February 19, 2020

Boston Scientific Corporation
Eric Elliott
Regulatory Affairs Manager
Three Scimed Place
Maple Grove, Minnesota 55311-1566

Re: K192460
Trade/Device Name: Sentinel Cerebral Protection System
Regulation Number: 21 CFR 870.1251
Regulation Name: Temporary Catheter for Embolic Protection During Transcatheter Intracardiac Procedures
Regulatory Class: Class II
Product Code: PUM
Dated: January 17, 2020
Received: January 21, 2020

Dear Mr. Elliott:

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,

Jaime Raben, Ph.D.
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192460

Device Name
Sentinel Cerebral Protection System

Indications for Use *(Describe)*

The Sentinel Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid.

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.

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510(k) Summary
per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Eric Elliott Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-1654
Date Prepared	September 06, 2019
Proprietary Name	Sentinel™ Cerebral Protection System
Common Name	Temporary catheter, embolic protection, transcatheter intracardiac procedures
Product Code	PUM
Classification	Class II, 21 CFR Part 870.1251
Predicate Device	Sentinel Cerebral Protection System DEN160043 June 1, 2017

Device Description

The Sentinel™ Cerebral Protection System (Sentinel CPS) is a 6 French, 95 cm working length, single use, temporary, percutaneously delivered embolic protection device, inserted into the radial or brachial artery. The system is designed to capture and remove debris dislodged during transcatheter aortic valve replacement (TAVR) procedures. The Sentinel CPS utilizes an embolic filter delivered to the brachiocephalic artery (Proximal Filter) and a second embolic filter delivered to the left common carotid artery (Distal Filter). At the completion of the procedure, the filters and debris are recaptured into the catheter and removed from the patient. The device is provided sterile and is single-use only.

The Sentinel CPS is available with a Proximal Filter size of 15 mm (target vessel size of 9 – 15 mm) and a Distal Filter size of 10 mm (target vessel size of 6.5 – 10 mm).

Indications for Use / Intended Use

The Sentinel Cerebral Protection System is indicated for use as an embolic protection device to capture and remove thrombus/debris while performing transcatheter aortic valve replacement procedures. The diameters of the arteries at the site of filter placement should be between 9 – 15 mm for the brachiocephalic and 6.5 – 10 mm in the left common carotid.

Comparison of Technological Characteristics

Replacement of filter film polyurethane material with a similar polyurethane is required due to material obsolescence by the supplier. Comparisons of the new and currently marketed predicate device cleared under DEN160043 show that the technological characteristics such as filter performance, materials, design, sterilization, packaging, and intended use/ indications for use are substantially equivalent. The subject Sentinel Cerebral Protection System indications for use, design, and principles of operation are identical to the currently marketed predicate cleared under DEN160043.

Non-clinical Performance Data

Modifications to the predicate device were assessed according to risk-based failure mode effects analysis and with consideration of FDA Guidance, *Coronary and Carotid Embolic Protection Devices – Premarket Notification [510(k)] Submission* (issued February 15, 2008). The following non-clinical testing was successfully completed on the modified device.

- Simulated Use Proximal and Distal Filter Deployment Force
- Simulated Use Proximal and Distal Filter Retrieval Force
- Dimensional Verification – Filter Pore Size
- Tensile Characterization – Filter Film
- Shelf Life Evaluation

Testing demonstrated that the modified Sentinel Cerebral Protection System met all previously established acceptance criteria. No new safety or effectiveness issues were raised during verification and validation activities; thereby supporting a determination of substantial equivalence.

Biocompatibility testing was also assessed with consideration of evaluation recommendations per ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: *Evaluation and testing within a risk management process* and FDA Guidance on ISO 10993-1 (issued June 16, 2016) for devices categorized as externally communicating with limited (<24 hours) direct circulating blood contact. The following is a list of biocompatibility tests conducted on the modified Sentinel Cerebral Protection System.

- MEM Elution Cytotoxicity
- Guinea Pig Maximization Sensitization
- Intracutaneous Reactivity
- Acute Systemic Injection
- Material Mediated Rabbit Pyrogen
- Hemolysis (direct and extract methods)
- Complement Activation (SC5b-9 method)
- USP Physiochemical test <661>
- Natural Rubber Latex ELISA Inhibition Assay for Antigenic Protein
- Partial Thromboplastin Time (PTT)
- Platelet/Leucocyte testing

Results confirm that the modified device remains biocompatible for its intended use.

Conclusion

Successful design verification and biocompatibility testing support substantial equivalency of the Sentinel Cerebral Protection System to the currently marketed predicate device. There were no new safety or effectiveness issues raised during verification and testing activities.