November 8, 2019

Codman & Shurtleff, Inc.
Kirsten Franco, MS, RAC
Regulatory Affairs Manager
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K191237
Device Name: CERENOVUS Large Bore Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 7, 2019
Received: October 9, 2019

Dear Kirsten Franco:

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,

Xiaolin Zheng, Ph.D.
Director (*Acting)*
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191237

Device Name
CERENOVUS Large Bore Catheter

Indications for Use *(Describe)*

The CERENOVUS Large Bore 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 CERENOVUS Large Bore Catheter is also indicated for use as a conduit for retrieval devices.

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 - K191237

Pursuant to the requirements of 21 CFR Section 807.92(c), this 510(k) summary is provided as part of this Premarket Notification containing sufficient details to understand the basis for a determination of substantial equivalence.

Submitter

Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact

Kirsten Franco
Phone: (484) 868-7991
Email: kfranco5@its.jnj.com

Date Prepared

June 19, 2019

Device Trade or Proprietary Name

CERENOVUS Large Bore Catheter

Device Classification

Regulatory Classification:	II
Common or Usual Name:	Catheter, Percutaneous
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Classification Panel:	Cardiovascular

Predicate Device

510(k) Number	Date Cleared	Device Name	Manufacturer
K183463	March 13, 2019	AXS Catalyst Distal Access Catheter	Stryker Neurovascular

Continued on next page

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. 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 and insertion of catheters. The peel away introducer sheaths are designed to protect the distal tip of the catheter during insertion into the hemostasis valve.

Indications for Use

The CERENOVUS Large Bore 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 CERENOVUS Large Bore Catheter is also indicated for use as a conduit for retrieval devices.

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 1**.

Table 1. Subject and Predicate Device Comparison Summary

Description	Subject Device: CERENOVUS Large Bore Catheter (K191237)	Predicate Device: AXS Catalyst Distal Access Catheter (K183463)
Product Code	DQY	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 CERENOVUS Large Bore 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 CERENOVUS Large Bore Catheter is also indicated for use as a conduit for retrieval devices.	The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.
Dimensions:		
Length	125 - 135 cm	115 – 132 cm
ID	0.071”	0.068”
Distal OD	0.081"	0.082"
Proximal OD	0.0825"	0.0825"
Catheter Coating	Hydrophilic	Hydrophilic
Coating Length	30 cm	Same
Materials:		
Marker Band	Metal Platinum (90%) / Iridium (10%)	Same
Braid	Stainless Steel	Nitinol wire and polymer fiber
Liner	PTFE Liner	Same
Hub	Polyamide	Nylon
Strain Relief		Thermoplastic rubber (Polyolefin)

Description	Subject Device: CERENOVUS Large Bore Catheter (K191237)	Predicate Device: AXS Catalyst Distal Access Catheter (K183463)
Outer Jacket	Pebax, Urethane, Nylon	Pebax with Nylon, Tecoflex
Accessories Included:		
Hemostasis valve	Hemostasis Valve with Side Port Extension Tubing	Rotating Hemostasis Valve; Tuohy Borst Valve with Sideport
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

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 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 Codman & Shurtleff, Inc. Design Control procedures. The bench testing included the following tests:

Test	Test Summary	Result
Visual Inspection	Confirm that the CERENOVUS Large Bore 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
Introducer ID	Verify that the introducer 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
Introducer OD	Verify that the introducer outer diameters meet the requirements	PASS: Samples met the established acceptance criteria
Catheter Working Length	Confirm the working length of a catheter as defined in ISO10555-1 Section 3.6.	PASS: Samples met the established acceptance criteria
Introducer Working Length	Confirm the working length of the introducer	PASS: Samples met the established acceptance criteria
Distal Tip Length	Verify the distal tip length of the catheter	PASS: Samples met the established acceptance criteria
Hub Luer Taper	Verify that the catheter hub luer taper fit standard luer fittings using a taper device	PASS: Samples met the established acceptance criteria
Air Leak testing	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

