October 16, 2024

Cerenovus, Inc.
Cara Feely
Regulatory Affairs Manager
6303 Waterford District Drive, Suites 215 & 315
Miami, Florida 33126

Re: K241221
Trade/Device Name: CEREGLIDE 42 Intermediate Catheter; CEREGLIDE 57 Intermediate Catheter; Cerenovus Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: September 2, 2024
Received: September 13, 2024

Dear Cara Feely:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
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Neurodiagnostic Devices
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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)*
K241221

Device Name
CEREGLIDE 42 Intermediate Catheter
CEREGLIDE 57 Intermediate Catheter
Cerenovus Aspiration Tubing Set

Indications for Use *(Describe)*

The CEREGLIDE 42 Intermediate Catheter and the CEREGLIDE 57 Intermediate Catheter, with the Cerenovus Aspiration Tubing Set and a compatible aspiration pump, are 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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71, 57 or 42 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.

510(k) Summary – K241221

I. Submitter

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Suites 215 & 315
Miami, FL 33126
United States

Contact Person: Cara Feely (Regulatory Affairs Manager)
Tel: 00353863335253
Email: Cfeely@its.jnj.com

II. Date Prepared

October 14, 2024

III. Device Information

Table 1. Device Information	
Device Proprietary Name	CEREGLIDE™ 42 Intermediate Catheter CEREGLIDE™ 57 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.**

Table 2. Primary Predicate Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K190338	August 2, 2019	Zenith Flex Aspiration System (046 Zenith Flex Catheter)	InNeuroCo, Inc.

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510(k) Summary, continued

V. Device Description

Both the CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter are variable stiffness, single lumen catheters 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™ 42 Intermediate Catheter and the CEREGLIDE™ 57 Intermediate Catheter are designed for use in the removal of thrombus from the neurovasculature using continuous aspiration from an external vacuum source. The CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter are intended to be used with a compatible aspiration pump as a vacuum source that provides a minimum vacuum pressure of -68 kPa [-20 inHg] and a maximum vacuum pressure of -95 kPa [-28 inHg], and minimum 17 L/min flow rate, with a collection canister of at least 1000 mL volume.

The CEREGLIDE™ 42 Intermediate Catheter and the CEREGLIDE™ 57 Intermediate Catheter are intended to be connected to the vacuum source using the Cerenovus Aspiration Tubing Set which is an externally manufactured tubing set with an internal diameter (ID) of 0.110” and overall length of 112”, containing an integrated flow control switch.

VI. Indications for Use

The CEREGLIDE 42 Intermediate Catheter and the CEREGLIDE 57 Intermediate Catheter, with the Cerenovus Aspiration Tubing Set and a compatible aspiration pump, are 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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71, 57 or 42 Intermediate Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

VII. Predicate Comparison

A comparison of the similarities and differences of product features between the CEREGLIDE™ 42 Intermediate Catheter, the CEREGLIDE™ 57 Intermediate Catheter, and the predicate device are presented in **Table 3**.

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510(k) Summary, continued

Table 3. Predicate and Subject Device Comparison			
Description	**Predicate Device: Zenith Flex Aspiration System (046 Zenith Flex Catheter) (K190338)**	**Subject Device: CEREGLIDE™ 42 Intermediate Catheter; Cerenovus Aspiration Tubing Set**	**Subject Device: CEREGLIDE™ 57 Intermediate Catheter; Cerenovus Aspiration Tubing Set**
Indications For Use	The Zenith Flex Aspiration System, including the 046 Zenith Flex Catheter, Aspiration Tubing Set, and VC-701 Cliq Aspirator Pump, is indicated 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 therapy are candidates for treatment.	The CEREGLIDE 42 Intermediate Catheter and the CEREGLIDE 57 Intermediate Catheter, with the Cerenovus Aspiration Tubing Set and a compatible aspiration pump, are 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 thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment. The Cerenovus Aspiration Tubing Set is intended to connect the Cerenovus Large Bore Catheter or the CEREGLIDE™ 71, 57 or 42 Intermediate Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.	
Product Code	NRY	Same as predicate	
Regulatory Name	Percutaneous Catheter	Same as predicate	
Classification	Class II - 21 CFR 870.1250	Same as predicate	
Basic Design	Variable stiffness single lumen catheter	Same as predicate	
Length	153 cm 160 cm	115 cm 125 cm 132 cm 144 cm 152 cm 160 cm	115 cm 125 cm 132 cm 137 cm
Inner Diameter (ID)	0.046”	0.042”	0.057”
Distal Outer Diameter (OD)	0.056”	0.053” (1.35 mm)	0.068” (1.73 mm)
Proximal OD	0.058”	0.0535” (1.36 mm)	0.0685” (1.74 mm)
Catheter Coating	Hydrophilic	Hydrophilic	
Coating Length	Not Specified	55 cm	
Tip Configuration	Not Specified	Non-shapeable tip	
Marker Band	Platinum/ Iridium	Same as predicate	
Braid	Stainless Steel/Nitinol	Stainless Steel	
Liner	PTFE Liner	Same as predicate	
Hub	Polycarbonate	Same as predicate	
Strain Relief	Polyolefin	Same as predicate	
Outer Jacket	Polyether Block Amide (Pebax), Urethane, Nylon	Pebax, Urethane	
Hemostasis Valve	Included	Same as predicate	
Introducer Sheath	Peel-Away Introducer	Slit Introducer (2)	
Sterilization Method	Ethylene Oxide	Same as predicate	
Sterility Assurance Level (SAL)	Not Specified	10^{-6}	
Packaging	Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton	Polyethylene Hoop and Mounting Card, Tyvek® Pouch, Carton	
Shelf Life	Not Specified	3 years	

