November 29, 2023

Cerenovus, Inc.
Ariell Joiner, Ph.D.
Manager, Regulatory Affairs
6303 Waterford District Drive, Suites 215 & 315
Miami, Florida 33126

Re: K230726
Trade/Device Name: CEREGLIDE 92 Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP
Dated: October 30, 2023
Received: October 31, 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 (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)*
K230726

Device Name
CEREGLIDE 92 Intermediate Catheter

Indications for Use *(Describe)*
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.

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 K230726

I. Submitter

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Contact Person: Ariell Joiner
Tel: (908) 726-9577
Email: ajoiner@its.jnj.com

II. Date Prepared

November 27, 2023

III. Device Information

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

IV. Predicate and Reference Device Information

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

Table 2. Predicate Device			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K212224	September 20, 2021	Zoom 88 Large Distal Platform	Imperative Care, Inc.

Table 3. Reference Devices			
510(k) Number	**Date Cleared**	**Name**	**Manufacturer**
K191237	November 8, 2019	CERENOVUS Large Bore Catheter	Medos International SARL*
K192804	February 27, 2020	CEREBASE DA Guide Sheath	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).			

V. Device Description

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.

510(k) Summary (continued)

V. Device Description (continued)

The CEREGLIDE™ 92 Intermediate Catheter is packaged with a Tuohy Borst hemostasis valve (RHV) with a side port and two slit introducer accessories. The RHV with side port is used for flushing and 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 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.

VII. Predicate Comparison

A comparison of indications for use and technological characteristics between the CEREGLIDE™ 92 Intermediate Catheter and the predicate device is presented in **Table 4**.

Table 4. Subject and Predicate Device Comparison Summary

Description	Subject Device: CEREGLIDE™ 92 Intermediate Catheter	Predicate Device: Zoom 88 Large Distal Platform (K212224)
Product Code	QJP	QJP, DQY
Regulatory Name	Percutaneous Catheter	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 Zoom 88 Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Dimensions:		
Length	114 - 135 cm	80 – 110 cm
ID	0.092” (2.34 mm)	0.088”
Distal OD	0.102” (2.59 mm)	0.106”
Proximal OD	0.108” (2.74 mm)	0.110”
Catheter Coating	Hydrophilic	Same
Materials	Commonly used medical grade plastics & metals with hydrophilic coating	Same
Accessories Included:		
Hemostasis Valve	Included: Tuohy Borst Hemostasis Valve with Side Port Extension Tubing	Rotating Hemostasis Valve (RHV)
Introducer Sheath	Slit Introducer (2)	None
Sterilization Method	Ethylene Oxide	Same
Sterility Assurance Level (SAL)	10^{-6}	Same
Packaging	Polyethylene Hoop and Mounting Card, Tyvek® Pouch, Carton	The catheters are placed in a protective polyethylene tube, mounted with accessory RHV onto a polyethylene packaging card, placed into a pouch, sealed and labeled. The sealed pouch and IFU are placed in a labeled shelf carton box.
Shelf Life	6 months	1 year

510(k) Summary (continued)

VIII. Non-Clinical Performance Testing

Performance Testing – Bench

Appropriate testing was identified based on design, risk analyses and the intended use of the CEREGLIDE™ 92 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 design control procedures. The bench testing included the following tests:

Table 5. Performance Testing Summary

Test	Test Summary	Result
Design Verification		
Visual Inspection	Confirm that the CEREGLIDE 92 Intermediate 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 CEREGLIDE 92 Intermediate Catheter internal diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Catheter OD	Verify that the CEREGLIDE 92 Intermediate Catheter outer diameters meet the requirements.	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working length of the CEREGLIDE 92 Intermediate Catheter as defined in ISO 10555-1 Section 3.6.	PASS: Samples met the established acceptance criteria
Catheter Tip Length	Verify the tip length of the CEREGLIDE 92 Intermediate Catheter.	PASS: Samples met the established acceptance criteria
Hub Luer Taper	Verify that the catheter hub Luer taper fit standard Luer fittings using taper device.	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 CEREGLIDE 92 Intermediate 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
Burst Pressure	Confirm the maximum hydrostatic pressure the CEREGLIDE 92 Intermediate Catheter can withstand using a Crescent Hydraulic Burst-leak Tester.	PASS: Samples met the established acceptance criteria
Hub Pull Testing	To verify the CEREGLIDE 92 Intermediate Catheter hub to joint strength meets acceptance criteria.	PASS: Samples met the established acceptance criteria
Shaft Tensile Strength	Verify that the 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 Intermediate Catheter under simulated use conditions with comparison to the predicate and reference devices.	PASS: Samples met the established acceptance criteria
Coating Lubricity and Durability	Verify the lubriciousness and durability of the CEREGLIDE 92 Intermediate Catheter's hydrophilic coating.	PASS: Samples met the established acceptance criteria
Coating Length	Verify that the CEREGLIDE 92 Intermediate Catheter hydrophilic coating length meets the design requirements.	PASS: Samples met the established acceptance criteria
Kink Resistance (Distal & Proximal)	Confirm that the CEREGLIDE 92 Intermediate Catheter meets the requirement for the catheter to remain stable and not kink during use.	PASS: Samples met the established acceptance criteria
Delamination of PTFE Liner	Verify that the PTFE has appropriately adhered to the inner lumen of the CEREGLIDE 92 Intermediate Catheter with braid reinforcement.	PASS: Samples met the established acceptance criteria

510(k) Summary (continued)

VIII. Non-Clinical Performance Testing (continued)

Table 5. Performance Testing Summary (continued)		
Test	**Test Summary**	**Result**
Design Verification (continued)		
Tip Movement	Confirm that the CEREGLIDE 92 Intermediate Catheter meets the tip column stiffness requirement.	PASS: Samples met the established acceptance criteria
Tip Linear Stiffness	Test the tip flexibility of the CEREGLIDE 92 Intermediate Catheter, relative to other devices of similar intended use and design.	PASS: Samples met the established acceptance criteria
Trackability	Confirm that the CEREGLIDE 92 Intermediate Catheter meets the trackability requirement.	PASS: Samples met the established acceptance criteria
Torque Strength	Confirm that the CEREGLIDE 92 Intermediate Catheter meets the torque strength requirement.	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
Design Validation		
In Vitro Usability Studies	The in vitro studies were conducted to evaluate usability parameters such as trackability, tip stability, durability, and (ancillary) device compatibility with tracking of the CEREGLIDE 92 Intermediate Catheter to target sites and delivery of a worst-case interventional device in the neurovascular model.	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 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™ 92 Intermediate Catheter and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CEREGLIDE™ 92 Intermediate Catheter and all accessories are for single use only.

Shelf-Life

The CEREGLIDE™ 92 Intermediate Catheter 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 CEREGLIDE™ 92 Intermediate Catheter 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 6. Biocompatibility Test Summary for CEREGLIDE™ 92 Intermediate Catheter and Introducer

Test Method	Acceptance Criteria	Result
Cytotoxicity	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
ASTM Partial Thromboplastin Time (PTT)	Average clotting time > 50% of the negative control	PASS
ASTM Heparinized Platelet and Leukocyte Count	% platelet and leukocyte comparison to control article	PASS
Comparative Surface Assessment	150x microscopic comparative evaluation of the surface and geometric features between the subject device and reference device as part of the thrombogenicity assessment.	PASS

IX. Conclusion

Based upon the intended use, design, materials, function, biocompatibility testing, and side-by-side *in-vitro* testing, it is concluded that the subject CEREGLIDE™ 92 Intermediate Catheter is substantially equivalent to the predicate Zoom 88 Large Distal Platform (K212224). The differences in materials and design 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.