Test	Test Summary	Result
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 CERENOVUS Large Bore 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 CERENOVUS Large Bore Catheter meets the tip column stiffness requirement	PASS: Samples met the established acceptance criteria
Tip Linear Stiffness	Test the tip flexibility of the CERENOVUS Large Bore Catheter, relative to other devices of similar design	PASS: Samples met the established acceptance criteria
Coating Lubricity & Durability	Verify the lubriciousness and durability of the catheter 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
Catheter 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 Separation Force	Confirm the force required to separate the peel-away introducer accessory	PASS: Samples met the established acceptance criteria
Particle Count	Verify that the coating integrity of the catheter's outer surface meets the requirements for content of particulates.	PASS: Samples met the established acceptance criteria
Burst Pressure (static)	Confirm the maximum hydrostatic pressure a catheter can withstand using a Crescent Hydraulic Burst-leak Tester	PASS: Samples met the established acceptance criteria
In-vitro Usability Studies	Evaluate catheter usability parameters such as trackability, tip stability and visibility under fluoroscopy, durability, etc. Subject and Predicate devices were tracked to the target site to deliver a stent-retriever in the neurovascular model that replicates the tortuosity, diameter and location of the arteries in the neurovasculature.	PASS: Samples met the established acceptance criteria
Packaging Visual Inspection	Confirm that the proposed packaging system has no visible defects that would result in exposure of the primary package or IFU	PASS: Samples met the established acceptance criteria
Packaging Dye Leak	Evaluate sterile package integrity by detecting and locating defects in package seals and pinholes in the packaging materials	PASS: Samples met the established acceptance criteria

Performance Testing - Animal

No animal testing was required as appropriate verification and validation of the subject device were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Performance Testing - Clinical

No clinical studies were required as appropriate verification and validation of the subject device were achieved based on the similarities of the proposed device to the predicate device, and from results of bench testing.

Sterilization

The CERENOVUS Large Bore 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 11135-1. The CERENOVUS Large Bore Catheter and all accessories meet EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The CERENOVUS Large Bore Catheter and all accessories are for single use only.

Shelf-Life Testing

The CERENOVUS Large Bore 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

The CERENOVUS Large Bore Catheter was assessed for biocompatibility in accordance with International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices – Part 1: Evaluation of Testing within a Risk Management Process."* and FDA Guidance for Industry and FDA Staff: *Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'* (Issued June 16, 2016). 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:

Summary of Catheter Biocompatibility Testing		
Test	**Summary of Results**	**Conclusion**
Cytotoxicity (MEM Elution)	The test article extract showed no evidence of causing cell lysis or toxicity (grade = 0). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	The test article is considered non-cytotoxic. PASS
Sensitization (Maximization Study)	The test article exacts showed no evidence of causing delayed dermal contact sensitization (all erythema scores =0).	The test article was not considered a sensitizer. PASS
Irritation (Intracutaneous Reactivity)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control overall mean score was 0.0 for both the saline and the sesame oil test article extracts.	The test article is considered a non-irritant. PASS
Acute Systemic Toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into the mice. Each test article extract met the requirements of the study.	The test article does not indicate signs of toxicity. PASS
Pyrogenicity (Material Mediated)	No single animal showed a temperature rise of 0.5 °C or more above its baseline temperature. The total rise of the rabbits' temperature during 3 hours was 0.4 °C. The total rise of rabbit temperatures during the 3 hour observation period was within the acceptable USP limits.	The test article was judged as nonpyrogenic. PASS
In Vitro Hemolysis	The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the test article extract was 0.0%.	The test article is non-hemolytic. PASS

