December 4, 2018

Spartan Micro, Inc.
℅ Vikki O'Connor
Regulatory Affairs Consultant
Ambriel Associates, Inc.
411 Walnut Street, Unit 9236
Green Cove Springs, Florida 32043

Re: K180653
Trade/Device Name: Spartan eCoil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG, KRD
Dated: November 1, 2018
Received: November 5, 2018

Dear Vikki O'Connor:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K180653

Device Name
Spartan eCoil™ System

Indications for Use *(Describe)*

The Spartan eCoil™ System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Spartan eCoil™ System is also indicated for arterial and venous embolizations in the peripheral vasculature.

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: Spartan eCoil™ System

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular, 21 CFR Part 807.92, the following summary of information is provided:

Submitter / Owner:	Spartan Micro Inc. 3167 Skyway Court Fremont, CA 94539 Phone: (512) 270-8501
Contact Person	Ms. Vikki M. O'Connor Regulatory Affairs Consultant Phone: 1-207-214-8535 Email: vikki0730@yahoo.com
Date Prepared	November 2, 2018
Trade Name	Spartan eCoil™ System
Proposed Class	Class II
Classification Name and Number	882.5950 - Neurovascular Embolization Device 870.3300 - Vascular Embolization Device
Common Name	Neurovascular Embolization Device
Product Code / Panel	HCG, Neurology KRD, Cardiovascular
Predicate Device	Micro Therapeutics Inc. Axium Prime Detachable Coil System – K162704
Special Controls	Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices

Performance Data	The following performance testing was performed to establish substantial equivalence: * Visual and Dimensional Inspection; * Simulated Use Flow Model Testing; * Magnetically Induced Displacement Force; * Magnetically Induced Torque; * RF Heating; * MR Artifact Evaluation; * Corrosion Resistance; * Fatigue Resistance; * Torsional Resistance; * Friction (Pull / Push) Sterilization, biocompatibility, packaging and accelerated aging data were also collected. No clinical or animal testing was performed, as the subject device has a similar safety profile and a similar effectiveness profile when compared to the predicate device. In addition, there is no change in the indications for use or the fundamental scientific technology of the device that requires additional testing.

Device Description	The Spartan eCoil™ System is a mechanically detachable embolic coil system that consists of an embolic coil (the Spartan eCoil™) attached to a delivery wire with a fluoroscopic marker band and the system is housed in an introducer sheath. The system is provided sterile and requires no additional equipment to be employed by the user.

Indications for Use	The Spartan eCoil™ System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Spartan eCoil™ System is also indicated for arterial and venous embolizations in the peripheral vasculature.
Summary of Technological Characteristics	The Spartan eCoil™ System is designed to deliver, deploy and detach embolic coils of various sizes, shapes and profiles and to embolize or occlude blood flow in vascular abnormalities of the neurovascular and peripheral vessels. As such, the system is constructed of implant grade materials. The system comes in 57 different configurations, two (2) shape configurations and a range of primary and secondary diameters and coil lengths. The Spartan eCoil™ System is designed to work with market available microcatheters with minimum working inner diameters of at least 0.017". The Delivery Wire includes a radiopaque marker used as a positioning reference.
Conclusion	Based on the indications for use, technological characteristics, materials, required performance testing, principles of operation, anatomical site, safety characteristics and comparison to the predicate device, Spartan's eCoil™ System has been shown to be substantially equivalent to the legally marketed predicate device.

Device Comparison

The table below provides a comparison of the subject device and the currently cleared predicate Axium device line.

Characteristics	**Subject Device Spartan eCoil System K180653**	**Predicate Device Axium Prime K162704**	**Rationale for Differences / Comments**
FDA Classification	Class II	Class II	Same
FDA Product Code	HCG, KRD	HCG, KRD	Same
FDA Regulation	882.5950, 870.3300	882.5950, 870.3300	Same
Special Guidance	Guidance for Industry and Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices	Guidance for Industry and Staff – Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices	Same

Characteristics	Subject Device Spartan eCoil System K180653	Predicate Device Axium Prime K162704	Rationale for Differences / Comments
Indications for Use	The Spartan eCoil™ System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Spartan eCoil™ System is also indicated for arterial and venous embolizations in the peripheral vasculature.	The Axium Prime Detachable Coil System is indicated for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities, such as arteriovenous malformations and arteriovenous fistulae. The Axium Prime Detachable Coils are also indicated for arterial and venous embolization in the peripheral vasculature.	Same

