May 6, 2022

Boston Scientific Corporation
Laura (Kuroski) Meehan
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K212582
Trade/Device Name: SpyGlass Discover Balloon Dilation Cathether
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: GCA
Dated: April 7, 2022
Received: April 8, 2022

Dear Laura (Kuroski) Meehan:

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,

Je Hi An, 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)*
K212582

Device Name
SpyGlass™ Discover Balloon Dilation Catheter

Indications for Use *(Describe)*
The SpyGlass Discover Balloon Dilation Catheter is indicated for laparoscopic and open surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.

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 SpyGlass™ Discover Balloon Dilation Catheter

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Laura Meehan
Principal Regulatory Affairs Specialist
Telephone: 508-382-0442
E-Mail: Laura.Meehan@bsci.com

Date Prepared: April 7, 2022

2. Device:

Trade Name:	SpyGlass™ Discover Balloon Dilation Catheter Common
Name:	Biliary catheter for stone removal that may also allow for irrigation and contrast injection
Classification Name:	Biliary catheter and accessories
Product Code:	GCA
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Number:	21 CFR §876.5010

3. Predicate Device:

Trade Name:	Advance Biliary Balloon Catheter
Manufacturer:	Cook Incorporated
Clearance Number:	K173414
Common Name:	Biliary catheter for stone removal that may also allow for irrigation and contrast injection
Classification Name:	Biliary catheter and accessories
Product Code:	GCA
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Number:	21 CFR §876.5010

4. Device Description

The SpyGlass Discover Balloon Dilation Catheter is a sterile, single use device. The device is a double-lumen catheter manufactured with a nylon copolymer shaft. The distal tip of the catheter consists of a NyBax™ balloon and is available in diameters of 6, 7, and 8 millimeters, and a length of 40 millimeters. The SpyGlass Discover Balloon Dilation Catheter accepts a 0.035-inch diameter guidewire.

5. Indications for Use:

The SpyGlass Discover Balloon Dilation Catheter is indicated for laparoscopic and open surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.

6. Proposed Device and Predicate Device Technological Characteristics

Device Characteristic		Predicate Device Cook Incorporated Advance Biliary Balloon Catheter (K173414)	Proposed Device Boston Scientific Corporation SpyGlass Discover Balloon Dilation Catheter (K212582)
Classification Number		21 CFR §876.5010	Identical to Predicate
Product Code		GCA	Identical to Predicate
Classification		II	Identical to Predicate
Indications for Use		The Advance Biliary Balloon Catheter is indicated for laparoscopic and general surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.	The SpyGlass Discover Balloon Dilation Catheter is indicated for laparoscopic and open surgical procedures for the dilation of the cystic duct to facilitate common bile duct exploration.
Single Use		Yes	Identical to Predicate
Duration of Use		Limited (≤ 24 hours)	Identical to Predicate
Imaging Technique to Visualize Device		Fluoroscopy, Laparoscopic Imaging	Identical to Predicate
Principles of Operation		Balloon inflation to open or widen biliary lumen	Identical to Predicate
Delivery System		Over-the-wire	Identical to Predicate
Balloon of Catheter	**Inflated Outer Diameter (mm)**	6, 8	6, 7, 8
	Nominal Pressure	PTA 6 mm – 10 atm PTA 8 mm – 8 atm ATB 8 mm – 5 atm	6 mm – 10 atm 7 mm – 10 atm 8 mm – 10 atm
	Rated Burst Pressure	PTA 6 mm – 15 atm PTA 8 mm – 11 atm ATB 8 mm – 15 atm	6 mm – 15 atm 7 mm – 15 atm 8 mm – 15 atm
	Length (mm)	40	Identical to Predicate
	Material	Nylon	NyBax™
Shaft of Catheter	**Outer Diameter (Fr)**	5	5.3
	Length (cm)	40, 80	40
	Material	Nylon copolymer	Identical to Predicate
	Marker Bands	Yes	Identical to Predicate
	Number of Lumens	2	Identical to Predicate
	Guidewire Compatibility (in)	0.035	Identical to Predicate
	Introducer Sheath Compatibility (Fr)	6	6 - 12
Sterilization Method		Ethylene Oxide	Identical to Predicate

The SpyGlass Discover Balloon Dilation Catheter is substantially equivalent to the Cook Incorporated Advance Biliary Balloon Catheter in terms of technological characteristics. The proposed device and the predicate device have the same principal of operation and fundamental dual-lumen balloon dilation catheter design. The differences in balloon materials, shaft outer diameter, and introducer sheath compatibility do not raise different questions of safety or effectiveness because:

- Balloon materials - Biocompatibility testing for the proposed device demonstrates that the device is biocompatible for its intended use and bench testing demonstrates that the material used allows the device to meet all pre-defined performance specifications.

- Shaft outer diameter - Both the proposed device and the predicate device are designed to be compatibility with a minimum 6Fr sheath.

- Introducer Sheath Compatibility - Bench testing demonstrates that the proposed device is compatible with an introducer sheath size from 6 Fr to 12 Fr.

7. Performance Data

Non-clinical performance bench testing was completed to evaluate the design of the SpyGlass Discover Balloon Dilation Catheter for its intended use. Testing includes:

- Balloon Diameter at Nominal Pressure – testing was conducted to evaluate the balloon diameter at nominal pressure of the subject device. Test results indicated an acceptable balloon diameter at nominal pressure.

- Balloon Compliance – testing was conducted to evaluate the balloon compliance of the subject device. Test results indicated an acceptable balloon compliance.

- Rated Burst Pressure / Burst Mode – testing was conducted to evaluate the balloon failure pressure and burst mode of the subject device. Test results indicated an acceptable balloon burst pressure and burst mode.

- Balloon Multiple Inflation – testing was conducted to evaluate the balloon stability after multiple inflations of the subject device. Test results indicated an acceptable balloon stability.

- Proximal Balloon Bond Tensile Strength – testing was conducted to ensure the appropriate bond strength of the proximal bond of balloon to catheter shaft. Test results indicated that the bond strength is appropriate.

- Manifold Bond Tensile Strength – testing was conducted to ensure the appropriate bond strength of the hub to catheter shaft. Test results indicated that the bond strength is appropriate.

- Catheter Shaft Tensile Strength – testing was conducted to ensure the appropriate strength of the catheter shaft. Test results indicated that the catheter shaft strength is appropriate.

- Distal Balloon Bond Tensile Strength – testing was conducted to ensure the appropriate bond strength of the distal balloon to the catheter shaft. Test results indicated that the bond strength is appropriate.

- Distal Tip Bond Tensile Strength – testing was conducted testing to ensure the appropriate bond strength of the distal tip to the catheter shaft. Test results indicated that the bond strength is appropriate.

- Catheter Shaft Length – testing was conducted to evaluate the catheter shaft length of the subject device. Test results indicated an acceptable catheter shaft length.

- Catheter Shaft Outer Diameter – testing was conducted to evaluate the catheter shaft outer diameter of the subject device. Test results indicated an acceptable catheter shaft outer diameter.

- Guidewire Compatibility – testing was conducted to evaluate the guidewire compatibility of the subject device. Test results indicated an acceptable guidewire compatibility.

- Initial Sheath Insertion and Withdrawal Force – testing was conducted to evaluate the introducer sheath compatibility of the subject device. Test results indicated an acceptable introducer sheath compatibility.

8. Conclusion

The information provided in this submission demonstrates that the proposed SpyGlass Discover Balloon Dilation Catheter is substantially equivalent to the Cook Incorporated Advance Biliary Balloon Catheter (K173414) in terms of performance, technological characteristics, and intended use.