DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 30, 2016

Boston Scientific Corporation
Michael Secondini
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K160637
Trade/Device Name: Rotatable Snares
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI, FGX
Dated: March 4, 2016
Received: March 7, 2016

Dear Michael Secondini,

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160637

Device Name
Rotatable Snare s

Indications for Use *(Describe)*
The Rotatable Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

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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Section 5: 510(K) Summary

1. **Submitter**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact:	Michael Secondini
	Sr. Regulatory Affairs Specialist
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Date Prepared: March 4, 2016

2. **Device**

Trade Name:	Rotatable Snares
Common Name:	Rotatable Snares
Classification Name:	Snare, Flexible
	Snare, Non-Electrical
Regulation Number:	876.4300
	876.4730
Product Code:	FDI
	FGX
Classification:	Class II

3. **Predicate Device**

Trade Name:	Rotatable Snares
Common Name:	Rotatable Snares
Manufacturer:	Boston Scientific Corporation
Clearance Numbers:	K131700
Classification Name:	Snare, Flexible
	Snare, Non-Electrical
Regulation Number:	876.4300
	876.4730
Product Code:	FDI
	FGX
Classification:	Class II

Boston Scientific

4. Reference Device

Trade Name:	Single Use Polypectomy Snares
	Captivator II, Single Use Polypectomy Snares
Common Name:	Polypectomy Snares
Manufacturer:	Boston Scientific Corporation
Clearance Numbers:	K133987
Classification Name:	Snare, Flexible
	Snare, Non-Electrical
Regulation Number:	876.4300
	876.4730
Product Code:	FDI
	FGX
Classification:	Class II

5. Device Description

The Rotatable Snare consists of a flexible wire cable (core wire) and loop which can be extended and retracted from the Snare's flexible outer sheath using a three-ring handle. The flexible cable and loop can also be rotated 360° using the rotation actuator on the handle. The inner diameter of the sheath is Polyglide™ coated to provide minimal friction during extension, rotation, and retraction of the loop from the sheath. When passed through an endoscope and activated, the Snare delivers a monopolar electrical current to cut and cauterize tissue with the loop.

6. Indications for Use

The Rotatable Snare is used endoscopically in the removal and/or and cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the gastrointestinal tract.

7. Technological Characteristics

This change is modifying the design of the Rotatable Snare to improve ergonomics of the device handle by moving the rotation actuator of the snare to the handle from its current position along the main sheath. The proposed Rotatable Snares are similar in materials, design, and manufacturing process to the predicate Rotatable Snares (K131700) and will use many of the same components as the reference Captivator II Snares (K133987). There are no new patient contacting materials used on the proposed snares.

8. Performance Data

In-vitro Testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. A summary of the test results has been provided for Working Length, Tortuous Path Functionality, Rotation Capability, Handle to Core

Wire Tensile Strength, Electrical Resistance, Electrical Safety, and Snare Actuation. The results of all testing were passing.

9. Conclusion

Boston Scientific Corporation has demonstrated that the proposed Rotatable Snares are substantially equivalent to Boston Scientific Corporation's currently marketed Rotatable Snares (K131700).