March 9, 2023

Cerenovus, Inc.
Ariell Joiner, Ph.D.
Manager, Regulatory Affairs
6303 Blue Lagoon Drive, Suite 315
Miami, Florida 33126

Re: K221934
Trade/Device Name: CEREGLIDE 71 Intermediate Catheter; Cerenovus Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: February 2, 2023
Received: February 3, 2023

Dear Ariell Joiner:

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 -S

Naira Muradyan, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221934

Device Name
CEREGLIDE™ 71 Intermediate Catheter; Cerenovus Aspiration Tubing Set

Indications for Use *(Describe)*

CEREGLIDE™ 71 Intermediate Catheter

The CEREGLIDE™ 71 Intermediate 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.

Cerenovus Aspiration Tubing Set

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 Aspiration Tubing Set is also intended to connect 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 K221934

I. Submitter

Cerenovus, Inc.
6303 Blue Lagoon Drive
Suites 215 & 315
Miami, FL 33126 USA

Contact Person: Ariell Joiner
Tel: (908) 249-0182
Email: ajoiner@its.jnj.com

II. Date Prepared

March 8, 2023

III. Device Information

Table 1. Device Information	
Device Proprietary Name	CEREGLIDE™ 71 Intermediate 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

IV. Predicate Device Information

The primary predicate device is listed below in **Table 2** and the reference device is listed in **Table 3**.

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

Table 3. Reference Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K173200	June 11, 2018	SOFIA Plus Aspiration Catheter	MicroVention, Inc.

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510(k) Summary, continued

V. Device Description

The CEREGLIDE™ 71 Intermediate 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 to reduce friction during navigation in the vasculature. 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 Tuohy Borst rotating hemostasis valve (RHV) with a side port and two slit introducers as accessories. The RHV with side port is used for flushing, insertion of catheters, and connection to an external aspiration system. The slit introducers are designed to introduce the catheter into the base catheter and protect the distal tip of the catheter during insertion into the RHV of the base catheter.

The CEREGLIDE™ 71 Intermediate Catheter can be connected to a compatible aspiration pump using the Cerenovus Aspiration Tubing Set.

VI. Indications for Use

The CEREGLIDE™ 71 Intermediate 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 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 Aspiration Tubing Set is also intended to connect the CEREGLIDE™ 71 Intermediate Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

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510(k) Summary, continued

VII. Predicate Comparison

A comparison of the similarities and differences of product features between the CEREGLIDE™ 71 Intermediate Catheter, Cerenovus Aspiration Tubing Set and the predicate device is presented in **Table 4**.

Table 4. Subject and Predicate Device Comparison Summary

Description	Subject Device: CEREGLIDE™ 71 Intermediate Catheter; Cerenovus Aspiration Tubing Set	Predicate Device: CERENOVUS Large Bore Catheter (K193380)
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
Indications For Use	The CEREGLIDE™ 71 Intermediate 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 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 Aspiration Tubing Set is also intended to connect the CEREGLIDE™ 71 Intermediate Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.	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 fail IV t-PA therapy 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.
Dimensions:		
Length	115 - 137cm	125 - 135cm
Inner Diameter (ID)	0.071”	Same
Distal Outer Diameter (OD)	0.082” (0.0825” max)	0.081”
Proximal OD	0.0837” max	0.0825”
Catheter Coating	Hydrophilic	Same
Coating Length	55 cm	30 cm
Tip Configuration	Non-shapeable tip	Same
Materials:		
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 and Urethane	Pebax, Urethane, Nylon

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510(k) Summary, continued

Table 4. Subject and Predicate Device Comparison Summary, continued		
Description	**Subject Device: CEREGLIDE™ 71 Intermediate Catheter; Cerenovus Aspiration Tubing Set**	**Predicate Device: CERENOVUS Large Bore Catheter (K193380)**
Accessories Included:		
Hemostasis Valve	Included: Tuohy Borst Hemostasis Valve with Side Port Extension Tubing	Same
Introducer Sheath	Introducer (2)	Peel-Away Sheath Introducer (2)
Sterilization Method	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	Same
Packaging	Polyethylene Hoop and Mounting Card, Tyvek® Pouch, Carton	Same
Shelf Life	1 year	1 year
Required Additional Accessories	Cerenovus Aspiration Tubing Set (K193380) Compatible aspiration pump	Same
Aspiration Pump Requirements:		
Minimum Aspiration Pressure	-20 inHg (-68 kPa)	Same
Maximum Aspiration Pressure	-28 inHg (-95 kPa)	-29 inHg (-98kPa)
Flowrate (Air)	0 to 60LPM	Same
Aspiration Tubing Requirements:		
Tubing ID	0.110 in minimum	Same
Tubing Length	112 in	Same
Flow Control Mechanism	Flow Control Switch	Same

VIII. Non-Clinical Performance Data

Performance Testing – Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the CEREGLIDE™ 71 Intermediate Catheter to demonstrate that it is substantially equivalent to the legally marketed predicate device. The following performance data are being provided in support of the substantial equivalence determination. All testing was conducted using sampling methods as required by internal procedure. The bench testing included the following tests:

Table 5. Performance Testing Summary		
Test	**Test Summary**	**Result**
Design Verification		
Visual Inspection	Confirm that the 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
Catheter OD	Verify that the Catheter outer diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working length of the catheter as defined in ISO 10555-1 Section 3.6.	PASS: Samples met the established acceptance criteria
Catheter Tip Length	Verify the catheter tip length of the Catheter.	PASS: Samples met the established acceptance criteria
System Air Leakage	Verify that there is no air leak into the hub subassembly.	PASS: Samples met the established acceptance criteria

