May 9, 2024

Cerenovus, Inc.
Niall Fox
Director of Regulatory Affairs
6303 Waterford District Drive, Suites 215 & 315
Miami, Florida 33126

Re: K233982
Trade/Device Name: CEREGLIDE 92 Catheter System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: April 9, 2024
Received: April 9, 2024

Dear Niall Fox:

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
and Neurodiagnostic Devices
OHT5: Office of Neurological
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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)*
K233982

Device Name
CEREGLIDE 92 Catheter System

Indications for Use *(Describe)*
The CEREGLIDE 92 Catheter System is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.

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.

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510(k) Summary K233982

I. Submitter

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Contact Person: Niall Fox
Tel: +353 86 1730678
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II. Date Prepared

07th May, 2024

III. Device Information

Table 1. Device Information	
Device Proprietary Name	CEREGLIDE 92 Catheter System
Common or Usual name	Catheter, Percutaneous, Neurovasculature
Classification Name	21 CFR 870.1250 – Percutaneous Catheter
Regulatory Classification	II
FDA Product Code	QJP

IV. Predicate Device Information

Table 2. Predicate Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K230726	November 29, 2023	CEREGLIDE™ 92 Intermediate Catheter	Cerenovus, Inc.

V. Device Description

The CEREGLIDE™ 92 Catheter System consists of the CEREGLIDE™ 92 Intermediate Catheter and associated accessories, including the INNERGLIDE™ 9 Delivery Aid, Rotating Hemostasis Valve (RHV), and Slit Introducers.

The CEREGLIDE™ 92 Intermediate Catheter is a single lumen, variable stiffness catheter designed to be introduced over a steerable guidewire along with a microcatheter and/or compatible support device into the neuro vasculature. The catheter consists of a lubricious PTFE lined inner lumen to facilitate movement of the guidewires and other devices, variable pitch stainless steel and tungsten braid, and various durometer polymer jackets. These jackets provide distal flexibility and gradually transition to a stiffer proximal shaft to facilitate the advancement of the catheter in the anatomy. The outer surface of the catheter is hydrophilic coated in order to reduce friction during manipulation in the vessel. A radiopaque marker at the distal end of the catheter provides fluoroscopic visualization of the catheter tip. The proximal end of the catheter incorporates a standard Luer adapter to facilitate the attachment of accessories, a hub, and an ID band.

The CEREGLIDE™ 92 Catheter System is packaged with an INNERGLIDE™ 9 Delivery Aid, an RHV with a side port, and two Slit Introducer accessories. The INNERGLIDE™ 9 Delivery Aid is a compatible support device comprising of a single lumen catheter with a tapered tip, hydrophilic coating for increased lubricity, radiopaque tip for fluoroscopic visualization, and a proximal luer hub that is designed to be used as part of the CEREGLIDE™ 92 Catheter System to facilitate delivery of the CEREGLIDE™ 92 Intermediate Catheter to select blood vessels in the neurovasculature. The RHV with side port is used for flushing and

510(k) Summary (continued)

V. Device Description (continued)

insertion of catheters. The Slit Introducers are designed to introduce the CEREGLIDE™ 92 Intermediate Catheter into the base catheter and protect the distal tip of the CEREGLIDE™ 92 Intermediate Catheter during insertion into the hemostasis valve of the base catheter.

VI. Indications for Use

The CEREGLIDE 92 Catheter System is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.

VII. Predicate Comparison

A comparison of indications for use and technological characteristics between the CEREGLIDE™ 92 Catheter System and the predicate device is presented in **Table 3**.

