July 20, 2019

Cerus Endovascular, Inc.
Theresa Brandner
Vice President of Regulatory
47757 Fremont Boulevard
Fremont, California 94538

Re: K182487
Trade/Device Name: CerusEndo Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 11, 2019
Received: June 19, 2019

Dear Theresa Brandner:

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.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182487

Device Name
CerusEndo Microcatheter

Indications for Use *(Describe)*

The CerusEndo Microcatheter is intended for general intravascular use to deliver therapeutic devices to the peripheral, coronary, and neurovasculature.

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
K182487

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Submitter Name: Cerus Endovascular, Inc.

Address: 47757 Fremont Boulevard,
Fremont, CA 94538

Phone Number: (510) 651-4000

Fax Number: (510) 405-8356

Contact Person: Theresa Brandner
VP of Regulatory

Date Prepared: July 17, 2019

II. DEVICE

Name of Device: CerusEndo Microcatheter

Common Name: Catheter, Percutaneous

Classification Name: Percutaneous Catheter
21 CFR 870.1250

Regulatory Class: Class II

Product Code: DQY

III. PREDICATE DEVICE

K093160: Headway 21 Microcatheter manufactured by MicroVention Inc.

The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The subject device is a microcatheter available in three versions: a 150 cm length microcatheter with a 15 cm length distal segment; a 150 cm length microcatheter with a 34 cm length distal segment; and a 160 cm length microcatheter with a 42 cm length

distal segment. The distal segment of the catheter is flexible to facilitate access into tortuous anatomy, and the distal tip of the catheter is formable, allowing the physician to shape it according to the needs of the procedure at the point of use. The CerusEndo Microcatheter has a hydrophilic coating, radiopaque marker, Luer hub on the proximal end, polymer tapered shaft construction, stainless steel reinforced shaft, and Teflon lined inner lumen. The subject device is controlled by user manipulation to access discrete locations within the vascular anatomy. It is intended to deliver other interventional or therapeutic devices through its inner lumen. It is designed to be used in peripheral, coronary, and neurovascular locations.

V. INDICATIONS FOR USE

The CerusEndo Microcatheter is intended for general intravascular use to deliver therapeutic devices to the peripheral, coronary, and neurovasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has similar design, dimensions, materials, intended use, and technological characteristics to the legally marketed predicate cleared under K093160. Non-clinical testing has been performed to demonstrate that any differences in technological characteristics do not raise new questions of safety and effectiveness. A table comparing the intended use and technical characteristics of the proposed device and the legally marketed predicate is provided in **Table 1**.

Table 1 – Comparison Table of Proposed Device and Predicate Device

Manufacturer	**Subject Device** CerusEndo Microcatheter (Cerus Endovascular)	**Predicate Device** Headway Microcatheter (MicroVention)	**Comparison**
Clinical Attributes			
Indications for Use	The CerusEndo Microcatheter is intended for general intravascular use to deliver therapeutic devices to the peripheral, coronary, and neurovasculature.	The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.	Same
Environments of Use	Hospital interventional neuroradiology suites	Hospital interventional neuroradiology suites	Identical
Patient Population	Patients undergoing vascular procedures	Patients undergoing vascular procedures	Identical
Contraindications	No known contraindications	No known contraindications	Identical
Functions	To facilitate introduction of therapeutic devices into the vasculature	To facilitate introduction of diagnostic and therapeutic devices into the vasculature	Same

Manufacturer	**Subject Device** CerusEndo Microcatheter (Cerus Endovascular)	**Predicate Device** Headway Microcatheter (MicroVention)	**Comparison**
Patient Access	Device access is gained using an introducer sheath inserted into the vasculature and is advanced over a guidewire and through a guide catheter	Device access is gained using an introducer sheath inserted into the vasculature and is advanced over a guidewire and through a guide catheter	Identical
Intraoperative Use	Yes	Yes	Identical
Technological Attributes			
General Description	Percutaneous Catheter Intravascular Catheter	Percutaneous Catheter Diagnostic Intravascular Catheter	Same
Device Configuration	Proximal Luer hub, hydrophilic coating, radiopaque marker, polymer tapered shaft construction, stainless steel reinforced shaft, and lined inner lumen	Proximal Luer hub, hydrophilic coating, radiopaque marker, polymer tapered shaft construction, stainless steel reinforced shaft, and lined inner lumen	Same
Catheter Body Materials	Polyether outer layer, stainless steel polyether inner layer, braid/coil, PTFE/polyether liner	Polyurethane outer layer, polyether/polyamide inner layer, stainless steel braid/coil, PTFE/polyolefin liner	Similar
Marker	Platinum/iridium	Platinum/iridium	Same
Hub	Nylon	Nylon	Same
Strain Relief	Pebax	Pebax	Same
Introducer	Not applicable	Pebax	The CerusEndo Microcatheter is not provided with an introducer
Shaping Mandrel	Stainless Steel	Stainless steel	Same
Proximal ID/OD	0.0205 in min / 0.036 in	0.021 in min / 0.033 in (2.5 Fr)	Similar
Distal ID/OD	0.0205 in min / 0.031 in	0.021 in min / 0.026 in (2.0 Fr)	Similar
Effective Length	150 cm, 160 cm	150 cm, 156 cm	Similar
Coating	Hydrophilic coating	Hydrophilic coating	Similar
Tip Configuration	Straight – Steam Shapeable by physician prior to use	Straight – Steam Shapeable by physician prior to use	Same
Guidewire Compatibility	≤ 0.018 in	≤ 0.018 in	Same
Accessories	Shaping mandrel	Shaping mandrel, introducer	The CerusEndo Microcatheter is provided with a shaping mandrel but is not provided with an introducer
Method of Supply	Sterile, single use	Sterile, single use	Same
Sterilization	Ethylene oxide, single patient use	Ethylene oxide, single patient use	Same
Biocompatibility	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1	Same

There are no significant technological differences between the subject device and predicate device. The technological differences between the subject and predicate device are indicated in the table above.