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510(k) Summary, continued

Table 3. Predicate and Subject Device Comparison			
Description	**Predicate Device: Zenith Flex Aspiration System (046 Zenith Flex Catheter) (K190338)**	**Subject Device: CEREGLIDE™ 42 Intermediate Catheter; Cerenovus Aspiration Tubing Set**	**Subject Device: CEREGLIDE™ 57 Intermediate Catheter; Cerenovus Aspiration Tubing Set**
Required Additional Accessories	Vacuum Pump, Aspiration Tubing	Cerenovus Aspiration Tubing Set Compatible Aspiration Pump	
Minimum Aspiration Pressure	-22 inHg	-20 inHg (-68 kPa)	
Maximum Aspiration Pressure	-28 inHg	-28 inHg (-95 kPa)	
Flowrate (Air)	Not Specified	0 to 60LPM	
Tubing ID	Not Specified	0.110 in minimum	
Tubing Length	Not Specified	112 in	
Flow Control Mechanism	Not Specified	Flow Control Switch	

VIII. Non-Clinical Performance Data

Performance Testing – Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter to demonstrate that they are 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 4. Performance Testing Summary		
Test	**Test Summary**	**Result**
Design Verification		
Visual Inspection	Confirm that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters meet the visual requirement described in ISO 10555-1 Section 4.4.	PASS: Samples met the established acceptance criteria
Catheter ID	Verify that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters' internal diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Catheter OD	Verify that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters' outer diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working lengths of the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters 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 CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters.	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
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

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510(k) Summary, continued

VIII. Non-Clinical Performance Data, continued

Table 4. Performance Testing Summary		
Test	**Test Summary**	**Result**
Design Verification		
Kink	Confirm that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters meet 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 CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters meet the tip column stiffness requirement.	PASS: Samples met the established acceptance criteria
Distal Tip Stiffness	Test the tip flexibility of the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters, relative to other devices of similar design.	PASS: Samples met the established acceptance criteria
Peak Tensile Strength	Verify that the catheter joint strength meets the acceptance criteria of Section 4.5 of ISO 10555-1.	PASS: Samples met the established acceptance criteria
Particulate Count and Coating Integrity	Verify the particulate size and counts of the CEREGLIDE™ 42 Intermediate Catheter under simulated use conditions with comparison to the predicate device. Coating integrity was visually inspected and verified to be free of coating defects after simulated use.	PASS: Samples met the established acceptance criteria
Burst Pressure	Verify the CEREGLIDE™ 42 and CEREGLDIE™ 57 Intermediate Catheters meet minimum static burst pressure specifications.	PASS: Samples met the established acceptance criteria
Torque Strength	Confirm that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters meet the torque strength requirement.	PASS: Samples met the established acceptance criteria
Trackability	Confirm that the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters meet the trackability requirement.	PASS: Samples met the established acceptance criteria
Design Validation		
In Vitro Usability Studies	The *in-vitro* studies were conducted to demonstrate thrombus retrieval patency/durability, ancillary and accessory device compatibility, and to evaluate user requirements related to trackability and tip stability during thrombus removal.	PASS: Samples met the established acceptance criteria

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™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter are packaged with included accessories and sterilized using a validated 100% Ethylene Oxide (EO) sterilization process to ensure sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135. The CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter, and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter, and all accessories are for single use only.

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510(k) Summary, continued

VIII. Non-Clinical Performance Data, continued

Shelf-Life

The CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter will have a shelf life of three years. Shelf-life testing was adopted from CEREGLIDE™ 71 Intermediate Catheter (K221934) that shares the same materials, design features, and manufacturing processes as the subject devices. Prior to aging, all samples were exposed to standard transportation conditioning. Results of shelf-life performance testing all met established acceptance criteria.

Biocompatibility Testing

A biological safety evaluation was conducted for the CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™ 57 Intermediate Catheter in accordance with the FDA biocompatibility guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"" (issued September 2023), considering differences from the CEREGLIDE™ 71 Intermediate Catheter (K221934).

Additionally, biocompatibility testing conducted on the CEREGLIDE™ 71 Intermediate Catheter (K221934), per ISO 10993-1 and applicable regulatory requirements, adequately evaluates the biocompatibility profile of the CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters for endpoints recommended by the FDA biocompatibility guidance for an externally communicating device with limited (≤24 hours) duration of contact with circulating blood. The CEREGLIDE™ 42 and CEREGLIDE™ 57 Intermediate Catheters have met the requirements of biocompatibility assessments.

IX. Conclusion

Based upon the intended use, design, materials, function, and side-by-side *in-vitro* testing, it is concluded that the subject devices, the CEREGLIDE™ 42 Intermediate Catheter and CEREGLIDE™57 Intermediate Catheter, are substantially equivalent to the predicate device, Zenith Flex Aspiration System (046 Zenith Flex Catheter) (K190338). The differences in materials and design do not raise new questions regarding the safety and effectiveness of the devices. The subject devices, as designed, manufactured, packaged, and sterilized, are substantially equivalent to the primary predicate device currently marketed under the Federal Food, Drug and Cosmetic Act.

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