Table 3. Predicate and Subject Device Comparison Summary

Description	Predicate Device: CEREGLIDE™ 92 Intermediate Catheter K230726	Subject Device: CEREGLIDE™ 92 Catheter System K233982
Product Code	QJP	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 92 Intermediate Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.	The CEREGLIDE 92 Catheter System is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the neurovascular system.
CEREGLIDE 92 Intermediate Catheter Dimensions:		
Length	114 - 135 cm	Same
ID	0.092” (2.34 mm)	Same
Distal OD	0.102" (2.59 mm)	Same
Proximal OD	0.108” (2.74 mm)	Same
Catheter Coating	Hydrophilic	Same
Coating Length	50 cm	Same
Materials:		
Marker Band	Stainless Steel and Tungsten	Same
Braid	Stainless Steel and Tungsten	Same
Liner	PTFE Liner	Same
Hub	Nylon	Same
Strain Relief		
Outer Jacket	Pebax, Urethane, Nylon	Same
Accessories Included:		
Hemostasis valve	Tuohy Borst Hemostasis Valve with Side Port Extension Tubing	RHV with Side Port
Introducer Sheath	Slit Introducer (2)	Same
INNERGLIDE™ 9 Delivery Aid — **Dimensions:**		
Length	None	165 cm
ID		0.030” (0.76 mm)
Distal OD		0.042” (1.07 mm)
Proximal OD		0.078” (1.98 mm)
Catheter Coating		Hydrophilic
Coating Length		50 cm

Continued the next page

510(k) Summary (continued)

INNERGLIDE™ 9 Delivery Aid	**Materials:**		
	Marker Band	None	Tungsten
	Liner		PTFE Liner
	Hub		Makrolon
	Strain Relief		Pebax
	Outer Jacket		Pebax, Vestamid
Sterilization Method		Ethylene Oxide	Same
Sterility Assurance Level (SAL)		10^{-6}	Same
Packaging		Polyethylene Hoop and Mounting Card, Tyvek Pouch, Carton	Same
Shelf Life		6 months	Same

VIII. Non-Clinical Performance Testing

Performance Testing – Bench

There are no changes to the CEREGLIDE 92 Intermediate Catheter (K230726). Appropriate testing was identified based on design, risk analyses, and the intended use of the INNERGLIDE 9 Delivery Aid to demonstrate that the CEREGLIDE 92 Catheter System 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 design control procedures.

Table 4. Performance Testing Summary

Test	Test Summary	Result
Design Verification		
Visual Inspection	Confirm that the INNERGLIDE 9 Delivery Aid meets the visual requirements described in ISO 10555-1 Section 4.4.	PASS: Samples met the established acceptance criteria
Catheter ID	Verify that the INNERGLIDE 9 Delivery Aid internal diameters meet the design requirements.	PASS: Samples met the established acceptance criteria
Catheter OD	Verify that the INNERGLIDE 9 Delivery Aid outer diameters meet the design requirements.	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working length of the INNERGLIDE 9 Delivery Aid as defined in ISO 10555-1 Section 3.6.	PASS: Samples met the established acceptance criteria
Catheter Tip Length	Verify that the tip length and navigation length of the INNERGLIDE 9 Delivery Aid meet the design requirements.	PASS: Samples met the established acceptance criteria
Hub Luer	Verify that the hub luer on the INNERGLIDE 9 Delivery Aid meets dimensional, interconnectability, and performance requirements defined in ISO 80369-7.	PASS: Samples met the established acceptance criteria
System Air Leak Resistance	Verify that the INNERGLIDE 9 Delivery Aid has no air leak.	PASS: Samples met the established acceptance criteria
System Liquid Leak Resistance	Verify that the INNERGLIDE 9 Delivery Aid 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
Hub Pull Testing	Verify that the INNERGLIDE 9 Delivery Aid and CEREGLIDE 92 Intermediate Catheter hub to joint strength meets acceptance criteria.	PASS: Samples met the established acceptance criteria
Shaft Tensile Strength	Verify that the INNERGLIDE 9 Delivery Aid and CEREGLIDE 92 Intermediate Catheter joint strength meets the acceptance criteria.	PASS: Samples met the established acceptance criteria
Particulate Count	Verify the particulate size and counts of the CEREGLIDE 92 Catheter System under simulated use conditions with comparison to the predicate devices.	PASS: Samples met the established acceptance criteria

