June 21, 2023

Boston Scientific Corporation
Carter Navarro
Fellow, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K231533
Trade/Device Name: Habib EndoHPB
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: May 26, 2023
Received: May 26, 2023

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,

Glenn B. Bell -S

Glenn B. Bell, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231533

Device Name
Habib EndoHPB

Indications for Use *(Describe)*
The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts.

The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.

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 Habib EndoHPB

1. Submitter

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E-mail: carter.navarro@bsci.com

Date Prepared: May 26, 2023

2. Device

Trade Name:	Habib EndoHPB
Common Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)
Product Code:	KNS
Device Class:	Class II
Device Panel:	Gastroenterology/Urology
Classification Regulation:	21 CFR 876.4300, Endoscopic electrosurgical unit and accessories

3. Predicate Device

Trade Name:	Habib EndoHPB
510(k) Number:	K180165
Common Name:	Unit, Electrosurgical, Endoscopic (With Or Without Accessories)
Product Code:	KNS
Device Class:	Class II
Device Panel:	Gastroenterology/Urology
Classification Regulation:	21 CFR 876.4300, Endoscopic electrosurgical unit and accessories

4. Device Description

The Habib EndoHPB is an 8F RF bipolar catheter that consists of a catheter with 2 ring electrodes, introduced via an endoscope's biopsy channel. It has an attached cable which connects the device to an RF Generator. RF is applied to the two electrodes at the top of the catheter so that heat is applied to tissue surrounding the catheter.

5. Indications for Use

The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to perform partial or complete ablation of tissue in the pancreatic and biliary tracts. The Habib EndoHPB is also intended for use to ablate malignant or benign tissue, notably to perform endoscopic biliary drainage or decompression, prior to stent placement or afterwards, to clear occluded stent.

6. Technological Characteristics

The technological characteristics of the proposed Habib EndoHPB are identical to those of the predicate device.

7. Substantial Equivalence

The proposed Habib EndoHPB is identical to the predicate device, with no changes in technology, engineering, performance, or materials. The only difference is the recommended generator settings for using the Habib EndoHPB with the Erbe VIO 3 electrosurgical unit. These settings do not raise new questions of safety or effectiveness, and the subject device is considered substantially equivalent to the predicate device.

8. Performance Data

The new settings have been evaluated using the same methods described in the predicate device 510(k), with additional controls, and the resulting performance data show substantial equivalence.

9. Conclusion

Boston Scientific has demonstrated that the proposed Habib EndoHPB is substantially equivalent to the currently marketed predicate device.