May 5, 2022

Spartan Micro, Inc.
Gary Avedovech
Senior Director Quality and Compliance
3184 Airway Avenue, Suite C
Costa Mesa, California 92626

Re: K220716
Trade/Device Name: Spartan SC 069
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: March 10, 2022
Received: March 11, 2022

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)*
K220716

Device Name
Spartan SC 069™

Indications for Use *(Describe)*
The Spartan SC 069™ is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

[X] 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

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.
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Costa Mesa, CA 92626

Phone: 949-409-8581

Contact Person: Gary Avedovech
Date Prepared: May 4, 2022

II. DEVICE

Name of Device: Spartan SC 069™
Common or Usual Name: Support Catheter
Regulatory Class: II
Product Codes:
- DQY Percutaneous catheter (21 CFR 870.1250)
- QJP Percutaneous catheter, neurovasculature (21 CFR 870.1250)

Review Panel: Cardiovascular, Neurology

III. PREDICATE and REFERENCE DEVICES

Predicate: React™ 68 Catheter
510(k) Number: K180715
Manufacturer: Micro Therapeutics, Inc. d/b/a/ ev3 Neurovascular
This device has not been subject to a design-related recall.

Reference: Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter
510(k) Number: K150107
Manufacturer: Micro Therapeutics, Inc. d/b/a/ ev3 Neurovascular
This device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Spartan SC 069™ is a support catheter designed for the introduction of interventional devices into the peripheral and neuro vasculature. The SC 069™ is a single lumen, flexible, variable stiffness composite catheter with a Nitinol structure. A radiopaque marker band on the distal tip of the device is used for visualization under fluoroscopy. The distal section of the catheter is coated with a hydrophilic coating to reduce the overall frictional force during intravascular use. The device is supplied sterile and intended for single use only.

V. INDICATIONS FOR USE

Subject Device	Predicate	Reference
K220716; DQY, QJP	K180715; DQY	K150107; DQY
The Spartan SC 069™ is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The React™ 68 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	The Arc™ Intracranial Support Catheter and Arc™ Mini Intracranial Support Catheter are indicated for the introduction of interventional devices into the peripheral and neurovasculature.

The indications for use are the same for the subject device and the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

Dimensions	**Spartan SC 069™**	**React™ 68 Catheter (K180715)**	**Arc™ Intracranial Support Catheter (K150107)**
Proximal OD	0.0815”	0.083”	0.0825”
Distal OD	0.0815”	0.083”	0.071”
Proximal ID	0.069”	0.068”	0.069”
Distal ID	0.069”	0.068”	0.061”
Effective Length	95, 115, 133 cm	132 cm	132 – 135 cm
Inner Lumen	PTFE lined	same	same
Number of Lumens	Single lumen	same	same
Coating Length	60cm	40cm	unknown

Materials	**Spartan SC 069™**	**React™ 68 Catheter (K180715)**	**Arc™ Intracranial Support Catheter (K150107)**
Shaft Materials	Tecothane and polyether block amide	Grilamid™ Pebax®	Polymetric plastic material
Hub	Polycarbonate	Trogamid	unknown
Strain Relief	RNF	DynaFlex	unknown
Shaft Reinforcement	Nitinol	same	same
Marker Band	Platinum/Iridium	Platinum/Iridium	Platinum
Coating	Hydrophilic	same	same

Packaging	**Spartan SC 069™**	**React™ 68 Catheter (K180715)**	**Arc™ Intracranial Support Catheter (K150107)**
Pouch Material	PET/PE/Tyvek	same	same
Packaging Card	HDPE	Polyethylene	same
Packaging Hoop	HDPE	Polyethylene	same

Sterilization	**Spartan SC 069™**	**React™ 68 Catheter (K180715)**	**Arc™ Intracranial Support Catheter (K150107)**
Method	Ethylene Oxide (EO)	same	same
Shelf Life	2 years	3 months*	6 months

*Shelf life based on Riptide Aspiration System (React 68 Catheter) per K180705.

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

VII. PERFORMANCE DATA

Performance Data – Bench:

The following non-clinical bench testing was performed to evaluate the performance of the Spartan SC 069™. The passing result of the testing supports the substantial equivalence to the predicate.