User Population	Patients with vascular abnormalities and hemorrhagic vascular trauma	Patients with vascular abnormalities and hemorrhagic vascular trauma	Same
Technical Method	Provides scaffolding, packaging, and an embolic reaction in vascular anatomy	Provides scaffolding, packaging, and an embolic reaction in vascular anatomy	Same
Target Area	Neurovascular and peripheral vascular anatomy	Neurovascular and peripheral vascular anatomy	Same
Method of Supply	Inserted in a rigid HDPE Hoop, in a Tyvek Pouch, placed in a shelf card, in a shipping carton	Stored within Dispenser Coil, in Tyvek pouch, in a shipping carton	Similar Spartan utilizes a shelf card (i.e., Cardboard carton) to hold each Tyvek Pouch
Implant Design	Alloy coil with atraumatic tip and various shapes and sizes to accommodate different arterial spaces.	Alloy coil with atraumatic tip and various shapes and sizes to accommodate different arterial spaces.	Same

Detachment Mechanism	Mechanical release induced by exposing internal release wire, to free a spherical component previously captured by a mechanical interference feature.	Mechanical release induced by exposing internal release wire, to free a spherical component previously captured by a mechanical interference feature.	Same
Number of Models	57	140	Subject device falls within the range of model offerings as the currently cleared predicate device models.
Sterilization (EO Residuals and Bioburden)	Ethylene Oxide - Pass	Ethylene Oxide - Pass	Same
Implant Shape	Helix and 360	Helix and 3D	Subject device shape is similar to the predicate
Device Size / Range Primary Diameter	0.0110” – 0.0145”	0.0108” – 0.0145”	Subject device size range falls within the currently cleared

			predicate device size range
Device Size / Range Secondary Diameter	3mm – 25mm	1mm – 25mm	Subject device size range falls within the currently cleared predicate device size range
Size Range Length (in sheath)	5.5cm – 50cm	1cm – 50cm	Subject device size range falls within the currently cleared predicate device size range

Characteristics	Subject Device Spartan eCoil System K180653	Predicate Device Axium Prime K162704	Rationale for Differences / Comments
Visual Positioning Aides	Radiopaque Marker and Flouro-Saver Marker	Radiopaque Marker	The subject device contains an additional Flouro-Saver Marker for device visibility.
Stretch Resistant Member	Yes	Yes	Same
Catheter Compatibility	Micro catheters with a minimum I.D. of .017”	Micro catheters with a minimum I.D. of .017”	Same
Materials (Implant Coil)			
Primary Coil	92% Platinum 8% Tungsten Alloy	92% Platinum 8% Tungsten Alloy	Same
Stretch Resistant Monofilament	Polypropylene	Polypropylene	Same
Coil Shell	92% Platinum 8% Tungsten Alloy	92% Platinum 8% Tungsten Alloy	Same

Detach Subassembly	Cobalt Chromium – MP35N Alloy Cobalt Chromium – 35N LT Alloy Pt (92%) / W (8%)	SS 316LVM	Subject device utilizes Cobalt Chromium, which performed adequately in terms of corrosion resistance, MRI compatibility, and material strength when compared to the predicate device.

Materials (Delivery System)			
Unibody	SS 304	SS 304	Same
Outer Jacket	PET	PTFE	Subject device utilizes PET to laminate the delivery wire.
Marker Coil	92% Platinum 8% Tungsten Alloy	92% Platinum 8% Tungsten Alloy	Same
Lumen Stop	N/A	SS 304	Subject device does not use this component in the implant.
Inner Liner	PTFE	PTFE	Same
Coupler Tube	N/A	SS 304	Subject device does not use this component in the implant.

Actuator Interface	N/A	SS 304	Subject device does not use this component in the implant.
Release Wire	SS 304	SS 304	Same
Retainer Ring	N/A	SS 304	Subject device does not use this component in the implant.
Break Indicator	PET Shrink Tubing	PET Shrink Tubing	Same
Positive Load Indicator	N/A	PET Shrink Tubing	Subject device does not use this component in the implant.
Introducer Sheath	Nylon 12	Polypropylene / HDPE	Subject devices utilizes Nylon 12 for retention of the Spartan eCoil System when packaged.

Table 1: Test Results

Test	Test Method	Test Results	Comments
Bench Testing			
Coil Tensile Study	Compare the accepted values to the minimum acceptable specification limit. All tensile strengths must be equal or greater than the minimum spec. Further, a minimum confidence and reliability level of 95% and 95% respectively must be demonstrated.	Pass	N/A
eCoil Anchor Bond	Test the Coil to anchor component bond joint and determine the tolerance limit of the tensile strength of the bond joint from the anchor	Pass	N/A

	component to the eCoil joint. A confidence and reliability interval of 95%/95% is required.		
Coil Deformation	Test to attain a coil deformation force and observe the average resultant force of the test articles as compared to the predicate. The first loop is compressed to a deformation distance of 20% of the coil's loop OD. The peak force is recorded.	Pass	Equivalent
Tab Compression and Rebound Study	Test to provide evidence from direct observation that the lock tab returns to its unfolded position when the lock component is	Pass	N/A

	removed.		
Deformation Force	The first loop is compressed to a deformation distance of 20% of the coil's loop OD. The peak force is recorded.	Pass	N/A
Tip Buckling	Test to prove the delivery wire tip buckling forces are equal or better than the tip buckling forces produced by the predicate delivery wire.	Pass	Equivalent
Hypotube Weld and Tension Strength	Test the weld tensile strengths of the cannula weldment component of the delivery wire.	Pass	N/A
Pusher Tensile	Determine tensile strength of the DEC Tube. Must be equal to or greater than 250 g.	Pass	N/A
Friction in	Test the friction	Pass	Equivalent