VIII. Non-Clinical Performance Testing (continued)

Table 4. Performance Testing Summary (continued)		
Test	**Test Summary**	**Result**
Design Verification (continued)		
Coating Durability and Friction	Verify that the friction force and durability of the hydrophilic coating on the INNERGLIDE 9 Delivery Aid meet the design requirements.	PASS: Samples met the established acceptance criteria
Coating Length	Verify that the INNERGLIDE 9 Delivery Aid hydrophilic coating length meets the design requirements.	PASS: Samples met the established acceptance criteria
Coating Thickness	Verify that the INNERGLIDE 9 Delivery Aid hydrophilic coating thickness meets the design requirements.	PASS: Samples met the established acceptance criteria
Coating Integrity	Verify that the coating on the INNERGLIDE 9 Delivery Aid is free of uncoated individual voids when evaluated with Congo Red Dye Coverage Test.	PASS: Samples met the established acceptance criteria
Kink Resistance	Confirm that the INNERGLIDE 9 Delivery Aid meets the requirement to remain stable and not kink during use.	PASS: Samples met the established acceptance criteria
Tip Flexibility	Test the tip flexibility of the INNERGLIDE 9 Delivery Aid, relative to cleared devices of similar design.	PASS: Samples met the established acceptance criteria
Torque Performance	Confirm that the INNERGLIDE 9 Delivery Aid meets the torque strength requirement.	PASS: Samples met the established acceptance criteria
Trackability (Delivery and Withdrawal Force)	Confirm that the INNERGLIDE 9 Delivery Aid trackability meets the design requirements.	PASS: Samples met the established acceptance criteria
Burst Pressure	Verify the CEREGLIDE 92 Intermediate Catheter continues to meet minimum static burst pressure requirements.	PASS: Samples met the established acceptance criteria
Design Validation		
In Vitro Usability Studies	In vitro studies were conducted in a neurovascular model to evaluate compatibility, trackability, and durability of the INNERGLIDE 9 Delivery Aid and use for delivery of the CEREGLIDE 92 Intermediate Catheter.	PASS: Samples met the established acceptance criteria

Performance Testing – Animal

No animal studies were required as appropriate verification and validation of the subject 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 subject 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™ 92 Catheter System, 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™ 92 Catheter System and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CEREGLIDE™ 92 Catheter System and all accessories are for single use only.

Shelf-Life

The CEREGLIDE™ 92 Catheter System will have a shelf life of 6 months 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.

510(k) Summary (continued)

VIII. Non-Clinical Performance Testing (continued)

Biocompatibility Testing

The INNERGLIDE 9 Delivery Aid was assessed for biocompatibility in accordance with International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," and FDA Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"," (issued September 4, 2020). 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:

Table 5. Biocompatibility Test Summary for the INNERGLIDE 9 Delivery Aid

Test Method	Acceptance Criteria	Result
Cytotoxicity - MEM Elution	Grade ≤ 2	PASS
Sensitization – Guinea Pig Maximization	Grade < 1	PASS
Irritation – Rabbit Intracutaneous Reactivity	Difference of ≤ 1 from control mean score	PASS
Acute Systemic Toxicity in Mice	No biologically significant signs of systemic toxicity	PASS
Pyrogenicity – Materials Mediated Rabbit Pyrogen	Temperature change (ΔT) < 0.5°C	PASS
ASTM Hemolysis Study - Direct and Extraction Methods	Hemolytic Index < 2%	PASS
SC5b-9 Complement Activation Assay	Results evaluated based on comparison to negative controls	PASS
In Vivo Thromboresistance	Results evaluated based on comparison to negative controls	PASS

IX. Conclusion

Based upon the intended use, design, materials, function, performance testing and biocompatibility testing, it is concluded that the subject device, CEREGLIDE™ 92 Catheter System (K233982) is substantially equivalent to the predicate CEREGLIDE™ 92 Intermediate Catheter (K230726). The addition of the INNERGLIDE™ 9 Delivery Aid did not raise any new questions regarding the safety and effectiveness of the device. The CEREGLIDE™ 92 Catheter System, as designed, manufactured, packaged, and sterilized, is substantially equivalent to the predicate device currently marketed under the Federal Food, Drug and Cosmetic Act.