Large Bore Catheter and all accessories are for single use only.

Shelf-Life Testing

The CERENOVUS Large Bore Catheter will have a shelf life of one year based on the successful completion of stability testing. Shelf life testing was performed using standard test methods and acceptance criteria. Prior to aging, all samples were exposed to standard transportation conditioning. Results of testing on the subject device all met established acceptance criteria. The CERENOVUS Aspiration Tubing will have a shelf life of three (3) years based on the successful completion of stability testing conducted by the manufacturer.

Biocompatibility Testing

The CERENOVUS Large Bore Catheter 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), as previously presented in K191237. 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:

Biocompatibility testing previously presented in K191237 is representative of the subject CERENOVUS Large Bore Catheter because the subject device is comprised of the same materials and manufacturing processes.

Codman also confirmed that the CERENOVUS Aspiration Tubing Set is biocompatible for its intended use. Biological evaluation of the aspiration tubing was conducted pursuant to the recommendations in FDA guidance document titled: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". As the aspiration tubing does not have any patient contact, it was evaluated for intact skin contact as a worst-case scenario. All test results passed, indicating that the aspiration tubing is biocompatible for the intended use.

Summary of Catheter Biocompatibility Testing		
Test	**Summary of Results**	**Conclusion**
Cytotoxicity (MEM Elution)	The test article extract showed no evidence of causing cell lysis or toxicity (grade = 0). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	The test article is considered non-cytotoxic. PASS
Sensitization (Maximization Study)	The test article exacts showed no evidence of causing delayed dermal contact sensitization (all erythema scores =0).	The test article was not considered a sensitizer. PASS
Irritation (Intracutaneous Reactivity)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control overall mean score was 0.0 for both the saline and the sesame oil test article extracts.	The test article is considered a negligible irritant. PASS

Conclusion

Based upon the intended use, design, materials, function, side-by-side *in-vitro* testing and animal testing, it is concluded that the subject device, CERENOVUS Large Bore Catheter is substantially equivalent to the primary predicate device, ACE 68 Catheter (K161064, cleared 12 June 2016). The differences in verbiage in the Indications for Use statement, materials, design, and packaging, do not raise any questions regarding the safety and effectiveness of the device. The device, as designed, manufactured, packaged and sterilized, is substantially equivalent to the primary and referenced predicate device(s) currently marketed under the Federal Food, Drug and Cosmetic Act.