November 28, 2023

Boston Scientific
Lingling Guo
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marborough, Massachusetts 01752

Re: K232633
Trade/Device Name: Gold Probe Bipolar Electrohemostasis Catheter; Injection Gold Probe Bipolar Electrohemostasis Catheter
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: August 29, 2023
Received: August 30, 2023

Dear Lingling Guo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232633

Device Name
Gold Probe Bipolar Electrohemostasis Catheter; Injection Gold Probe Bipolar Electrohemostasis Catheter

Indications for Use *(Describe)*
Gold Probe Bipolar Electrohemostasis Catheter is indicated for use in transendoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract.

Injection Gold Probe Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. The Injection Gold Probe Catheter also has irrigation capability. Any other use is not recommended.

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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K232633
510(k) Summary

1. Submitter

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Date Prepared: November 20, 2023

2. Proposed Devices

Trade Name:	Gold Probe Bipolar Electrohemostasis Catheter
Common 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:	Injection Gold Probe Bipolar Electrohemostasis Catheter
Common 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 (*Primary predicate is listed first*)

Trade Name:	Gold Probe Bipolar Electrohemostasis Catheter
Clearance Number:	K970278
Common 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:	Injection Gold Probe Bipolar Electrohemostasis Catheter
Clearance Number:	K133933
Common 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:	Gyrus BiCoAG Hemostasis Probe
Clearance Number:	K123319
Common Name:	Endoscopic electrosurgical unit and accessories
Product Code:	KNS
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.4300

4. Device Description

The Gold Probe is a bipolar electrohemostasis catheter with irrigation capabilities. When passed through an endoscope and activated, it will deliver a bipolar current to cauterize tissue. The Gold Probe is available in 7 Fr and 10 Fr with a working length of 300cm (7 and 10 Fr) and 350cm (7 Fr), compatible with a minimum of 2.8 mm and 3.7 mm scope channels, respectively. The catheter shaft provides firmness for perpendicular and tangential use, while the HemoGlide Coating on the catheter promotes minimal friction during endoscope passage.

1. Irrigation

   Irrigation with saline or sterile water is performed by connecting the irrigation hub to the irrigation port of the bipolar generator or to a 30 cm^3 (30 cc) or 60 cm^3 (60 cc) luer-lock syringe or mechanical irrigation system for generators without irrigation capability.

2. Bipolar Electrohemostasis

   The gold-spiral electrode on the probe tip provides bipolar electrical continuity, necessary hemostasis depths, and minimum tissue adhesion. The Gold Probe connects directly to the Endostat family of Bipolar Electrosurgical Generators. Or utilize the Bipolar Cable Adapter supplied by Boston Scientific for other bipolar electrosurgical generators.

The Injection Gold Probe is an injection therapy and bipolar electrohemostasis catheter with irrigation capabilities. The Injection Gold Probe is available in a working length of 210 cm with outer diameters of 7F (2.3 mm) and 10F (3.3 mm), compatible with a minimum of 2.8 mm and 3.7 mm scope channels, respectively. The catheter shaft provides firmness for perpendicular and tangential use, while the HemoGlide Coating on the catheter promotes minimal friction during endoscope passage.

1. Injection Therapy
   Each Injection Gold Probe contains a 25-gauge injection needle for injection therapy. The catheter handle contains the injection needle hub. Injection is performed by attaching a luer-lock syringe to the "Injection" hub and advancing the needle.

2. Bipolar Electrohemostasis
   The gold-spiral electrode on the probe tip provides bipolar electrohemostasis. The Injection Gold Probe connects directly to the Endostat family of Bipolar Electrosurgical Generators. Or utilize the Bipolar Cable Adapter supplied by Boston Scientific for other bipolar electrosurgical generators.

3. Irrigation
   Irrigation with saline or sterile water is performed by connecting the irrigation hub to the irrigation port of the bipolar generator or to a 30 cm^3 (30 cc) or 60 cm^3 (60 cc) luer-lock syringe or mechanical irrigation system for generators without irrigation capability.

5. Indications for Use

Gold Probe Bipolar Electrohemostasis Catheter is indicated for use in transendoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract.

Injection Gold Probe Bipolar Electrohemostasis Catheter is indicated for use in endoscopic injection therapy (to deliver pharmacological injection agents, such as vasoconstrictors) and endoscopic electrohemostasis (cauterization of tissue and coagulation of blood) of actual or potential bleeding sites in the gastrointestinal tract. The Injection Gold Probe Catheter also has irrigation capability. Any other use is not recommended.

6. Technological Characteristics

The technological characteristics of the devices remain unchanged from the predicate devices Gold Probe Bipolar Electrohemostasis Catheter cleared under K970278, Injection Gold Probe Bipolar Electrohemostasis Catheter cleared under K133933 and similar as the predicate Gyrus BiCoAG Hemostasis Probe (K123319).

7. Performance Data

The proposed Gold Probe Bipolar Electrohemostasis Catheter and Injection Gold Probe Bipolar Electrohemostasis Cathter technological characteristics remain unchanged from predicate Gold Probe Bipolar Electrohemostasis Catheter (K970278) and Injection Gold Probe Bipolar Electrohemostasis Catheter (K133933) respectively; therefore, no further performance testing was required.

8. Conclusion

Boston Scientific Corporation has determined that the proposed Gold Probe Bipolar Electrohemostasis Catheter is substantially equivalent to the predicate Gold Probe Bipolar Electrohemostasis Catheter (K970278) and Gyrus BiCoAG Hemostasis Probe (K123319), and that the proposed Injection Gold Probe Bipolar Electrohemostasis Catheter is substantially equivalent to the predicate Injection Gold Probe Bipolar Electrohemostasis Catheter (K133933) and Gyrus BiCoAG Hemostasis Probe (K123319).