February 9, 2018

Boston Scientific Corporation
Thomas Hirte
Senior Manager, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K173400
Trade/Device Name: ORISE™ Tissue Retractor System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FED, ODB, GAD
Dated: January 11, 2018
Received: January 12, 2018

Dear Thomas Hirte:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	K173400
Device Name:	ORISE™ Tissue Retractor System
Indications For Use:	This device is indicated for use in conjunction with an endoscope in the gastrointestinal tract for tissue or foreign body manipulation and/or where multiple removal and insertions of an endoscope are required.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart 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)

SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Thomas Hirte
Senior Manager, Regulatory Affairs
Date Prepared: October 30, 2017

2. Proposed Device:

Trade Name: ORISE™ Tissue Retractor System
Classification Name: Endoscope and Accessories
Regulation Number: 876.1500
Product Code: FED, ODB, GAD
Classification: Class II

3. Predicate Device:

Trade Name: LumenR Cannula Retractor System
510(k) Number: K153698
Classification Name: Endoscope and Accessories
Regulation Number: 876.1500
Product Code: FED, ODB, GAD
Classification: Class II

4. Proposed Device Description:

The ORISE Tissue Retractor System is comprised of the ORISE Tissue Retractor (OTR) consisting of the handle, the flexible shaft with expandable distal end (chamber) and the associated instrument guides called the ORISE Instrument Guides (OIGs) which are flexible conduits, guiding other instruments such as graspers. The OIG is available in three (3) tip configurations; with 45˚, 60˚ and 90˚ tip bend angles. Shaft Markers are used for reference purposes for aid in placing the retractor.

The proposed ORISE™ Tissue Retractor System has the same design intent and meets the same performance requirements as the predicate LumenR Cannula Retractor System. Minor design modifications and material modifications have been made to enhance the manufacturability.

5. Indications for Use:

This device is indicated for use in conjunction with an endoscope in the gastrointestinal tract for tissue or foreign body manipulation and/or where multiple removal and insertions of an endoscope are required.

6. Technological Characteristics:

The ORISE™ Tissue Retractor System is a device that can accommodate an endoscope and is used to create a stable environment in the GI tract by the deployment of retractor arms. The system allows the Gastroenterologist or surgeon to perform surgical tasks such as to grasp, retract, dissect, cut and coagulate tissue.

7. Performance Data:

A series of performance tests were conducted which demonstrated the quantitative mechanical performance, tolerance and usability of the ORISE™ Tissue Retractor System in endoscopic procedures.

Bench Testing:

Functional and performance tests were performed on the proposed ORISE™ Tissue Retractor system to demonstrate substantial equivalence and to satisfy all design verification requirements. The ORISE™ Tissue Retractor System passed all tests. In-vitro testing that has been performed and all components, subassemblies, and/or full devices met the required specifications.

The proposed ORISE™ Tissue Retractor System met the same performance requirements as the predicate LumenR Cannula Retractor System in order to establish substantial equivalence in performance, in the following tests: OTR and OIG dimensional testing, OTR and OIG performance testing including simulated use testing, Tensile strength testing, OTR scope compatibility, OIG instrument compatibility and OTR/OIG compatibility.

Biocompatibility Testing:

The proposed ORISE™ Tissue Retractor System was evaluated in accordance with EN ISO 10993-1: 2009. The following tests were performed: Cytotoxicity, Sensitization, Intracutaneous Irritation, Material Mediated Pyrogen, Chemical Characterization and Analysis.

8. Conclusion:

All biocompatibility tests conducted on the ORISE™ Tissue Retractor System passed. Therefore, the System is considered biocompatible for its intended use.

All device bench and biocompatibility test results were acceptable. The data demonstrate that the System sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific Corporation has demonstrated that the proposed ORISE™ Tissue Retractor System is substantially equivalent to the currently marketed LumenR Cannula Retractor System (K153698) and can be safely and effectively used for its proposed indication.