Test	Test Method Summary	Results
Coating Lubricity (Friction Force)	The Spartan SC 069™ and the predicate device were evaluated for coating lubricity under simulated use conditions.	The Spartan SC 069™ was found to have acceptable friction force under simulated use conditions similar to the predicate device.
Hub Functional & Dimensional	The Spartan SC 069™ was evaluated per ISO 594-1:1986-06-15 First edition and ISO 594-2:1998-09-01 Second edition.	The Spartan SC 069™ met the acceptance criteria for hub functional and dimensional requirements.
Torque Strength	The Spartan SC 069™ was evaluated for torsional strength during use in a simulated path model.	The Spartan SC 069™ exhibited acceptable torsional strength similar to the predicate device.
Tensile	The Spartan SC 069™ was evaluated per ISO 10555-1:2013 Annex B.	The Spartan SC 069™ met the acceptance criteria for tensile strength.
Air Aspiration	The Spartan SC 069™ was tested for air leakage into the hub during aspiration per ISO 10555-1:2013(E) Annex D.	The Spartan SC 069™ met the acceptance criteria for air aspiration.
Liquid Leak	The Spartan SC 069™ was tested per ISO 10555-1:2013(E) Annex C.	The Spartan SC 069™ met the acceptance criteria for liquid leakage.
Particulate and Coating Integrity	The Spartan SC 069™ 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 SC 069™ met the acceptance criteria for particulate generation and coating integrity, and was found substantially equivalent to the predicate.
Stiffness	A stiffness profile across the catheter length was measured and compared to the predicate device stiffness profile.	The Spartan SC 069™ met the acceptance criteria for catheter stiffness and found substantially equivalent to the predicate.

Test	Test Method Summary	Results
Kink Resistance	The ability of the Spartan SC 069™ to withstand bends 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.	The Spartan SC 069™ met the acceptance criteria for kink resistance and was found substantially equivalent to the predicate.
Radiopacity	The visibility of the Spartan SC 069™ under fluoroscopy was compared to the predicate device.	The Spartan SC 069™ met the acceptance criteria for radiopacity and was found substantially equivalent to the predicate.
Corrosion	The Spartan SC 069™ was evaluated for corrosion per ISO 10555-1:2013(E) Annex A.	The Spartan SC 069™ met the acceptance criteria for corrosion resistance.
Static Burst Pressure	The Spartan SC 069™ was tested to evaluate the burst pressure under static conditions per ISO 10555-1:2013(E) Annex F.	The Spartan SC 069™ met the acceptance criteria for static burst pressure.
Buckling	The Spartan SC 069™ was evaluated for its resistance to buckling and tip deflection properties and compared to the predicate device.	The Spartan SC 069™ met the acceptance criteria for tip deflection and buckling and was found substantially equivalent to the predicate.
Design Validation	The Spartan SC 069™ was tested in a model representing a challenging use setting and evaluated against the predicate device on interventional device introduction, trackability, stability, guidewire interaction, and overall device integrity.	The Spartan SC 069™ 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 SC 069™ met the dimensional requirements.
Visual Inspection	The subject device was visually inspected and compared to acceptance criteria.	The Spartan SC 069™ met the visual inspection requirements.
Dead Space Volume	The dead space volume was calculated following a dead space evaluation protocol.	The Spartan SC 069™ 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 SC 069™ 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 SC 069™ support catheter was conducted in accordance with the FDA guidance, "Use of International Standard ISO 10993-1, '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 SC 069™.

Test	Test Method Summary	Results
Effect: Sensitization Test Name: Guinea Pig Maximization Test Standard: ISO 10993-10	Spartan SC 069 elicited no reaction at the challenge following an induction phase. Therefore, as defined by the acceptance criteria the test article is classified as a non-sensitizer.	Non-sensitizer.

Test	Test Method Summary	Results
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	No reactivity was observed until 72 hours; therefore, no cell lysis or reduction of cell growth was observed in the triplicate wells at 24 and 48 hours. The test article meets the requirements of the test. Therefore, the test article is considered as 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. 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. Therefore, the test article meets the requirements of the test.	No systemic toxicity.

Test	Test Method Summary	Results
Effect: Pyrogenicity Test Name: Rabbit Pyrogen Test (Material Mediated) Standard: ISO 10993-11 Continuing Testing: Limulus Amebocyte Lysate (LAL) Standard: USP <85> Bacterial Endotoxin Test	The temperature increases for the test animals did not exceed the test limit for the maximum individual temperature rise. Therefore, the test article meets the requirement of the test to be 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% and 0%, respectively. Both are <5% which is the threshold for acceptance.	Non-hemolytic.

Effect: Hemocompatibility Test Name: Partial Thromboplastin Time Test (Direct Contact) Standard: ISO 10993-4	The study was conducted in compliance to ASTM International F2382-18: Standard Test Method for Assessment of Circulating Blood- Contacting Medical Device Materials on Partial Thromboplastin Time (PTT). When comparing the test article clotting time to the comparison article clotting time with ANOVA, the results for the test article and the comparison article are not significantly different from each other. • The test article average clot time was greater than the vehicle control.	Hemocompatible.

Test	Test Method Summary	Results
	• The test article average clot time was not significantly different ($p \geq 0.05$) from the vehicle control.	
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: Platelet and Leukocyte Binding Test (Direct Contact) – ISO Standard: ISO 10993-4	The reduction of human platelets and leukocytes were studied to assess the ability of the test and comparison article to induce thrombus formation. The test article, based on criteria of the protocol, is not considered to have an effect on platelet and leukocyte concentrations.	Hemocompatible.

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 2-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, 75 days) to achieve the 2-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 2 years.

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 device 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 SC 069™.