VII. PERFORMANCE DATA

Non-clinical tests were performed to demonstrate safety and substantial equivalence. Bench testing performed is summarized in **Table 2**. Biocompatibility testing performed is summarized in **Table 3**.

Table 2 – Bench Testing Summary

Test	Test Method Summary	Results
Tensile Strength	This test measures the tensile strength of the catheter bonds using a tensile tester and are pulled to failure.	Device met acceptance criteria
Shaft Flexibility (stiffness)	This test measures the bending stiffness of the distal and proximal catheter shaft segments.	Device met acceptance criteria
Shape Retention	This test measures the ability of the catheter tip to form and retain a steam shape using conventional catheter lab shaping techniques.	Device met acceptance criteria
Kink Resistance	This test measures the distal and proximal catheter shaft resistance to kinking.	Device met acceptance criteria
Static Burst	This test measures the catheters resistance to burst failure by using a high pressure injector to pressurize the lumen while the distal tip is occluded.	Device met acceptance criteria
Simulated Use	The device was used in accordance to the Instructions for Use.	Device met acceptance criteria
Particulate	This test assesses the coating integrity by measuring the quantity and size of particles generated during simulated use of the device in an anatomical model.	Device met acceptance criteria
Coating Friction and Durability	This test measures the lubricity of the coating and the durability after repeated abrasion cycles.	Device met acceptance criteria
Sterilization Validation	These tests confirms a minimum 6 log sterility assurance level, assesses ethylene oxide sterilant residual levels, and detects pyrogens.	Device met acceptance criteria

Table 3 – Biocompatibility Testing Summary

Test	Extract/Test System	Results
Cytotoxicity (MEM Elution)	The test extract, a positive control, and a negative control were extracted at 37°C for 24 hours in MEM solution (5% serum supplemented cell culture medium) and exposed to mouse fibroblast cells.	Non-cytotoxic. The test article is considered non-cytotoxic to cells.
Sensitization (ISO Kligman Guinea Pig Maximization Test)	Test samples and control blanks were extracted in normal saline and in cotton seed oil at 37°C for 72 hours.	Non-sensitizing. The test article did not elicit a sensitization response.
Irritation/ ISO Intracutaneous Toxicity in Rabbits	Test samples were extracted in normal saline and in cotton seed oil at 37°C for 72 hours.	Non-irritant. No evidence of irritation.
Systemic Toxicity (ISO Systemic Injection)	Test samples and negative control blanks were extracted and were prepared in normal saline and in cotton seed oil at 37˚C for 72 hours.	Non-cytotoxic. No weight loss, mortality, or evidence of systemic toxicity from the extract exposure to the mice.
Systemic Toxicity (Rabbit Material-Mediated Pyrogenicity)	Test samples were extracted and negative control blanks were prepared in normal saline and in cotton seed oil at 37°C for 72 hours.	Non-pyrogenic. All individual rabbits for both the test article and negative control showed a total rise in temperature of < 0.5ºC and were determined to be nonpyrogenic.
Hemocompatibility (ISO In Vitro Hemocompatibility – Direct Contact)	Blood samples from three human donors were pooled and diluted. The test article is added to aliquots of human blood and incubated at 37 °C for a minimum of 3 hours.	Non-hemolytic. There were no differences between the hemolytic index of the test article and the negative control.
Hemocompatibility (Hemolysis – Indirect)	Test samples were extracted in phosphate buffered saline at 37°C for 72 hours. The test article extract was incubated at 37°C for a minimum of 3 hours.	Non-hemolytic. There were no significant differences between the test article extract/solid and negative control article results.

Hemocompatibility (ISO Complement Activation C3 and SC5b-9 Test – Direct Contact)	The test article, predicate, negative control, and positive control (latex) were added to the serum pooled from three human blood samples. All were incubated at 37 °C for 30, 60, and 90 minutes.	C3a and SC5b-9 complement proteins were considered to be non-activated as compared to the negative control.
Genotoxicity – Gene Mutation (Ames Assay, S-9 Activation)	Test samples and negative control blanks were extracted in normal saline and PEG 400 at 37°C for 72 hours.	Non-mutagenic. Based on the acceptance criteria under the experimental conditions utilized, the test article extracts were both deemed non-mutagenic in all strains under both non-activated and activated conditions.
Genotoxicity – Micronucleus	Test samples and negative control blanks were extracted in polar (saline) and non-polar solvents at 37 °C for 72 hours. The extracts are placed on Chinese Hamster Ovary (CHO) cells with and without metabolic activations (S-9). The cells are then incubated at 37 °C, with 5% CO_2, for 15 – 21 hours. The cells are harvested and the chromosomes stained and examined for aberrations.	Not genotoxic. No significant increase of aberrations when compared to the negative controls
Hemocompatibility (Thrombogenicity)	Devices were placed in a canine carotid vessel.	Non-thrombogenic. No significant thrombus was observed on any of the subject catheters, and the device was determined to not show thrombogenic potential.

VIII. CONCLUSION

Differences between the subject device and the predicate device do not raise different questions of safety and effectiveness. After a comparison of the subject CerusEndo Microcatheter intended use, technological characteristics, and expected performance to the legally marketed predicate, the Headway 21 Microcatheter (K093160), Cerus Endovascular concludes that the CerusEndo Microcatheter performs as safely and effectively as the predicate device for the same intended use.