SECTION 5
510(k) SUMMARY

JAN 2 4 2014

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4560
Fax: 508-683-5939

Contact: Janis F. Taranto M.S., RAC
Sr. Regulatory Affairs Specialist
Date Prepared: December 24, 2013

2. Device

Trade Name: Single Use Polypectomy Snares
Captivator II, Single-Use Polypectomy Snares
Common Name: Polypectomy Snare
Classification Name: 1) Snare, Flexible, 2) Snare, Non-Electrical
Regulation Number: 1) 876.4300, 2) 876.4730
Product Code: 1) FDI, 2) FGX
Classification: Class II

3. Predicate Devices

Trade Name: Sensation Short Throw, Single-Use Polypectomy Snares
Captiflex, Single-Use Polypectomy Snares
Captivator, Single-Use Polypectomy Snares
Captivator II, Single-Use Polypectomy Snares
Profile, Single-Use Polypectomy Snares
Manufacturer and Clearance Number: Boston Scientific Corporation, K131700
Classification Name: 1) Snare, Flexible, 2) Snare, Non-Electrical
Regulation Number: 1) 876.4300, 2) 876.4730
Product Code: 1) FDI, 2) FGX
Classification: Class II

Trade Name: SnareMaster
Manufacturer and Clearance Number: Olympus, K955650
Classification Name: 1) Snare, Flexible, 2) Electrode, electrosurgical, active, urological
Regulation Number: 876.4300
Product Code: 1) FDI, 2) FAS
Classification: II

4. Device Description

The Polypectomy Snares consists of a flexible wire cable and loop which can be extended and retracted from the snare's flexible outer sheath using a three-ring handle. When passed through an endoscope the snare can be activated to deliver a monopolar electrical current to cut and cauterize tissue with the loop.

5. Indication for Use:

The Polypectomy Snares are used endoscopically in the removal and /or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

6. Technological Characteristics:

This change is adding snare loop sizes to the current Polypectomy Snare Family and modifying the handle design. The proposed Polypectomy Snares are similar in design, materials, and manufacturing processes to the predicate Polypectomy Snares (K131700) and the Olympus SnareMaster (K955650).

7. 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 Loop Extension Functionality, Loop Retraction Functionality, Cable to Handle Tensile, Active Cord Compatibility, Active Cord Attachment, Loop Width and Electrical Resistance.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Polypectomy Snares are substantially equivalent to Boston Scientific Corporation's currently marketed Polypectomy Snares (K131700) and the Olympus SnareMaster (K955650).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 24, 2014

Boston Scientific Corporation
Janis F. Taranto, M.S., RAC
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K133987
Trade/Device Name: Single Use Polypectomy Snares
Captivator II, Single-Use Polypectomy Snares
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI, FGX
Dated: December 24, 2013
Received: December 26, 2013

Dear Janis F. Taranto,

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Benjamin R. Fisher -S

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

SECTION 4
INDICATIONS FOR USE
STATEMENT

Indications for Use:

510(k) Number (if known): K133987

Device Name: Single Use Polypectomy Snares
Captivator II, Single-Use Polypectomy Snares

Indications for Use:

The Polypectomy Snares are used endoscopically in the removal and /or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

Prescription Use __X__ (Part 21 CFR 801 Part D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
2014.01.24 09:56:47 -05'00'