July 28, 2020

Boston Scientific Corporation
Ms. Aoife Tobin
Senior Regulatory Affairs Specialist
3 Scimed Place
Maple Grove, Minnesota 55311

Re: K201792
Trade/Device Name: TRUSELECT™ Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: June 29, 2020
Received: June 30, 2020

Dear Ms. Tobin:

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,

Gregory O'Connell
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201792

Device Name
TRUSELECT™ Microcatheter

Indications for Use *(Describe)*
The TRUSELECT™ Microcatheters are intended for peripheral vascular use. The microcatheter can be used for selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

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

510(k) Summary Complying with 21 CFR 807.92

I. SUBMITTER INFORMATION

Submitter name: Boston Scientific Corporation

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Contact person name: Aoife Tobin
Date Prepared: July 27, 2020

II. DEVICE INFORMATION

Trade Name: TRUSELECT™ Microcatheter

Table 1 and 2 as follows summarizes the relevant device information for the subject devices.

Table 1. TRUSELECT™ Microcatheter Name of Devices

UPN	GTIN	Product Description
M001394101050	08714729976608	TRUSELECT™ 105cm Straight Tip
M001394101300	08714729976615	TRUSELECT™ 130cm Straight Tip
M001394101550	08714729976622	TRUSELECT™ 155cm Straight Tip
M001394101750	08714729976639	TRUSELECT™ 175cm Straight Tip
M001394111050	08714729976646	TRUSELECT™ 105cm Bern Tip
M001394111300	08714729976653	TRUSELECT™ 130cm Bern Tip
M001394111550	08714729976660	TRUSELECT™ 155cm Bern Tip
M001394111750	08714729976677	TRUSELECT™ 175cm Bern Tip

Table 2 Additional Device Information

Common or Usual Name	Classification Number	Classification Name	Product Code	Product Code Name	Regulatory Class
Microcatheter	21 CFR Part 870.1210	Continuous Flush Catheter	KRA	Continuous Flush Catheter	II

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device

Direxion™ Microcatheter, K163701

Predicate devices referenced above have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The TRUSELECT™ Microcatheter is a low profile 2.0F microcatheter intended for use in the peripheral vasculature. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the sub-selective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels.

Diagnostic, therapeutic and embolic agents such as heparinized saline, contrast media, chemotherapy agents such as doxorubicin and irinotecan, polyvinyl alcohol (PVA) flakes and polymer and hydrogel spherical embolics (microspheres) can be delivered to targeted vessels. The microcatheter maintains chemotherapy chemical compatibility.

It has a straight internal diameter design (021" ID, (0.53 mm)) with a 2.0F OD tapered tip. The microcatheter includes eight UPNs, covering a range of lengths (105, 130, 155 and 175cm) and tip shapes (straight or bern), and is compatible with 0.040" ID guide catheters and 0.014" & 0.016" guidewires. It is compatible with embolic particles of up to 700 microns and 0.018" (0.46 mm) embolic coils.

The TRUSELECT™ Microcatheters are provided sterile, using 100% ethylene oxide (EO) gas sterilization, and are intended for hospital and single use only. These devices utilize HydroPass Hydrophillic Coating for the reduction of surface friction during placement.

V. INDICATIONS FOR USE

The TRUSELECT™ Microcatheters are intended for peripheral vascular use. The microcatheter can be used for selective infusion of diagnostic, embolic, or therapeutic materials into the vessel

Predicate and subject device Intended use and Indications for Use are the same.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

There are differences in the technological characteristics between the predicate and subject devices. However, the differences in materials, dimensions and packaging, as documented in the following table, do not raise new questions of safety and effectiveness in comparison to the predicate device (K163701).

Materials	Catheter shaft materials and coating differ from the predicate.
Dimensions	The catheter is available in an additional length, 175cm, compared to the predicate. The outer diameter of the subject device distal tip is 2.0 Fr compared to the predicate outer tip diameter of 2.4 Fr.
Packaging	The predicate device also uses a mounting card in addition to the carrier tube assembly to contain the microcatheter in the pouch.

The purpose of this 510(k) submission is to receive clearance for the different technological differences between the subject and predicate devices.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing.

The following biocompatibility tests were completed on the TRUSELECT™ Microcatheter:

Cytotoxicity ISO 10993-5
Sensitization ISO 10993-10
Irritation ISO 10993-10
Material Mediated Pyrogenicity ISO 10993-11
Acute Systemic Toxicity ISO 10993-11
Hemocompatibility ISO 10993-4
Genotoxicity ISO 10993-3

The following in-vitro performance tests were completed for the TRUSELECT™ Microcatheter:

Catheter Design / Material Changes	Manifold Connection
	Guidewire Compatibility
	Guide Catheter Compatibility
	Proximal OD/ Outside Diameter
	Catheter ID
	Microcatheter Coating Lubricity & Durability
	Microcatheter Coating Length
	Distal End Flexibility (Distal 5cm)
	Proximal End Stiffness
	Proximal Shaft Kink

	Distal Shaft Kink
	Effective Length
	Tip OD
	Steam Shaping Mandrel Compatibility
	Shapability
	Infusion Stability
	Marker Band Location/Tip Length
	Microcatheter to Microspheres Compatibility
	Microcatheter to PVA particle Compatibility
	Microcatheter to Gelfoam Compatibility
	Microcatheter to .018 Embolic Coil Compatibility
	Dead Space Volume
	Max Infusion Pressure (Dynamic Burst)
	Static Burst
	Chemical Compatibility
	Flow Rate
	Marker Band Tensile
	Full Catheter Tensile
	Tip Tensile
	Tip Shape
	Particulate Matter
	Corrosion Resistance

VIII. CONCLUSION

Based on the intended use, technological characteristics, and non-clinical performance data provided, the TRUSELECT™ Microcatheter is substantially equivalent to the predicate device K163701. The design and material changes for the subject device do not raise new questions of safety or effectiveness.