April 23, 2021

Boston Scientific Corporation
Lingling Guo
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K211072
Trade/Device Name: Safety Trocar Cannula
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 9, 2021
Received: April 12, 2021

Dear Lingling Guo:

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,

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K211072

Device Name
Safety Trocar Cannula

Indications for Use *(Describe)*
The Safety Trocar Cannula is intended to be used for guidewire introduction during gastrointestinal procedures such as PEG (percutaneous Endoscopic Gastrotomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

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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SECTION 5
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Lingling Guo
Senior Regulatory Affairs Specialist
Tel: (508) 382-0456
Date Prepared: April 9, 2021

2. Proposed Device:

Trade Name: Safety Trocar Cannula
Classification Name: Gastrointestional Tube and Accessories
Regulation Number: 21CFR §876.5980
Product code: KNT
Classification: Class II

3. Predicate Device:

Trade Name: Modified TFX Medical Safety Needle with Introducer
Classification Name: Gastrointestional Tube and Accessories
Regulation Number: 21CFR §876.5980
Product code: KNT
Classification: Class II
510(k) Clearance Number: K043258

4. Device Description:

The Safety Trocar Cannula is a sterile, single use needle used for guidewire introduction during a gastrointestinal procedure. The device consists of a safety trocar with passive sharps protection and a cannula.

During a gastrointestinal procedure requiring access via a guidewire, the device is inserted into the stomach under direct visualization via an endoscope. Once inserted, the safety trocar is removed from the cannula that provides smooth surface for the needle to slide out during removal as well as a lumen to facilitate guidewire introduction. The passive safety feature of the proposed Safety Trocar Cannula is activated when the safety trocar is separated from the cannula.

5. Indications for Use:

The Safety Trocar Cannula is indicated to be used for guidewire introduction during gastrointestinal procedures such as PEG (percutaneous Endoscopic Gastrotomy), PEJ (Percutaneous Endoscopic Jejunostomy) or other endoscopic gastrointestinal procedures requiring placement of a guidewire.

6. Technological Characteristics:

The proposed Safety Trocar Cannula and the predicate device are both sterile, single use devices. They are identical with regard to principle of operation, materials, needle characteristics, sheath ID, sheath OD, and offer identical passive sharps protection. The proposed and predicate device both offer a non-peelable insertion sheath that fits over the needle and allows the needle to extend past the needle.

7. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed Safety Trocar Cannula is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics.

8. Performance Data:

The Safety Trocar Cannula was evaluated via bench top testing, biocompatibility testing, and sterilization testing.

The following tests were performed on the Safety Trocar Cannula:

- Sheath Stiffness
- Sheath Outer Diameter (OD)
- Device Functionality
- Sheath Inner Diameter (ID) - Needle Compatibility
- Sheath to Sheath Hub Tensile Strength
- Cover Tube Tensile Strength
- Needle Tube to Needle Hub Bond Strength
- Sheath/Sheath Hub to Needle/Needle Hub Connection
- Needle Tip Puncture Optimization
- Sheath Inner Diameter (ID) - Accessory Compatibility
- Sheath Lie Distance
- ISO 9626
- ISO 23908

The Safety Trocar Cannula met all pre-defined testing requirements. The testing performed demonstrates that the Safety Trocar Cannula meets the performance requirements and is substantially equivalent to the predicate, Modified TFX Medical Safety Needle with Introducer (K043258)

The Safety Trocar Cannula meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals",

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Safety Trocar Cannula sufficiently meets design requirements and is substantially equivalent to the currently cleared Modified TFX Medical Safety Needle with Introducer (K043258) and can be safely and effectively used for its proposed indication.