Inderdeep Tiwana,
Sr. Regulatory Affairs Specialist, Endoscopy
Boston Scientific Corporation
100 Boston Scientific Way,
Marlborough, MA 01752

May 21, 2020

Re: K200483
Trade/Device Name: SpyGlass Discover Digital Catheter, SpyGlass Discover Digital Controller
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: FBN
Dated: February 27, 2020
Received: February 28, 2020

Dear Inderdeep Tiwana:

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,

Neil R.P. Ogden, MS
Assistant Director THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*

K200483

Device Name
SpyGlass Discover Digital Catheter; SpyGlass Discover Digital Controller

Indications for Use *(Describe)*

The SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The SpyGlass Discover Digital System comprises two components: the SpyGlass Discover Digital Catheter and the SpyGlass Discover Digital Controller.

The SpyGlass Discover Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. The SpyGlass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic

Controller:
The SpyGlass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

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 SpyGlass Discover Digital System
(SpyGlass Discover Digital Catheter and SpyGlass Discover Digital Controller)

1. Submitter

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

Contact:

Primary Contact: Inderdeep Tiwana
Sr. Regulatory Specialist
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Secondary Contact: Ashley Santos
Director, Regulatory Affairs-Endoscopy
Phone: (508) 683-4359
Email: Ashley.santos@bsci.com

Date Prepared: February 26, 2020

2. Device

Trade Name:	SpyGlass Discover Digital System
Common Name:	Choledochoscope and accessories, flexible/rigid; Surgical camera and accessories; LED light source
Product Code:	FBN, KQM, NTN
Device Class and Panel:	Class II, Gastroenterology/Urology (FBN, NTN) Class I, General and plastic surgery (KQM)
Classification Regulation:	21 CFR 876.1500 (FBN, NTN) 21 CFR 878.4160 (KQM)

3. Predicate Devices

Catheter:

Trade Name:	SpyGlass DS Direct Visualization System
Device Name:	SpyScope DS II Access and Delivery Catheter
Manufacturer:	Boston Scientific Corp.
Clearance Number:	K183636
Common Name:	Choledochoscope and accessories, flexible/rigid;
Product Code:	FBN, NTN
Device Class and Panel:	Class II, Gastroenterology/Urology (FBN, NTN)
Classification Regulation:	21 CFR 876.1500 (FBN, NTN)

Trade Name:	Flexible Video-Uretero-Choledochoscope System
Manufacturer:	Karl Storz
Clearance Number:	K142556
Common Name:	Class II, Gastroenterology/Urology (FBN, FGB)
Product Code:	FBN, FGB
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Trade Name:	URF-P2 Ureterorenofiberscope / Choledoschofirberscope
Manufacturer:	Olympus Medical System Corp.
Clearance Number:	K912120
Common Name:	Class II, Gastroenterology/Urology (FBN)
Product Code:	FBN
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Controller:

Trade Name:	SpyGlass DS Direct Visualization System
Device Name:	SpyGlass DS Digital Controller
Manufacturer:	Boston Scientific Corp.
Clearance Number:	K183636
Common Name:	Surgical camera and accessories; LED light source
Product Code:	KQM
Device Class and Panel:	Class I, General and plastic surgery (KQM)
Classification Regulation:	21 CFR 878.4160 (KQM)

4. Device Description

The SpyGlass Discover Digital System comprises two components: (1) a sterile, single-use endoscope, the SpyGlass Discover Digital Catheter (the "Catheter"); and (2) a non-sterile endoscopic video imaging system, the SpyGlass Discover Digital Controller (the "Controller").

The SpyGlass Discover Digital Catheter comprises a handle, an insertion tube, and a connection cable. The handle includes two articulation control knobs, a lever to lock the control knobs in place, connectors for irrigation and aspiration, a working channel port. The insertion tube contains one working channel for accessory devices and aspiration, two channels for irrigation, two optical fibers to transmit illumination from the Controller, and wiring to transmit video signals to the Controller. The bending section at the distal portion of the insertion tube is controlled by the user via the articulation control knobs on the handle. The distal end of the insertion tube contains a camera for capturing video and transmitting it to the Controller, elements for transmitting illumination from the Controller, and the distal openings of the irrigation and working channels. The catheter cable connects the catheter handle to the Controller for transmitting illumination and video signals.

The Controller is an endoscopic video imaging component that combines the functionality of a camera and an LED light source. The Controller receives video signals from the catheter, processes the video signals, and outputs video images to an attached monitor. The Controller also generates and controls the illumination transmitted to the distal end of the catheter. The user interface of the Controller comprises a power button, a receptacle to connect the catheter connection cable, buttons to turn illumination on or off and to control the illumination intensity, and an illumination intensity indicator. The Controller outputs video images to an attached monitor via DVI, VGA, or S-Video ports, and the user may select NTSC or PAL video formats according to the geographic region of use.

5. Indications for Use

The SpyGlass Discover Digital System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts. The SpyGlass Discover Digital System comprises two components: the SpyGlass Discover Digital Catheter and the SpyGlass Discover Digital Controller.

The SpyGlass Discover Digital Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass Discover Digital Controller is intended to provide illumination and receive, process, and output images from the SpyGlass Discover Digital Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

6. Technological Characteristics

The proposed SpyGlass Discover Digital System shares the same intended use and fundamental scientific technology as the predicate SpyGlass DS Direct Visualization System (K183636). The two systems share same indications for use and nearly identical technological characteristics, including CMOS image sensors for visualization, light-emitting diodes (LEDs) for illumination, and video output capabilities. Most of the SpyGlass Discover Digital Catheter components are identical in dimensions and in mechanical performance to its predicate. The primary design changes incorporated in the SpyGlass Discover Digital Catheter are; (1) a shorter working length, (2) modifications to the pulley to compensate for the shorter working length, (3) longer irrigation and aspiration tubing, and (4) removal of the strap and bracket. Besides these changes, the design, components and materials of SpyGlass Discover Digital Catheter are nearly identical to the SpyScope DS II Access and Delivery Catheter (K183636).

7. Substantial Equivalence

The proposed SpyGlass Discover Digital Catheter is substantially equivalent in design, features and functionality to the SpyScope DS II Access and Delivery Catheter. Its function consists of providing direct visualization of the pancreatico-biliary system. It is also used to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts. It provides imaging and illumination by means of a CMOS sensor and plastic optical fibers, 4-way steerable navigation, irrigation and aspiration.

The primary difference between the SpyGlass Discover Digital Catheter and the SpyScope DS II Access and Delivery Catheter is its catheter working length. Unlike the SpyScope DS II Access and Delivery Catheter, the SpyGlass Discover Digital Catheter is not intended to be used through a duodenoscope. The SpyGlass Discover Digital Catheter is intended to access target anatomy through three possible methods; Laparoscopically, percutaneously and open surgical.

The secondary predicate devices selected for SpyGlass Discover Digital Catheter are (1) Flexible Video-Uretero-Choledochoscope System (Karl Storz) K142556 and (2) URF-P2 Ureterorenofiberscope / Choledoschofirberscope (Olympus) K912120. These two catheters share similar working catheter length as the SpyGlass Discover Digital Catheter. Hence, the accessing method to the target anatomy is similar to the proposed SpyGlass Discover Digital Catheter.