November 22, 2021

Spartan Micro, Inc.
Gary Avedovech
Senior Director Quality and Compliance
3167 Skyway Court
Fremont, California 94539

Re: K213451
Trade/Device Name: Spartan MC 0165
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY, KRA
Dated: October 25, 2021
Received: October 26, 2021

Dear Gary Avedovech:

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,

Naira Muradyan, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213451

Device Name
Spartan MC 0165™

Indications for Use *(Describe)*
The Spartan MC 0165™ is intended for the introduction of interventional devices or infusion of diagnostic agents into the neuro, peripheral and coronary vasculatures.

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

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c) and follows FDA guidance document titled *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],* Appendix B. *The 510(k) Summary Document Requirements*, issued July 28, 2014.

I. SUBMITTER

Spartan Micro, Inc.
3167 Skyway Court,
Fremont, CA 94539

Phone: 512-270-8501

Contact Person: Gary Avedovech
Date Prepared: November 20, 2021

II. DEVICE

Name of Device: Spartan MC 0165™
Common or Usual Name: Microcatheter
Regulatory Class: II
Product Codes:
- DQY Catheter, Percutaneous (21 CFR 870.1250)
- KRA Catheter, Continuous Flush (21 CFR 870.1210)
- QJP Catheter, Percutaneous, Neurovasculature (21 CFR 870.1250)

Review Panels: Cardiovascular, Neurology

III. PREDICATE DEVICE

Phenom Catheters
510(k) Number: K151638
Manufacturer: Cathera, Inc.

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Spartan MC 0165™ is a sterile single-use microcatheter device. On the proximal end is a Luer connector for infusion of diagnostic agents. The microcatheter has a single lumen of 0.0165" ID, has a flexible and variable stiffness composite body, and 2 radiopaque marker bands on the distal tip for visualization under fluoroscopy. It comes with a sterile stainless steel shaping mandrel to shape the distal portion of the catheter.

V. INDICATIONS FOR USE

Subject Device	Predicate
K213451	K151638
The Spartan MC 0165™ is intended for the introduction of interventional devices or infusion of diagnostic agents into the neuro, peripheral and coronary vasculatures.	The Phenom Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.

The Spartan MC 0165 is intended for introduction of interventional device *or* infusion of diagnostic agents whereas the predicate is intended for the introduction of interventional devices *and* infusion of diagnostic *or therapeutic* agents.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Dimensions	**Spartan MC 0165™ (K213451)**	**Phenom™ Catheter (17) (K151638)**
Proximal OD	0.031" (2.4F)	0.029" (2.2F)
Distal OD	0.024" (1.8F)	Same
ID	0.0165" (0.42mm)	0.017" (0.43mm)
Max Guidewire OD	≤ 0.014"	Same
Effective Length	158 cm	150 cm
Inner Lumen	Lined with PTFE	Same
Number of Lumens	Single	Same
Shaft	Progressively softer from proximal end to distal tip	Same

Materials	**Spartan MC 0165™ (K213451)**	**Phenom™ Catheter (17) (K151638)**
Shaft Materials	PTFE, Polyether block amide (Pebax) and Polyamide (Grilamid)	PTFE and Pebax
Hub	Polypropylene	Polyamide

Materials	Spartan MC 0165™ (K213451)	Phenom™ Catheter (17) (K151638)
Strain Relief	Liquid Silicone Rubber	Thermoplastic elastomer
Shaft Reinforcement	Nitinol braid	Metallic (Stainless Steel) reinforced
Marker Band	Radiopaque marker band	same
Tip Markers	Radiopaque Pt/Ir	radiopaque
Tip Shaping	Steam shapeable straight tip	Steam shapeable straight tip, and Pre-shaped 45°, 90°, and J
Coating	Distal 120cm hydrophilic	Distal 100cm hydrophilic

Packaging	Spartan MC 0165™ (K213451)	Phenom™ Catheter (17) (K151638)
Pouch Material	PET/Tyvek	PET/Tyvek
Pouch Dimensions	10”x10.5”	11” x 12”
Carton	Cardboard	Cardboard, solid bleach sulfate

Accessories	Spartan MC 0165™ (K213451)	Phenom™ Catheter (17) (K151638)
Shaping Mandrel	Yes	same
Introducer Sheath	No	No

Sterilization	Spartan MC 0165™ (K213451)	Phenom™ Catheter (17) (K151638)
Method	Ethylene Oxide (EO)	same
Shelf Life	1 year	36 Months

The differences in technological characteristics do not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA

Performance Data – Bench:

The following non-clinical bench testing was performed to evaluate the performance of the Spartan MC 0165™. The passing result of the testing supports the substantial equivalence to the predicate device.

