April 19, 2022

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

Re: K220075
Trade/Device Name: Spartan Center Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 15, 2022
Received: March 21, 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,

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*
K220075

Device Name
Spartan Center Wire™

Indications for Use *(Describe)*
The Spartan Center Wire™ is indicated for general intravascular use in the peripheral vasculature. It can be deployed into the vessel to facilitate the selective placement of diagnostic or therapeutic catheters.

The device is not intended for use in the coronary or neuro 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.

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.
3184 Airway Ave, Suite C
Costa Mesa, CA 92626
Phone: 512-270-8501

Contact Person: Gary Avedovech

Date Prepared: April 18, 2022

II. DEVICE

Device Name: Spartan Center Wire™
Common Name: Catheter Guide Wire
Regulatory Class: II
Product Code: DQX
Regulation Description: Catheter Guide Wire
Regulation Number: 21 CFR 870.1330
Review Panel: Cardiovascular

III. PREDICATE DEVICE

Name: Transend™ 300 Floppy Guidewire, Model 46-815
510(k) Number: K022357
Manufacturer: Boston Scientific, Target

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

Reference Device: Solitaire™ Platinum Revascularization Device
510(k) Number: K193576
Product Codes: POL, NRY

Regulation: 882.5600
Regulation Name: Neurovascular Mechanical Thrombectomy Device for Acute Ischemic Stroke Treatment

IV. DEVICE DESCRIPTION

The Spartan Center Wire™ is a stabilizing exchange wire designed for temporary assistance in catheter exchange. The device is comprised of a tubular mesh tip attached to a pusher wire of adequate length to accommodate the exchanging of catheters commonly used for access, stabilization, or aspiration. The pusher wire diameter is 0.015" (0.38 mm) with length 350 cm to allow for the exchange of therapeutic devices without the use of extension wires or other exchange devices. The distal end is a permanently attached self-expanding mesh that is deployed out of an introducer sheath and into the vessel where it conforms to the vessel wall. There are 3 distal radiopaque markers and 1 proximal radiopaque marker visible under fluoroscopy. The deployed and stable mesh ensures that the wire is not displaced from the desired position and can be advantageously utilized in multiple exchanges or re-positioning of catheters. The Spartan Center Wire™ is offered in 2 available sizes to accommodate common vascular sizing. There is a 4 mm diameter basket with 15 mm useable length and a 6 mm basket with 30 mm useable length. Both sizes are compatible with catheters that have a minimum I.D. of 0.027".

V. INDICATIONS FOR USE

Spartan Center Wire™	Predicate K022357 Transend™ 300 Floppy Guidewire, Model 46-815
The Spartan Center Wire™ is indicated for general intravascular use in the peripheral vasculature. It can be deployed into the vessel to facilitate the selective placement of diagnostic or therapeutic catheters. The device is not intended for use in the coronary or neuro vasculature.	The Transend™ 300 ES Guidewire and Transend™ 300 Floppy Guidewire are intended for general intravascular use, including the neuro and peripheral vasculature. The guidewires can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. These devices are not intended for use in coronary arteries. A torque device (pin vise) is included to facilitate directional manipulation of the guidewires.

The Spartan Center Wire™ is indicated for use in the peripheral vasculature while the Transend™ 300 Floppy Guidewire is for use in the peripheral and neuro vasculature.

No torque device is needed or supplied with the Spartan Center Wire™.

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

Dimensions	**Spartan Center Wire™**	**Transend™ 300 Floppy Guidewire (K022357)**	**Solitaire™ Platinum Revascularization Device (K193576)**
Diameter (wire)	0.015”	0.014”	0.016”
Length	350 cm	300 cm	180 cm
Distal Mesh Diameter, Expanded	4mm 6mm	n/a (no distal mesh)	4mm 6mm
Distal Mesh Length, Expanded	15mm 30mm	n/a (no distal mesh)	20mm 24mm 40mm

Materials	**Spartan Center Wire™**	**Transend™ 300 Floppy Guidewire (K022357)**	**Solitaire™ Platinum Revascularization Device (K193576)**
Pusher Wire	NiTi, SS	SS	NiTi
Marker Bands	Pt90/Ir10	Pt	Pt90/Ir10
Sheath	PET, Nylon12, PTFE	Polytetrafluoroethylene, polyurethane	PTFE/Grilamid
Coating	None.	Lubricious coating	None.
Distal Mesh	NiTi, 316 SS, Loctite 3972	None.	Nitinol

Packaging	Spartan Center Wire™	Transend™ 300 Floppy Guidewire (K022357)	Solitaire™ Platinum Revascularization Device (K193576)
Pouch Material	PET/Tyvek	Not Listed	Not Listed
Pouch Dimensions	10”x10.5”	Not Listed	Not Listed
Carton	Cardboard	Not Listed	Not Listed

Accessories	Spartan Center Wire™	Transend™ 300 Floppy Guidewire (K022357)	Solitaire™ Platinum Revascularization Device (K193576)
Torque Aid	None	Pin Vise	None

Sterilization	Spartan Center Wire™	Transend™ 300 Floppy Guidewire (K022357)	Solitaire™ Platinum Revascularization Device (K193576)
Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)
Shelf Life	1 year	Not Listed	Not Listed

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 Center Wire™. The passing result of the testing supports the substantial equivalence to the predicate device.

