September 28, 2018

Boston Scientific
Jennifer Edouard
Senior Manager, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K180068
Trade/Device Name: ORISE™ Gel
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: PLL
Dated: August 23, 2018
Received: August 27, 2018

Dear Jennifer Edouard:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Mark R. Kreitz -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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180068

Device Name
ORISE Gel

Indications for Use *(Describe)*
This device is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early stage cancers, or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) SUMMARY

**1. Submitter:**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-6134
Fax: 508-683-5939

Contact: Jennifer Edouard
Regulatory Specialist II, Regulatory Affairs
Date Prepared: August 23, 2018

**2. Proposed Device:**

| | |
|---|---|
| Trade Name: | ORISE™ Gel |
| Classification Name: | Endoscope and Accessories |
| Regulation Number: | 876.1500 |
| Product Code: | PLL |
| Common Name: | Submucosal Injection Agent |
| Classification: | Class II |

**3. Predicate Device:**

| | |
|---|---|
| Trade Name: | SIC-8000 (Eleview™) |
| 510(k) Number: | K150852 |
| Classification Name: | Endoscope and Accessories |
| Regulation Number: | 876.1500 |
| Product Code: | PLL |
| Common Name: | Submucosal Injection Agent |
| Classification: | Class II |

**4. Proposed Device Description:**

The ORISE™ Gel device is a viscous dyed solution which is pre-filled into a standard luer lock syringe for use in submucosal injection to lift gastrointestinal mucosa during endoscopic mucosal resection (EMR), endoscopic mucosal dissection (ESD) and polypectomy procedures in the gastrointestinal tract. The device is intended for use in endoscopic resection procedures in the upper and the lower gastrointestinal tract, such as the esophagus, the stomach, the small intestine, the colon, the sigmoid colon, and the rectum, as a submucosal injectable agent during the removal of polyps, adenomas, early-stage cancers and other pathological lesions by EMR, ESD or polypectomy. The Injection Solution is injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope.

**5. Indications for Use:**

This device is indicated for use in gastrointestinal endoscopic procedures for submucosal lift of polyps, adenomas, early-stage cancers or other gastrointestinal mucosal lesions, prior to excision with a snare or other suitable endoscopic device.

**6. Technological Characteristics:**
The ORISE™ Gel is injected into the submucosal layer by means of a standard, commercially available, endoscopic injection needle, which is inserted into the working channel of the endoscope. The solution, when injected, creates a cushion in situ by lifting the gastrointestinal mucosa from the submucosal layer, allowing the endoscopist to perform a resection procedure (EMR, ESD or polypectomy). The proposed device will have a blue colorant added to provide the user with ability to visually see the raised lesion.

**7. Performance Data:**
A series of bench performance tests, animal studies and biocompatibility tests were conducted which demonstrated the quantitative mechanical performance, tolerance and usability of the ORISE™ Gel in endoscopic procedures. The following performance bench tests were performed; Solution Viscosity, Solution Color, Solution pH, Solution Osmolality, Injection Force, Connection Seal Integrity and Connection Separation Force.

Comparative bench testing was conducted, which compared the proposed ORISE™ Gel to the predicate Cosmo Technologies Ltd. SIC-8000 (Eleview™) device (K150852) for the following performance measures; Solution Viscosity, Solution Color, Solution pH, Solution Osmolality, and Injection Force. The results demonstrated that the proposed device is substantially equivalent to the predicate device for these performance measures.

Ex-Vivo testing was performed and compared directly to Eleview (the predicate) and dyed saline to evaluate initial height, and height at 5, 10, 20 and 30 minutes.

Preclinical testing was conducted to support substantial equivalence claims of our final ORISE™ Gel formulation as compared to the predicate device. The objective of this study was to evaluate the efficacy and safety of Boston Scientific's ORISE Gel (compared to a dyed saline control) for submucosal life during EMR/ESD procedures in the upper and lower GI tract of a porcine model. A total of 12 EMR and 11 ESD procedures were performed using the Test Article and 12 EMR and 11 ESD procedures were performed using the Control Article.

**8. Conclusion:**
All biocompatibility tests conducted on the ORISE™ Gel passed. Therefore, the System is considered biocompatible for its intended use.

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

Animal testing demonstrated that Boston Scientific ORISE Gel (Test Article) was comparable to the use of a dyed saline Control Article (Saline with Methlylene Blue) in terms of efficacy and comparable to the use of dyed saline Control article in terms of safety endpoints for submucosal lift during EMR and ESD procedures in the upper and lower GI tract of a porcine model.

Boston Scientific Corporation has demonstrated that the proposed ORISE™ Gel is substantially equivalent to the currently marketed SIC-8000 (Eleview™) device (K150852) and can be safely and effectively used for its proposed indication.