December 13, 2019

Boston Scientific Corporation
Carter Navarro
Sr. Regulatory Affairs Manager
100 Boston Scientific Way
Marlborough, MA 01752

Re: K193202
Trade/Device Name: EXALT Model D Single-Use Duodenoscope
EXALT Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FDT, FET
Dated: November 19, 2019
Received: November 20, 2019

Dear Carter Navarro:

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,

Shanil P. Haugen, Ph.D.
Acting 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)*

K193202

Device Name
EXALT Model D Single Use Duodenoscope; EXALT Controller

Indications for Use *(Describe)*

EXALT Model D Single Use Duodenoscope:
The EXALT Model D Single-Use Duodenoscope is intended for use with a Boston Scientific endoscopic video imaging system, for endoscopy and endoscopic surgery within the duodenum.

EXALT Controller:
The EXALT Controller is intended for use with a Boston Scientific endoscope for endoscopic diagnosis, treatment, and video observation.

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.

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510(k) Summary for EXALT Endoscopic Visualization System (EXALT Model D Single-Use Duodenoscope and EXALT Controller)

1. Submitter

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

Contact: Carter Navarro
Fellow, Regulatory Affairs
Phone: (508) 683-4793
E-mail: carter.navarro@bsci.com

Date Prepared: November 19, 2019

2. Device

Trade Name:	EXALT Model D Single-Use Duodenoscope
Common Name:	Duodenoscope and accessories, flexible/rigid
Product Code:	FDT
Device Class:	Class II
Panel:	Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500, Endoscope and accessories

Trade Name:	EXALT Controller
Common Name:	Endoscopic video imaging system/component, gastroenterology-urology
Product Code:	FET
Device Class:	Class II
Panel:	Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500, Endoscope and accessories

3. Predicate Devices

Trade Name:	EVIS EXERA II Duodenovideoscope TJF Type Q180V
Manufacturer:	Olympus Medical Systems Corp.
Clearance Number:	K143153
Common Name:	Duodenoscope and accessories, flexible/rigid
Product Code:	FDT
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500, Endoscope and accessories

Trade Name:	CV-170 Video System Center
Manufacturer:	Olympus Medical Systems Corp.
Clearance Number:	K122831
Common Name:	Endoscopic video imaging system/component, gastroenterology-urology
Product Code:	FET
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500, Endoscope and accessories

4. Device Description

The EXALT Model D Single-Use Duodenoscope is a sterile, single-use, flexible duodenoscope used to examine the duodenum and perform various procedures within the duodenum including endoscopy and endoscopic surgery. When connected to an EXALT Controller, the EXALT Model D Single-Use Duodenoscope provides imaging and illumination, 4-way steerable navigation, lens wash, insufflation, suction, facilitates image capture initiation, and allows the delivery of various ancillary devices.

The EXALT Controller is an endoscopic video imaging system that receives video signals from the EXALT Model D Single-Use Duodenoscope, processes the video signals, outputs video images to a video monitor, and outputs electrical signals that interface with external image capture systems. The EXALT Controller also controls the light transmitted by the tip of the EXALT Model D Single-Use Duodenoscope to illuminate the area of interest within the anatomy.

5. Indications for Use

The EXALT Model D Single-Use Duodenoscope is intended for use with a Boston Scientific endoscopic video imaging system, for endoscopy and endoscopic surgery within the duodenum.

The EXALT Controller is intended for use with a Boston Scientific endoscope for endoscopic diagnosis, treatment, and video observation.

6. Technological Characteristics

A direct comparison of key characteristics demonstrates that the EXALT Model D Single-Use Duodenoscope and EXALT Controller are substantially equivalent to their respective predicate devices in terms of intended use, technological characteristics, and performance characteristics.

The EXALT Model D Single-Use Duodenoscope and the EVIS EXERA II Duodenovideoscope TJF Type Q180V share similar mechanical and optical characteristics, including working length, diameters, articulation angles, flow rates, resolution, direction of view, and field of view. The EXALT Model D Single-Use Duodenoscope is sterile, single-use, and not intended for reprocessing, whereas the EVIS EXERA II Duodenovideoscope TJF Type Q180V is intended to be reprocessed.

The EXALT Controller and the Olympus CV-170 Video System Center share similar video formats and outputs and illumination technology, though the light-emitting diodes in the EXALT Endoscopic Visualization System are located in the EXALT Model D Single-Use Duodenoscope rather than the EXALT Controller; whereas the light sources in Olympus endoscopic systems (including the CV-170 Video System Center) are located in the capital equipment.

7. Performance Data

Non-clinical testing was successfully performed on the proposed EXALT Model D Single-Use Duodenoscope and EXALT Controller

Performance testing (bench) was successfully completed to establish substantial equivalence between the proposed EXALT Model D Single-Use Duodenoscope and EXALT Controller and the predicate devices. This testing included the following:

- Working Length
- Insertion Portion Diameter
- Articulation Angles
- Flow Rates
- Reliability
- Resolution
- Direction of View
- Field of View
- Light Output

Biocompatibility of the EXALT Model D Single-Use Duodenoscope was evaluated in accordance with ISO 10993-1. Electrical safety and electromagnetic compatibility of the EXALT Model D Single-Use Duodenoscope and EXALT Controller were evaluated in accordance with AAMI / ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-2, and IEC 60601-2-18.

Clinical testing was performed to confirm procedural performance of the EXALT Model D Single-Use Duodenoscope and EXALT Controller in endoscopic cholangio-pancreatography (ERCP) procedures.

8. Conclusion

The results of non-clinical and clinical testing demonstrate that the EXALT Model D Single-Use Duodenoscope and EXALT Controller are considered safe and effective for their intended uses. Boston Scientific has demonstrated that the proposed devices are substantially equivalent to the currently marketed predicate devices.