JUL 2 1 2014

SECTION 5
510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4296
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Contact: Tara Paul
Regulatory Affairs Specialist II
Date Prepared: March 21, 2014

2. Device

Trade Name:	Captivator™ EMR Device
Common Name:	Endoscopic Mucosal Resection (EMR) Device
Classification Name:	Endoscope and/or accessories
Regulation Number:	876.4300
Product Code:	FDI
Classification:	Class II

3. Predicate Devices

Cook Ireland Duette Multi-Band Mucosectomy Device (K050578)

4. Device Description

The Captivator™ EMR Device is an endoscopic mucosal resection device consisting of a ligator cap with ligation bands, a band ligator handle, an electrosurgical snare, and a pathology kit. The ligator cap and band ligator handle are attached to an endoscope, and bands are deployed one at a time to capture mucosal tissue as pseudopolyps, which are electrosurgically removed using the snare. The device is capable of performing multiple resections. The banding portion of the device is made up of a clear ligator cap with elastic bands stretched around the outer circumference of the cap. Bands are deployed by actuating the handle. The ligator device allows the introduction of an electrosurgical snare for endoscopic therapies. A pathology kit is also provided as a procedural aid which is used to handle tissue samples for histological processing.

5. Indication for Use:

The Captivator™ EMR Device is indicated for endoscopic mucosal resection in the upper GI tract

6. Technological Characteristics:

The proposed Captivator™ EMR Device shares similar design features and function with the Cook Ireland Duette Multi-Band Mucosectomy Device (K050578) and the cap size of the Olympus Distal Attachment (K984358).

The proposed device has the same intended use and is placed using the same methodology as the predicate device (Cook Ireland Duette Multi-Band Mucosectomy Device (K050578)) via ligation-assisted EMR. The Cook Ireland Duette Multi-Band Mucosectomy Device is a ligation-assisted device and the Olympus Distal Attachment is used to perform cap-assisted EMR. All three devices utilize a cap to suction and capture tissue during an EMR procedure. In addition to sharing a similar cap feature, the Captivator™ EMR Device and the Cook Ireland Duette Multi-Band Mucosectomy Device function similarly, as they are both used to perform ligation-assisted EMR.

7. Performance Data:

Non-clinical testing was successfully performed on the proposed Captivator™ EMR Device.

Biocompatibility Testing Summary:
Biocompatibility was evaluated in accordance with EN ISO 10993-1:2009, and the following tests were performed with acceptable results on the patient contacting portions of the Captivator™ EMR Device: Cytotoxicity, Sensitization, Irritation, Acute Systemic Toxicity, and USP Physicochemical Test.

Performance Testing Summary:
Non-clinical comparative performance bench testing was successfully completed to establish substantial equivalence between the proposed Captivator™ EMR Device and the predicate Cook Ireland Duette Multi-Band Mucosectomy Device (K050578). This testing included but was not limited to system suction delivery efficiency with snare, band ultimate tensile force, and snare loop to pull wire tensile strength.

8. Conclusion:

Boston Scientific has demonstrated that the proposed Captivator™ EMR Device is substantially equivalent to the currently marketed Cook Ireland Duette Multi-Band Mucosectomy Device (K050578).

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

July 21, 2014

Boston Scientific Corporation
Tara Paul
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlboro, MA 01752

Re: K140726
Trade/Device Name: Captivator™ EMR Device
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscope and/or accessories
Regulatory Class: Class II
Product Code: FDI
Dated: June 04, 2014
Received: June 06, 2014

Dear Tara Paul,

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" (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 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,

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

510(k) Number (if known):	To Be Determined
Device Name:	Captivator™ EMR Device
Indications for Use:	The Captivator™ EMR Device is indicated for endoscopic mucosal resection in the upper GI tract.

Prescription Use __X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Part D) (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
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