Catheter	load in the micro catheter and compare it to the predicate.		
Friction in Sheath	Test the friction load in the introducer sheath (must not buckle during advancement) as compared to the predicate.	Pass	Equivalent
Release Wire Tensile	Test the delivery wire to ensure the ultimate tensile strength of the release wire can withstand the frictional force required to initiate a detachment of the Spartan eCoil Implant.	Pass	N/A
Marker Radiopacity	Test the delivery wire radiopaque marker and compare the radiopacity of the radiopaque marker to the predicate device.	Pass	Equivalent

Physician Use Testing	The device was navigated through a tortuous benchtop model and deployed into a simulated silicone aneurysm in order to assess stability, neck coverage, conformability, softness and smoothness of delivery.	Pass	N/A
Stretch Resistant Polypropylene Tensile Test	Pull monofilament (tension) to failure.	Pass	N/A
Corrosion / Corrosion Resistance	Tested as per ASTM F2129-17, F3044-14	Pass	N/A
MRI Compatibility	ASTM testing to determine the safety and MR system scanning parameters for patients that will have this device. F2119-07, 2182-11a, F2213-06, F2052-15, ASTM 2503/IEC 62570	Pass	N/A

Visual and Dimensional, First Loop OD Post Sterilization, Fatigue and Knotting, Label Verification, Pusher Dimensions, Detachment Reliability	Testing to prove outputs equal inputs. Dimensions were measured and key characteristics of the implant coil were inspected.	Pass	All devices met acceptance criteria.
Biocompatibility			
eCoil Implant (permanent implant with direct blood contact) and eCoil Delivery System (limited (≤ 24 hrs)) contact with blood			
Cytotoxicity	MEM Elution Using L-929 Mouse Fibroblast Cells	Pass	Non-cytotoxic
Sensitization	Guinea Pig Maximization Sensitization	Pass	Non-sensitizer
Irritation	Intracutaneous Reactivity Test	Pass	Non-irritant
Acute Systemic Toxicity	Acute Systemic Injection Test	Pass	No acute systemic toxicity
Material Mediated Pyrogenicity	Rabbit Pyrogen Test	Pass	Non-pyrogenic

Hemocompatibility	Thrombogenicity assessment, Direct and Indirect Hemolysis tests, and SC5b-9 Complement Activation test comparing subject device data with a comparator control	Pass	Acceptable
eCoil Implant (permanent implant with direct blood contact)			
Genotoxicity	-Bacterial Mutagenicity Test (Ames Assay) -In Vitro Mouse Lymphoma Assay - Chemical Characterization and Toxicological Risk assessment	Pass	Non- mutagenic / clastogenic and Acceptable toxicological risk assessment
Carcinogenicity	Chemical Characterization and Toxicological Risk assessment	Pass	Acceptable carcinogenicity risk assessment
Implantation	Intramuscular Implantation Test (Rabbits) with Histopathology	Pass	No significant difference comparing to the comparator

			Control.
Sub-Acute / Sub-Chronic	14-day, 14 repeat dose intravenous and intraperitoneal Toxicity Study in Mice, with Histopathology - Chemical Characterization and Toxicological Risk assessment	Pass	No systemic toxicity and Acceptable toxicological risk assessment
Animal Studies			
Animal Studies	Substantial equivalence of the subject device has been established to the predicate device through the results of the bench testing that was performed as well as the testing that was adopted from the predicate device.	N/A	N/A
Sterilization			
Bacterial Endotoxin	USP 85 / ASTM ST72	Pass	N/A
EO Residuals	10993-7:2008 (R) 2012 Part 7	Pass	N/A

Pyrogen	Mediated Rabbit Pyrogen	Pass	Non-pyrogenic
Package Integrity			
Dye Penetration Test	ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging	Pass	N/A
Bubble Testing	ASTM F2096	Pass	N/A
Environmental Conditioning	ASTM D4332	Pass	N/A
Shelf Life			
Accelerated Aging	ASTM F1960	Pass	Justifies 1-year shelf life
Clinical Study			
Clinical Study	No clinical study was performed as substantial equivalence of the subject device has been established to the predicate device through the results of the bench testing that was performed.	N/A	N/A