Summary of Catheter Biocompatibility Testing (Continued)		
Test	**Summary of Results**	**Conclusion**
Complement Activation	The concentration of SC5b-9 in the Test Group 1 was 8,712.8 ± 427.3 ng/mL (mean ± S.D.) which was higher and statistically different (p=0.0059) than the activated NHS control, and was higher however not statistically different (p=0.2048) than the negative control. The concentration of SC5b-9 in the Test Group 2 was higher and statistically different than the activated NHS control, and was not higher nor statistically different than the negative control. The concentration of SC5b-9 in the Test Group 3 was higher however not statistically different than the activated NHS control, and was not higher nor statistically different than the negative control.	The test article was not considered to be a potential activator of the complement system. PASS
In Vivo Thromboresistance Study - Jugular Vein	Slight thrombus formation was noted with both the test and control articles (Grade ≤ 2). Therefore, both test and control articles were considered thromboresistant.	Both test and control articles were considered thromboresistant. PASS
ISO 10993-18 Chemical Characterization (Exaggerated Extraction)	FTIR: No bands of interest GC/MS: No semi-volatile compounds greater than the quantitation limit ICP/MS: trace amounts of Mg, Zn, and Sb detected UPLC/MS: No compounds greater than the quantitation limit GC/MS HS: No volatile compounds greater than the quantitation limit	Extractable compounds do not present a toxicological risk to patients
	FTIR: Most closely matches Pebax 4033 SN 00t GC/MS: 3 peaks identified UPLC/MS: Irganox 1010 standard analysis	Extractable compounds do not present a toxicological risk to patients
	FTIR: Most closely matches Nylon compound 600 GC/MS: No semi-volatile compounds greater than the quantitation limit UPLC/MS: Irganox 1010	Extractable compounds do not present a toxicological risk to patients

Summary of Introducer Biocompatibility Testing		
Test	**Summary of Results**	**Results**
Cytotoxicity (MEM Elution)	The test article extract showed no evidence of causing cell lysis or toxicity (grade = 0). The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity).	The test article is considered non-cytotoxic. PASS
Sensitization (Maximization Study)	The test article exacts showed no evidence of causing delayed dermal contact sensitization (all erythema scores =0). The test article was not considered a sensitizer.	The test article is not considered a sensitizer. PASS
Irritation (Intracutaneous Reactivity)	The test article met the requirements of the test since the difference between each test article extract overall mean score and corresponding control overall mean score was 0.0 for both the saline and the sesame oil test article extracts.	The test article is considered a non-irritant. PASS
Acute Systemic Toxicity	There was no mortality or evidence of systemic toxicity from the extracts injected into the mice. Each test article extract met the requirements of the study.	The test article does not indicate signs of toxicity. PASS
Pyrogenicity (Material Mediated)	No single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the rabbits' temperature during 3 hours was 0.0°C. The total rise of rabbit temperatures during the 3 hour observation period was within the acceptable USP limits. The test article was judged as nonpyrogenic.	The test article was judged as nonpyrogenic. PASS
In Vitro Hemolysis	The hemolytic index for the test article in direct contact with blood was 0.0%, and the hemolytic index for the test article extract was 0.0%. Both the test article in direct contact with blood and the test article extract were non-hemolytic.	The test article is non-hemolytic. PASS

Summary of Introducer Biocompatibility Testing (Continued)		
Test	**Summary of Results**	**Results**
Complement Activation	The concentration of SC5b-9 in the test article sample was higher and statistically different than the activated NHS control, and was higher however not statistically different than the negative control. The test article was not considered to be a potential activator of the complement system.	The test article was not considered to be a potential activator of the complement system. PASS
Chemical Characteriza-tion	No peaks of significant interest, nor any residues in the extract found above the quantitation limits.	No presence of extractables

Conclusion

Based upon the intended use, design, materials, function, and side-by-side in-vitro testing, it is concluded that the subject device, CERENOVUS Large Bore Catheter is substantially equivalent to the predicate device, AXS Catalyst Distal Access Catheter (K183463, cleared 13 March 2019). The differences in verbiage in the Indications for Use statement, materials, and design, do not raise any questions regarding the safety and effectiveness of the device. The device, as designed, manufactured, packaged and sterilized, is substantially equivalent to the primary and referenced predicate device(s) currently marketed under the Federal Food, Drug and Cosmetic Act.