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510(k) Summary, continued

VIII. Non-Clinical Performance Data, continued

Table 5. Performance Testing Summary, continued

Test	Test Summary	Result
Design Verification		
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 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 Catheter meets the tip column stiffness requirement.	PASS: Samples met the established acceptance criteria
Tip Linear Stiffness	Test the tip flexibility of the Catheter, relative to other devices of similar design.	PASS: Samples met the established acceptance criteria
Coating Lubricity and Durability	Verify the lubriciousness and durability of the Catheter's 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
Peak 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 ID	Verify that the introducer internal diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Particulate 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> counting methods and compared to the reference predicate device.	PASS: Samples met the established acceptance criteria
Burst Pressure	Confirm the maximum hydrostatic pressure the Catheter can withstand using a Crescent Hydraulic Burst-leak Tester.	PASS: Samples met the established acceptance criteria
Introducer Working Length	Confirm the working length of the introducer.	PASS: Samples met the established acceptance criteria
Introducer Separation Force	Confirm the force required to separate the introducer.	PASS: Samples met the established acceptance criteria
Torque Test	To determine the number of revolutions to failure of the Catheter in simulated anatomy.	PASS: Samples exceeded comparator devices in revolutions to failure
Design Validation		
In Vitro Usability Studies	The in-vitro studies were conducted to demonstrate thrombus retrieval patency/durability, (ancillary) device compatibility, and accessory durability. Studies also included simulated use evaluation of user requirements related to: trackability and tip stability during thrombus removal.	PASS: Samples met the established acceptance criteria

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510(k) Summary, continued

VIII. Non-Clinical Performance Data, continued

Performance Testing – Animal
No animal studies were required as appropriate verification and validation of the device design were achieved based on the similarities of the proposed device and the predicate device, and from results of bench testing.

Performance Testing – Clinical
Clinical studies were not required as appropriate verification and validation of the device design were achieved based on the similarities of the proposed device and the predicate device, and from results of bench testing.

Sterilization
The CEREGLIDE™ 71 Intermediate Catheter, 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. The CEREGLIDE™ 71 Intermediate Catheter and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CEREGLIDE™ 71 Intermediate Catheter and all accessories are for single use only.

Shelf-Life
The CEREGLIDE™ 71 Intermediate 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.

Biocompatibility Testing
A biological safety evaluation was conducted on the CEREGLIDE™ 71 Intermediate Catheter in accordance with the FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process", (Issued June 16, 2016)* based on the changes to the predicate device, CERENOVUS Large Bore Catheter (K193380). Biocompatibility testing was conducted in accordance with International Standard ISO 10993-1, "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing Within a Risk Management Process"* (2018).

The following testing was performed:

Table 6. Biocompatibility Test Summary for CEREGLIDE™ 71 Intermediate Catheter and Introducer

Test	Test Summary	Results
Chemical Characterization	Determination of extractable species from the test article was performed in purified water, isopropyl alcohol, and hexane.	PASS
Cytotoxicity	Cytotoxicity Study Using the ISO Elution Method (compliant with ISO 10993-5:2009/(R)2014 and ISO 10993-12:2012). 1X MEM extract (6 cm^2/ mL at 37°C for 72 hours) was evaluated for potential cytotoxic effects using monolayers of L-929 mouse fibroblast cells.	PASS

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510(k) Summary, continued

VIII. Non-Clinical Performance Data, continued

Table 6. Biocompatibility Test Summary for CEREGLIDE™ 71 Intermediate Catheter and Introducer, continued

Test	Test Summary	Results
Sensitization – Guinea Pig Maximization	Evaluation of the allergenic potential or sensitizing capacity of a test article by screening of contact allergens in guinea pigs and extrapolating the results to humans.	PASS
Irritation – Rabbit Intracutaneous Reactivity	Determination of any chemicals that may leach or be extracted from the test article capable of causing local irritation in the dermal tissues of rabbits.	PASS
Acute Systemic Toxicity in Mice	Screening of test article extracts for potential toxic effects as a result of a single-dose systemic injection in mice.	PASS
Pyrogenicity – Materials Mediated Rabbit Pyrogen	Determination if a saline extract of the test article causes a febrile response in rabbits.	PASS
ASTM Hemolysis Study: Direct and Extraction Methods	Evaluation of the hemolytic potential of the test articles and test article extract according to ASTM method (F756-17).	PASS
SC5b-9 Complement Activation Assay	Measure of complement activation in Normal Human Serum (NHS) indicates whether a test article is capable of generating the activation fragment, SC5b-9, which in turn contributes to the inflammatory immune response in humans.	PASS
ASTM Heparinized Platelet and Leukocyte Count	Determination if medical materials exposed to human whole blood would adversely affect the platelet and leukocyte ratios in whole blood.	PASS
ASTM Partial Thromboplastin Time (PTT)	Screening for detection of coagulation abnormalities in the intrinsic coagulation pathway. The PTT indirectly measures the formation of thrombin by its action on fibrinogen, forming the fibrin clot through a method compliant with ISO 10993-4.	PASS
In Vivo Thromboresistance	Evaluate the thrombogenic potential of a blood contacting medical device in comparison to a predicate device.	PASS

IX. Conclusion

Based upon the intended use, design, materials, function, and side-by-side *in-vitro* and *in-vivo* testing, it is concluded that the subject device, CEREGLIDE™ 71 Intermediate Catheter, Cerenovus Aspiration Tubing Set is substantially equivalent to the predicate device, CERENOVUS Large Bore Catheter, CERENOVUS Aspiration Tubing Set (K193380). The differences in materials and design do not raise new questions regarding the safety and effectiveness of the device. The device, as designed, manufactured, packaged and sterilized, is substantially equivalent to the primary predicate and reference devices currently marketed under the Federal Food, Drug and Cosmetic Act.