Test	Test Method Summary	Results
Coating Lubricity (Friction Force)	The Spartan MC 0165™ and the predicate device were evaluated for coating lubricity	The Spartan MC 0165™ was found to have acceptable friction force under

Test	Test Method Summary	Results
	under simulated use conditions.	simulated use conditions similar to the predicate device.
Hub Functional & Dimensional	The Spartan MC 0165™ was evaluated per ISO 594-1:1986-06-15 First edition and ISO 594-2:1998-09-01 Second edition.	The Spartan MC 0165™ met the acceptance criteria for hub functional and dimensional requirements.
Torque Strength	The Spartan MC 0165™ was evaluated for torsional strength during use in a simulated path model.	The Spartan MC 0165™ exhibited acceptable torsional strength similar to the predicate device.
Tensile	The Spartan MC 0165™ was evaluated per ISO 10555-1:2013 Annex B.	The Spartan MC 0165™ met the acceptance criteria for tensile strength.
Air Aspiration	The Spartan MC 0165™ was tested for air leakage into the hub during aspiration per ISO 10555-1:2013(E) Annex D.	The Spartan MC 0165™ met the acceptance criteria for air aspiration.
Liquid Leak	The Spartan MC 0165™ was tested per ISO 10555-1:2013(E) Annex C.	The Spartan MC 0165™ met the acceptance criteria for liquid leakage.
Particulate and Coating Integrity	The Spartan MC 0165™ was evaluated under simulated use conditions and compared with the predicate device to support substantial equivalence. The coating integrity was also visually examined after testing.	The Spartan MC 0165™ met the acceptance criteria for particulate generation and coating integrity, and was found substantially equivalent to the predicate.
Tip Shape	The Spartan MC 0165™ was evaluated for its ability to retain steam shaped tip shape and results compared to the predicate device.	The Spartan MC 0165™ met the acceptance criteria for tip shapeability and was found substantially equivalent to the predicate.
Stiffness	A stiffness profile across the catheter length was measured and compared to the predicate device's stiffness profile.	The Spartan MC 0165™ met the acceptance criteria for catheter stiffness and was found substantially equivalent to the predicate.
Kink Resistance	The ability of the Spartan MC 0165™ to withstand bends	The Spartan MC 0165™ met the acceptance criteria for

Test	Test Method Summary	Results
	was measured at various points across the catheter length by bending the catheter shaft around sequentially smaller mandrels. Results were compared to test results from the predicate.	kink resistance and was found substantially equivalent to the predicate.
Radiopacity	The visibility of the Spartan MC 0165™ under fluoroscopy was compared to the predicate device.	The Spartan MC 0165™ met the acceptance criteria for radiopacity and was found substantially equivalent to the predicate.
Corrosion	The Spartan MC 0165™ was evaluated for corrosion per ISO 10555-1:2013(E) Annex A.	The Spartan MC 0165™ met the acceptance criteria for corrosion resistance.
Static Burst Pressure	The Spartan MC 0165™ was tested to evaluate the burst pressure under static conditions per ISO 10555-1:2013(E) Annex F.	The Spartan MC 0165™ met the acceptance criteria for static burst pressure.
Torque Response	The Spartan MC 0165™ was tested for its response to torque forces and results compared to the predicate device.	The Spartan MC 0165™ met the acceptance criteria for torque response and was found substantially equivalent to the predicate.
Buckling	The Spartan MC 0165™ was evaluated for its resistance to buckling and tip deflection properties and compared to the predicate device.	The Spartan MC 0165™ met the acceptance criteria for tip deflection and buckling, and was found substantially equivalent to the predicate.
Design Validation	The Spartan MC 0165™ was tested in a model representing a challenging use setting and evaluated against the predicate device for interventional device introduction, trackability, interaction with embolic coil, stability, guidewire interaction, and overall device integrity.	The Spartan MC 0165™ met the requirements for which it was designed and tested.

Test	Test Method Summary	Results
Dimensional Testing	Dimensional properties of the subject device were measured and compared to device specifications.	The Spartan MC 0165™ met the dimensional requirements.
Visual Inspection	The subject device was visually inspected and compared to acceptance criteria.	The Spartan MC 0165™ met the visual inspection requirements.
Dead Space Volume	The dead space volume was calculated following a dead space evaluation protocol.	The Spartan MC 0165™ dead space volume was measured. The dead space volume is reported in the labeling.
Pressure Flow Testing with Contrast Media	Flow pressure calculations were conducted following a protocol for 100% saline, 50% saline - 50% contrast media, and 100% contrast media solutions.	The Spartan MC 0165™ pressure-flow performance was evaluated. Flow rates and pressures of various saline and contrast media solutions are reported in the labeling.

Biocompatibility

The biocompatibility evaluation for the Spartan MC 0165™ microcatheter was conducted in accordance with the FDA guidance, "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process'," and ISO 10993-1: "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process." The device is categorized as a limited exposure (<24 hrs), external communicating device contacting circulating blood. Tests for the following biocompatibility endpoints were performed on the Spartan MC 0165™.

