May 26, 2021

Boston Scientific Corporation
Lindsay Forys
Regulatory Affairs Manager
100 Boston Scientific Way
Marlborough, MA 01752

Re: K203322
Trade/Device Name: SpyGlass™ Discover Retrieval Basket
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: LQR
Dated: May 3, 2021
Received: May 4, 2021

Dear Lindsay Forys:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203322

Device Name
SpyGlass™ Discover Retrieval Basket

Indications for Use *(Describe)*
The SpyGlass Discover Retrieval Basket is indicated for the endoscopic removal of stones and stone fragments in the biliary system.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Lindsay Forys
Regulatory Affairs Manager
Telephone: 508-382-0498
E-Mail: Lindsay.Forys@bsci.com

Date Prepared: 26 May 2021

2. Device:

Trade Name:	SpyGlass™ Discover Retrieval Basket
Device Common Name:	Dislodger, Stone, Biliary
Regulation Name:	Biliary Catheter and Accessories
Regulation Number:	21 CFR 876.5010
Product Code:	LQR
Regulatory Class:	Class II

3. Predicate Device:

Trade Name:	Cook NCompass Nitinol Stone Extractor
510(k) Number:	K173009
Device Common Name:	Dislodger, Stone, Biliary
Regulation Name:	Biliary Catheter and Accessories
Regulation Number:	21 CFR 876.5010
Product Code:	LQR
Regulatory Class:	Class II

4. Device Description

The SpyGlass Discover Retrieval Basket is designed to be used with the SpyGlass Discover Digital Catheter (K200483), which is a single-use endoscope. The SpyGlass Discover Retrieval Basket is a self-expanding nitinol wire basket that is housed within a flexible sheath. The basket is extended from the sheath (opened) and retracted into the sheath (closed) using a thumb slide on the proximal handle. The basket cage is made of four nitinol wire legs. The basket wires are looped at the distal end featuring a tipless design with no exposed wire ends.

5. Indications for Use:

The SpyGlass Discover Retrieval Basket is indicated for the endoscopic removal of stones and stone fragments in the biliary system.

6. Technological Characteristics

The SpyGlass Discover Retrieval Basket is substantially equivalent to the Cook NCompass Stone Extractor in terms of technological characteristics. The baskets are designed to be viewed under endoscopic visualization, feature a thumb slide operating mechanism, and consist of a nitinol wire basket that self-expands in a 360° configuration once extended from the outer sheath.

The SpyGlass Discover Retrieval Basket features a 4-wire basket configuration while the Cook NCompass Nitinol Stone Extractor (K173009) features a 12 or 16-wire basket configuration. Comparative stone retention testing was conducted to demonstrate substantial equivalence.

7. Performance Data

Non-clinical performance bench testing and simulated use testing were completed to evaluate the design of the SpyGlass Discover Retrieval Basket for its intended use. Testing includes:

- Sheath Outer Diameter
- Working Length
- Basket Outer Diameter
- Basket Wire Spacing
- Tensile Pull Testing
- Simulated-Use Functionality & Durability
- Stone Capture
- Deflection Testing

Comparative stone retention testing was conducted on the SpyGlass Discover Retrieval Basket and the predicate Cook NCompass Nitinol Stone Extractor (K173009).

Testing was conducted per the requirements of ISO 10993-1 based on the biocompatibility classification of the device (category: externally communicating, contact duration: limited (<24 hours), and body contact: tissue). Testing performed per ISO 10993-1 confirms that the SpyGlass Discover Retrieval Basket is biocompatible for its intended use.

8. Conclusion

The information provided in this submission demonstrates that the proposed SpyGlass Discover Retrieval Basket is substantially equivalent to the Cook NCompass Nitinol Stone Extractor (K173009) in terms of performance, technological characteristics, and intended use.