January 17, 2024

Cerenovus, Inc.
Ryan Rivera
Senior Regulatory Affairs Project Lead
6303 Waterford District Drive, Suites 215 & 315
Miami, Florida 33216

Re: K233988
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: December 15, 2023
Received: December 18, 2023

Dear Ryan Rivera:

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,
Neurointerventional
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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)*
K233988

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 a compatible 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 fail IV t-PA therapy are candidates for treatment.

The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71 Intermediate Catheter to the canister of a compatible aspiration 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.

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510(k) Summary K233988

Submitter

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Contact

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Date Prepared

January 12, 2024

Device Trade or Proprietary Name

Cerenovus Large Bore Catheter

Cerenovus Aspiration Tubing Set

Device Information

Table 1. Device Information	
Device Proprietary Name	Cerenovus Large Bore Catheter; Cerenovus Aspiration Tubing Set
Common or Usual name	Catheter, Thrombus Retriever
Classification Name	21 CFR 870.1250 – Catheter, Percutaneous
Regulatory Classification	II
FDA Product Code	NRY

Predicate Device

Table 2. Predicate Device			
510(k) Number	**Date Cleared**	**Device Name**	**Manufacturer**
K193380	Jul 20, 2020	CERENOVUS Large Bore Catheter; CERENOVUS Aspiration Tubing Set	Cerenovus, Inc*.
*510(k) was previously held by Codman & Shurtleff, Inc. The 510(k) was transferred to Cerenovus, Inc., which is the current holder of the 510(k).			

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 a compatible aspiration pump using the Cerenovus Aspiration Tubing Set.

Indications for Use

The Cerenovus Large Bore Catheter, with the Cerenovus Aspiration Tubing Set and a compatible 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 fail IV t-PA therapy are candidates for treatment.

The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71 Intermediate Catheter to the canister of a compatible aspiration 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 predicate device is presented in **Table 3**.

Table 3. Subject and Predicate Device Comparison Summary

Description	Predicate Device (K193380): CERENOVUS Large Bore Catheter; CERENOVUS Aspiration Tubing Set	Subject Device (K233988): Cerenovus Large Bore Catheter; Cerenovus Aspiration Tubing Set
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

Table 3. Subject and Predicate Device Comparison Summary		
Description	**Predicate Device: CERENOVUS Large Bore Catheter (K193380)**	**Subject Device (K233988): Cerenovus Large Bore Catheter; 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.	The Cerenovus Large Bore Catheter, with the Cerenovus Aspiration Tubing Set and a compatible 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 fail IV t-PA therapy are candidates for treatment. The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71 Intermediate Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.
Length	125 - 135 cm	Same
ID	0.071 inch	Same
Distal OD	0.081 inch	Same
Proximal OD	0.0825 inch	Same
Catheter Coating	Hydrophilic	Same
Coating Length	30 cm	Same
Marker Band	Metal Platinum (90%) / Iridium (10%)	Same
Braid	Stainless Steel	Same
Liner	PTFE Liner	Same
Hub	Polyamide	Same
Strain Relief		Same
Outer Jacket	Pebax, Urethane, Nylon	Same
Tip Configuration	Non-shapeable tip	Same
Hemostasis Valve	Hemostasis Valve with Side Port Extension Tubing	Same
Introducer Sheath	Peel-Away Sheath Introducer (2)	Same
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	Same
Required Additional Accessories	CERENOVUS Aspiration Tubing Set NOUVAG Vacuson 60 Pump	Cerenovus Aspiration Tubing Set Compatible Aspiration Pump
Aspiration Pump Requirements:		
Minimum Aspiration Pressure	-20 inHg (-68 kPa)	Same
Maximum Aspiration Pressure	-29 inHg (-98 kPa)	Same
Flowrate (Air)	0 to 60 LPM	Same
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 support the proposed change and demonstrate that the subject device is substantially equivalent to the legally marketed predicate device. This testing was previously completed and submitted in K193380.

Table 4. Performance Testing Summary

Test	Test Summary	Result
Static Flow Rate	Determine the flow rate through the catheter.	PASS: Samples met the established acceptance criteria
Aspiration Flow Rate	Determine the aspiration flow rate through the catheter when the catheter is connected to a constant vacuum source.	PASS: Samples met the established acceptance criteria

Animal Testing

N/A – No animal studies were deemed necessary as appropriate verification and validation of the modifications were achieved based on the results of the previously completed bench testing, considering the similarities of the subject and predicate devices.

Shelf-Life Testing

N/A – Changes do not impact the shelf-life of the product.

Biocompatibility Testing

N/A – Changes do not impact biocompatibility.

Sterilization

N/A – Changes do not impact sterilization.

Conclusion

Based upon the intended use, design, materials, and function, it is concluded that the subject device, Cerenovus Large Bore Catheter is substantially equivalent to the predicate device, CERENOVUS Large Bore Catheter (K193380). The differences in wording of the Indications for Use statement do not raise any new questions regarding the safety and effectiveness of the device. The subject device, as designed, manufactured, packaged and sterilized, is substantially equivalent to the predicate device currently marketed under the Federal Food, Drug and Cosmetic Act.