January 16, 2020

Boston Scientific Corporation
Brooke Cuddy
Senior Regulatory Affairs Specialist
Urology and Pelvic Health
100 Boston Scientific Way
Marlborough, MA 01752

Re: K191538
Trade/Device Name: Resectr™ Tissue Resection Device
Regulation Number: 21 CFR 884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: Class II
Product Code: HIH
Dated: June 7, 2019
Received: June 10, 2019

Dear Brooke Cuddy:

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,

Jason R. Roberts, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology 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)*
K191538

Device Name
Resectr™ Tissue Resection Device

Indications for Use *(Describe)*
The Resectr Tissue Resection Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue, including focal lesions such as endometrial polyps.

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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510(k) Summary for Resectr ™ Tissue Resection Device – K191538

A. Sponsor

Boston Scientific Corporation
Urology and Pelvic Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

Brooke Cuddy
Senior Specialist, Regulatory Affairs
508-683-6434
Brooke.Cuddy@bsci.com

Date prepared: January 15, 2020

C. Device Name

Trade name:	Resectr ™ Tissue Resection Device
Common/usual name:	Hysteroscope (and accessories)
Regulation Name:	Hysteroscope and accessories
Regulation Number:	21 CFR 884.1690
Product Code	HIH (Hysteroscope and accessories)

D. Predicate Device

MyoSure MANUAL Tissue Removal Device (K173901)

The predicate device has not been subject to a design-related recall.

E. Device Description

Resectr ™ Tissue Resection Device (Resectr device)
The Resectr device is a non-powered manual hysteroscopic surgical instrument used to resect and remove tissue under direct visualization. The device is supplied sterile for single use only. The device is offered in two sizes (5F and 9F) for compatibility with hysteroscopes with a 1.65mm or 3.0mm working channel respectively.

The following models/dimensions are available for the subject device:

Model	Outer Diameter	Cannula Length	Resecting Window Length
M0065907051	5 Fr (1.65 mm)	35 cm	5.0 mm
M0065907041	9 Fr (3.0 mm)	35 cm	7.5 mm

The working length (13.9”), materials of construction, and handle are identical for both models of the subject device.

SECTION 5 510(k) SUMMARY

The Resectr devices consist of a handle that is manually squeezed and released to actuate a blade within the resecting window to resect and remove target tissue. The devices are provided assembled with a vacuum tube port for use with a suction source. As tissue is resected, it is evacuated through the length of the device and out the vacuum tube port.

F. Intended Use/Indications for Use

The Resectr Tissue Resection Device is intended for intrauterine use by physicians trained in hysteroscopy to resect and remove tissue, including focal lesions such as endometrial polyps.

H. Comparison of Intended Use and Technological Characteristics

The subject and the predicate devices have different indications for use statements. However, both devices are intended to be used hysteroscopically to resect and remove tissue. Therefore, the intended use of the subject and predicate device is the same.

The subject and predicate devices have similar technological characteristics, including method of use and mode of operation, outer tube rotation, resection aperture, tissue resection mechanism, device markings and sterility.

There are minor technological differences between the predicate and the proposed devices; however, the differences do not raise new questions of safety or effectiveness. The primary technological differences between the subject and predicate devices are:

- Outer Diameter: The Resectr device is offered in two sizes; 9F and 5F whereas the MyoSure device is only offered in 9F size.
- Working Length: The Resectr devices have a 13.9 inch cannula working length, whereas the MyoSure device has a 12.6 inch cannula working length.
- Vacuum and Tissue Collection: The Resectr devices are connected to an external vacuum source and tissue catch, whereas the MyoSure device is comprised of a hand-actuated vacuum and built-in tissue trap.
- Supplied Accessories: The MyoSure device is provided with an inflow tubing set, whereas the Resectr devices are not.
- Directionality of the Resection Blade: The resecting blade on the Resectr devices oscillates radially relative to the cannula, whereas the resecting blade on the MyoSure device reciprocates axially with each handle squeeze.
- Blade Actuation: Each handle squeeze and release on the Resectr devices rotates the blade bi-directionally for a total of six resection actions across the cannula window. Each handle squeeze and release on the MyoSure device completes one resection action across the cannula window.

SECTION 5 510(k) SUMMARY

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the Resectr devices have the same intended use and similar technological characteristics as compared to the predicate device. The differences between the subject device and predicate device do not raise different questions of safety or effectiveness.

J. Non-clinical Performance Data

Biocompatibility

Biocompatibility studies were performed in accordance with the 2016 FDA guidance document Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process" and ISO 10993-1:2009 as follows:

- Cytotoxicity (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10: 2010)
- Irritation or Intracutaneous Reactivity (ISO 10993:10)
- Acute systemic toxicity (ISO 10993-11:2017)
- Material Mediated Pyrogenicity (ISO 10993-11:2011, USP<151>)

The results of this testing demonstrated that the subject devices are biocompatible.

Sterilization

Ethylene Oxide sterilization validation was performed per ISO 11135:2014 and ANSI AAMI ISO 10993-7L2008(R)2012.

Package Integrity

Sterile barrier/packaging validation was performed following simulated shipping and handling (per ASTM D4169) as follows:

- Seal Inspection, Visual (ASTM F1886/F1886M)
- Bubble Leak Sterile Barrier Testing (ASTM F2096)
- Pouch Seal Peel Strength Testing (ASTM F88/F88M)

Mechanical Performance Testing/Shelf Life Testing

Performance testing for the Resectr devices was conducted on samples aged at T=0 and T=3 years accelerated aging (per ASTM F1980). The performance tests completed to demonstrate that the Resectr devices function as intended include:

- Cutting/Resection Performance
- Device/Scope Compatibility

SECTION 5 510(k) SUMMARY

- Dimensional Measurements
- Durability
- Functionality/User Interface
- Outer Tube (Cannula) Rotation
- Vacuum loss
- Flexibility
- Spring load rate
- Torque strength testing
- Tensile testing

All testing performed met the predefined acceptance criteria.

J. Conclusion

The results of the performance testing described above demonstrate that the Resectr ™ Tissue Resection Device is as safe and effective as the predicate device and supports a determination of substantial equivalence.