December 3, 2020

Boston Scientific Corporation
Jennifer Edouard
Senior Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K200404
Trade/Device Name: ORISE ProKnife
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: October 9, 2020
Received: October 13, 2020

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/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,

For Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant 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)*

K200404

Device Name

ORISE™ ProKnife

Indications for Use *(Describe)*

The ORISE™ ProKnife has been designed to be used with endoscopes and electrosurgical units to cut tissue within the gastrointestinal tract using high-frequency current. The electrosurgical knife also has the capability of delivering saline/ submucosal lifting agent into submucosal tissue layers under direct visualization through an endoscope.

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 ORISE™ ProKnife

1. Submitter

Boston Scientific Corporation
Endoscopy Division
200 Boston Scientific Way
Marlborough, MA 01752

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Date Prepared: October 9, 2020

2. Device

Trade Name:	ORISE™ ProKnife
Classification Name:	Endoscopic Electrosurgical Unit and Accessories
Product Code:	KNS
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.4300

3. Predicate Devices

Trade Name:	Single Use Electrosurgical Knife (Dual Knife J)
Manufacturer:	Olympus Medical Systems Corp.
Clearance Number:	K171158
Classification Name:	Endoscopic Electrosurgical Unit and Accessories
Product Code:	KNS
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.4300

Trade Name:	ERBE Hybrid Knife
Manufacturer:	ERBE USA Incorporated
Clearance Number:	K083608
Classification Name:	Jet Lavage
Product Code:	FQH – Lavage, Jet GEI – Electrosurgical, Cutting & Coagulation & Accessories
Device Class and Panel:	Class II, General & Plastic Surgery
Classification Regulation:	21 CFR 880.5475

4. Proposed Device Description

The ORISE™ ProKnife is an electrosurgical knife intended for use in Endoluminal surgery procedures, including but not limited to Endoscopic Submucosal Dissection (ESD). The ProKnife can deliver high frequency monopolar energy to facilitate incision of tissue. The ORISE™ ProKnife also has the capability of delivering saline/submucosal lifting agent through the electrode to maintain a submucosal fluid cushion without the need for a device exchange.

5. Indications for Use

The ORISE™ ProKnife has been designed to be used with endoscopes and electrosurgical units to cut tissue within the gastrointestinal tract using high-frequency current. The electrosurgical knife also has the capability of delivering saline/submucosal lifting agent into submucosal tissue layers under direct visualization through an endoscope.

6. Technological Characteristics

The ORISE ProKnife, the Olympus Single Use Electrosurgical Knife, and the ERBE Hybrid Knife are all sterile, single use devices and are identical with regard to lifting agent delivery pathway, electrode length, working length, endoscope compatibility, HF Generator Compatibility, Generator Operating Frequency Range and Voltage Capability and Maximum Power.

The proposed and predicate devices share similar characteristics, including principle of operation, tip outer diameter, shaft outer diameter, generator connection, Voltage Capability and Minimum Power, and materials.

7. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the ORISE™ ProKnife is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics.

8. Performance Data

Performance tests, which included bench-top and ex-vivo testing, electrical, and biocompatibility were conducted to demonstrate the performance and usability of the ORISE™ ProKnife in endoscopic procedures

Bench Testing:

Functional and performance tests were performed on the proposed ORISE™ ProKnife to satisfy all design verification requirements. The ORISE™ ProKnife passed all tests.

The following performance tests were performed to satisfy design verification requirements.

- Knife operation with the compatible endoscopes
- Dimension of each part of the knife

- General durability
- Injection capability

All results were passing and demonstrate that the proposed device meets its pre-defined performance specifications.

Electrical Testing:
Electrical safety was evaluated in accordance with the following standards:

- IEC 60601-1: 2005 + A1: 2012, Third Edition – Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance

- IEC 60601-2-2: 2017, Edition 6.0 – Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

- IEC 60601-2-18:2009, Ed. 3.0 – Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of endoscopic equipment

- IEC 60601-1-6:2010, AMD1:2013 – Medical electrical equipment Part 1-6 General requirements for safety – Collateral Standard: Usability

Biocompatibility Testing:
Biocompatibility of the ORISE™ ProKnife was evaluated in accordance with ISO 10993-1: 2018 *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk Management Process* and FDA Guidance Use of International Standard ISO 10993-1 (June 16, 2016) for devices categorized as limited (≤24 hours) surface, breached/compromised body contact.

The results of non-clinical testing demonstrate that the ORISE™ ProKnife is considered safe and effective for its intended use.

9. Conclusion

All performance testing, which include device bench and ex-vivo tests, electrical, and biocompatibility testing results were acceptable. The data demonstrates that the proposed device sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific has demonstrated that the proposed ORISE™ ProKnife is substantially equivalent to the currently marketed predicate devices and can be safely and effectively used for its proposed indication.