August 23, 2018

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

Re: K181439
Trade/Device Name: SpyGlass DS and DS II Direct Visualization System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FBN, NTN, KQM
Dated: July 26, 2018
Received: July 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*

K181439

Device Name
SpyGlass DS and DS II Direct Visualization System

Indications for Use *(Describe)*

The SpyGlass DS and DS II Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS and DS II Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter, and the SpyGlass DS Digital Controller.

The SpyScope DS Access and Delivery Catheter and SpyScope DS II Access and Delivery Catheter are 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 DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery 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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1. Submitter

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Date Prepared: August 23, 2018

2. Proposed Device

Trade Name:	SpyGlass DS and DS II Direct Visualization 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 Endoscope and Accessories

3. Predicate Device

Trade Name:	SpyGlass DS Direct Visualization System
Manufacturer:	Boston Scientific Corporation
Clearance Number:	K142922
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 Endoscope and Accessories

4. Device Description

The SpyGlass DS and DS II Direct Visualization System comprises two components: (1) a sterile, single-use choledochoscope, either the SpyScope DS Access and Delivery Catheter or the SpyScope DS II Access and Delivery Catheter (the "Scope"); and (2) a non-sterile endoscopic video imaging system, the SpyGlass DS Digital Controller (the "Controller").

The Scope is introduced into the pancreatico-biliary system via a duodenoscope. The Scope 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, and a strap to attach the Scope to the duodenoscope. 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 connection 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 Scope, 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 Scope. The user interface of the Controller comprises a power button, a receptacle to connect the Scope 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 DS and DS II Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS and DS II Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter, and the SpyGlass DS Digital Controller.

The SpyScope DS Access and Delivery Catheter and SpyScope DS II Access and Delivery Catheter are 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 DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter or SpyScope DS II Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system including the hepatic ducts.

6. Technological Characteristics

The proposed SpyGlass DS and DS II Direct Visualization System shares the same intended use and fundamental scientific technology as the predicate SpyGlass DS Direct Visualization System (K142922). The proposed device and the predicate device share the 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. The device components are identical in dimensions and mechanical performance. The proposed device incorporates (1) a new camera in the Scope; (2) minor design and adhesive changes to the distal cap of the Scope to accommodate the new camera; and (3) updated software for the Controller to accommodate the new camera and to provide High Dynamic Range (HDR) image processing when used with the SpyScope DS II Access and Delivery Catheter.

7. Performance Data

Non-clinical testing was successfully performed on the proposed SpyGlass DS and DS II Direct Visualization System.

Performance testing (bench) was successfully completed to establish substantial equivalence between the proposed SpyGlass DS and DS II Direct Visualization System and the predicate device. This testing included the following:

- Field of view
- Direction of view
- Resolution
- Irrigation flow rate
- Surface and edges
- Articulation reliability
- Image noise
- Video latency
- System frame rate
- Illumination intensity
- Automatic light control response time

Biocompatibility of the SpyScope DS II Access and Delivery Catheter was evaluated in accordance with FDA recognized consensus standards. The following tests were performed: Cytotoxicity, Irritation, and Sensitization. All acceptance criteria were met.

Electrical safety and electromagnetic compatibility of the SpyGlass DS and DS II Direct Visualization System were evaluated in accordance with FDA recognized consensus standards. All acceptance criteria were met.

The results of non-clinical testing demonstrate that the proposed SpyGlass DS and DS II Direct Visualization System is considered safe and effective for its intended use.

8. Conclusion

Boston Scientific has demonstrated that the proposed SpyGlass DS and DS II Direct Visualization System is substantially equivalent to the currently marketed SpyGlass DS Direct Visualization System (K142922).