Test	Test Method Summary	Results
Effect: Sensitization Test Name: Kligman Maximization Test Standard: ISO 10993-10	Spartan MC 0165 elicited no reaction at the challenge (0% sensitization), following an induction phase. Therefore, as defined by the grading scale of the USP, the test article is classified as a non-sensitizer.	Non-sensitizer.
Effect: Genotoxicity Test Name: Mouse Lymphoma Mutagenesis Assay with confirmation Standard: ISO 10993-3	The IMF of Test Article for all conditions was less than the GEF of 126×10^{-6}. Therefore, the test article meets the requirements of the test and is considered non-mutagenic.	Non-mutagenic.
Effect: Genotoxicity Test Name: Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay without Confirmation Standard: ISO 10993-3	The results of primary assay (plate incorporation) showed that neither of the test article extracts induced a statistically significant increase in the number of revertant colonies as compared to the negative controls in both non-activated and activated conditions.	Non-genotoxic.
Effect: Cytotoxicity Test Name: L929 MEM Elution Test Standard: ISO 10993-5	The test article meets the requirements of the test and there were no cultures treated with the test article that showed greater than a Mild reactivity (Grade 2). Therefore, the test article is considered non-cytotoxic.	Non-cytotoxic.
Effect: Irritation/Intracutaneous Reactivity Test Name: Intracutaneous Injection Test Standard: ISO 10993-10	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article (mean score difference = 0). Based on the criteria of the protocol, the test article meets the requirements of the test.	Non-irritant.

Effect: Acute Systemic Toxicity Test Name: Systemic Injection Test Standard: ISO 10993-11	The extracts of test article did not induce a significantly greater biological reaction than the control extracts following a single dose to Albino Swiss mice. Therefore, the test article meets the requirements of the test.	No systemic toxicity.
Effect: Pyrogenicity Test Name: Rabbit Pyrogen Test (Material Mediated) Standard: ISO 10993-11 Continuing Testing: Limulus Amebocyte Lysate (LAL) Standard: USP <85>	The temperature increase for all the test animals was 0.0 ℃. The increases did not exceed the test limit for the maximum individual temperature rise. The temperature increase of the control animal was 0.0 ℃. Therefore, the test article meets the requirement of the test and is considered non-pyrogenic.	Non-pyrogenic.
Effect: Hemocompatibility Test Name: Rabbit Blood Hemolysis Test (Complete) Standard: ISO 10993-4	For direct contact and indirect contact testing, the Hemolysis above negative were 0.13% and 0%, respectively, both are < 5%. Therefore, the test article meets the requirements of the test and is considered non-hemolytic.	Non-hemolytic.

Effect: Hemocompatibility Test Name: Unactivated Partial Thromboplastin Time Test (Direct Contact) Standard: ISO 10993-4	There was no statistically significant decrease found between the Unactivated Partial Thromboplastin Time (UPTT) of the plasma exposed to the test article and that of the plasma exposed to both the negative control article and the untreated control. Based on the criteria of the protocol, the test article meets the requirements of the test, and is not considered to have an effect on coagulation of human plasma via measurement of the UPTT.	Hemocompatible.
Effect: Hemocompatibility Test Name: SC5B-9 Complement Activation Test (Direct Contact) Standard: ISO 10993-4	There was no statistically significant increase found between the SC5b-9 concentrations in the plasma exposed to the test article and that of the plasma exposed to both the negative control article and untreated control. Based on the criteria of the protocol, the test article meets the requirements of the test, and is not considered to have activated the complement system in human plasma.	Hemocompatible.
Effect: Hemocompatibility Test Name: In Vitro Blood Flow Loop Standard: ISO 10993-4	An in-vitro Blood Flow Loop Assay study was performed using both the subject device and predicate to evaluate their thrombogenic potential. All devices tested received a Thrombus Formation Score of zero which means Minimal to nonexistent thrombus formation (1% or less).	Not Thrombogenic.

Sterilization

The EO sterilization validation testing was performed with reference to ISO 11135:2014 under the guidance provided for the adoption of new products into an existing validated cycle. The validation followed the overkill (half cycle) approach and was performed to a Sterility Assurance Level of 10^{-6}.

Pyrogenicity

Tests for pyrogens and endotoxins have been performed yielding results of acceptable levels. The Rabbit Pyrogen Test was conducted to test for non-endotoxin pyrogens and the LAL (Limulus Amebocyte Lysate) or BET (Bacterial Endotoxin Test) was conducted to test for bacterial endotoxins.

Shelf Life

Accelerated aging equivalent to 1-year real time was performed on devices and tested to validate the shelf life. The Arrhenius Equation formed the basis of rationale for the aging parameters selected (55 °C, 38 days) to achieve the 1-year equivalent in accelerated aging. The packaged devices were also subjected to simulated shipping and then tested thoroughly to ensure they remain safe and effective after at least 1 year.

Performance Data – Animal:

No animal testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness.

Performance Data – Clinical:

No clinical testing was conducted. The differences in technological characteristics do not raise new questions of safety and effectiveness.

VIII. CONCLUSION

The differences in technological characteristics between the subject and the predicate devices do not raise new questions of safety and effectiveness. The non-clinical bench testing using well-established scientific methods demonstrates that the subject device performs similar to the predicate device. The information provided in this submission supports a determination of substantial equivalence for the Spartan MC 0165™.