December 18, 2020

Boston Scientific Corporation
Elena Hennessey
Fellow, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K203162
Trade/Device Name: Advanix Biliary Stent with NaviFlex RX Delivery System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: October 21, 2020
Received: October 23, 2020

Dear Elena Hennessey:

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,

For Thelma I. Valdes, 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)*

K203162

Device Name

Advanix™ Biliary Stent with NaviFlex™ RX Delivery System

Indications for Use *(Describe)*

Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone..

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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SECTION 5
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Elena Hennessey
Fellow Regulatory Affairs Specialist
Tel: 508-683-4347
Date Prepared: December 15, 2020

2. Proposed Device:
Trade Name: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System
Common Name: Stents, Drains And Dilators For The Biliary Ducts
Regulation Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II

3. Predicate Device:

Predicate Device:
Trade Name: Advanix™ Biliary Stent with NaviFlex™ RX Delivery System
Common Name: Stents, Drains And Dilators For The Biliary Ducts
Regulation Name: Biliary Catheters and Accessories
Regulation Number: 876.5010
Product Code: FGE
Classification: Class II
510(k) Clearance Number: K101314

4. Device Description:
The Advanix™ Biliary Stent with NaviFlex™ RX Delivery System consists of biliary plastic stents and delivery system catheters. They are sold separately or in a pre-loaded configuration, in which a stent comes attached to the catheter via a suture. The system is comprised of two (2) primary components: stent and delivery catheter with a locking mechanism. The Advanix Biliary Stent allows for drainage of the biliary duct by preventing closure and maintaining the patency of the biliary duct. These biliary stents are provided in center bend and duodenal bend shapes and have leading and trailing bars, a tapered leading end tip to facilitate access through the papilla, and a rounded tailing end to match the profile of the push catheter portion of the delivery system. The Advanix Biliary Stent with NaviFlex RX Delivery System is currently cleared under K101314. This proposed material change will only impact the Advanix Biliary 7F and 8.5F stent singles and the 7F and 8.5F pre-loaded configurations as shown below in Table 4-1:

Table 4-1 - Advanix Biliary Stent Material Change Stent Configurations:

	Advanix Biliary Stent
Shape	• Center Bend • Duodenal Bend
Sizes (Fr)	• 7F • 8.5F
Lengths (cm)	• 5cm • 7cm • 9cm • 12cm • 15cm • 18cm
Single or Stent Set	• Center Bend Single Stent (no delivery system) • Duodenal Bend Single Stent (no delivery system) • Center Bend Pre-loaded (stent and delivery system) • Duodenal Bend Pre-loaded (stent and delivery system)

5. Indications for Use:

The proposed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is intended for delivery of the stent to the biliary tract for drainage of the bile ducts, for splinting of a bile duct during healing, or for providing bile duct patency in a stricture or past a stone.

6. Technological Characteristics:

The proposed Advanix™ Biliary Stent with NaviFlex™ RX Delivery System is identical to the predicates in design, intended use and all materials with the exception of the stent material.

7. Performance Data:

The proposed device meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a risk management process", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals".

The following Biocompatibility tests were performed on the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System: MEM Elution Cytotoxicity; Guinea Pig Maximization Sensitization; Intracutaneous Reactivity; Acute Systemic Injection; and Implantation. In addition, the results of chemical extractable studies are provided which meet FDA's Guidance document, entitled, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process."

The proposed device bench testing is in alignment with FDA guidance document, "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions". The following bench tests were performed on the Advanix™ Biliary Stent with NaviFlex™ RX Delivery System: Drainage Lumen ID; Stent Length; Stent OD; Stent Shape; Repositionability (pre-loaded system only); Deployment Force; Device Trackability Force; Guidewire Compatibility; Duodenoscopy Compatibility; Barb Flap Cover Compatibility; Tensile: Aged in Bile; and Lumen Patency. All tests met required acceptance criteria, therefore supporting a finding of substantial equivalence.

8. Conclusion:

The information Boston Scientific Corporation provided in this submission demonstrates that the proposed Advanix Biliary Stent with NaviFlex RX Delivery System is substantially equivalent to the currently cleared Advanix Biliary Stent with NaviFlex RX Delivery System
(K101314).