Test	Test Method Summary	Results
Simulated Use Testing	The Spartan Center Wire™ was tested in a model representing a challenging use setting and evaluated against the predicate or reference device for: -Device introduction into the microcatheter (compared with Solitaire Platinum) -Device Trackability (compared with Solitaire Platinum) -Device Deployment (compared with Solitaire Platinum) -Device Retraction (compared with Solitaire Platinum) -Device Stability During Exchange (compared to Transend 300 Floppy) -Device Retrieval (compared to Transend 300 Floppy) -Device Integrity (compared to Transend 300 Floppy)	The Spartan Center Wire™ met the requirements for which it was designed and tested.
Simulated Shipping and Packaging Testing	The Spartan Center Wire™ was evaluated for packaging integrity and ability to withstand shipping and distribution.	The Spartan Center Wire™ met the acceptance criteria.
Dimensional Inspection	Dimensional properties of the subject device were measured and compared to device specifications.	The Spartan Center Wire™ met the dimensional requirements.
Visual Inspection	The subject device was visually inspected and compared to acceptance criteria.	The Spartan Center Wire™ met the visual inspection requirements.

Test	Test Method Summary	Results
Af Temperature	The Af temperature of the subject device was measured.	The Spartan Center Wire™ met the Af temperature requirements.
Chronic Outward Force	The Spartan Center Wire™ chronic outward force was measured at a minimum vessel diameter.	The Spartan Center Wire™ met the acceptance criteria for Chronic Outward Force.
Tensile Test	The Spartan Center Wire™ was evaluated for tensile strength performance.	The Spartan Center Wire™ met the acceptance criteria for tensile strength.
Tip Pull	The Spartan Center Wire™ distal tip was evaluated for tensile strength.	The Spartan Center Wire™ met the acceptance criteria for tip pull.
Corrosion Resistance	The Spartan Center Wire™ was evaluated for corrosion per ISO 11070.	The Spartan Center Wire™ met the acceptance criteria for corrosion resistance.
Kink Resistance	The ability of the Spartan Center Wire™ to withstand bends was measured at various points across the guidewire length by bending around sequentially smaller mandrels.	The Spartan Center Wire™ met the acceptance criteria for kink resistance.
Torque Strength	The Spartan Center Wire™ was evaluated for torsional strength during use in a simulated path model.	The Spartan Center Wire™ exhibited acceptable torsional strength.

Test	Test Method Summary	Results
Particulate Evaluation	The Spartan Center Wire™ was evaluated under simulated use conditions and compared with the predicate device to support substantial equivalence.	The Spartan Center Wire™ met the acceptance criteria for particulate generation and was found substantially equivalent to the predicate.
Flex Test	The Spartan Center Wire™ was evaluated for resistance to damage by flexing per ISO 11070.	The Spartan Center Wire™ met the acceptance criteria.
Fracture Test	The Spartan Center Wire™ was evaluated for guidewire resistance to fracture per ISO 11070.	The Spartan Center Wire™ met the acceptance criteria.
Radiopacity	The visibility of the Spartan Center Wire™ under fluoroscopy was compared to the predicate device.	The Spartan Center Wire™ met the acceptance criteria for radiopacity and was found substantially equivalent to the predicate.

Biocompatibility

The biocompatibility evaluation for the Spartan Center Wire™ was conducted in accordance with the FDA guidance, "Use of International Standard ISO10993, '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 Center Wire™.

Test	Test Method Summary	Results
Effect: Sensitization Test Name: Kligman Maximization Test Standard: ISO 10993-10	Spartan Center Wire™ 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 showed greater than a Mild reactivity (Grade 2). Therefore, the test article is considered as noncytotoxic.	Non-cytotoxic.

Test	Test Method Summary	Results
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 0.2 ℃. Therefore, the test article meets the requirement of the test and to be considered nonpyrogenic.	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 0.20% and 0%, respectively. Both are < 5%. Therefore, the test article meets the requirements of the test and is considered non-hemolytic.	Non-hemolytic.

Test	Test Method Summary	Results
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: Dog Thrombogenicity Standard: ISO 10993-4	The test article implanted in 2 dogs did not show significant thrombosis unlike the control article.	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 nonendotoxin 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 (60 °C, 27 days) to achieve the 1year equivalent in accelerated aging. The packaged devices were also subjected to simulated shipping and then tested thoroughly to ensure they remain as safe and effective as the predicate device after at least 1 year.

Performance Data – Animal

The substantial equivalence of the Spartan Center Wire™ was demonstrated through use in a live porcine model. A comparison side by side with the predicate device and reference device support that the Spartan Center Wire™ is substantially equivalent.

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 Center Wire™.