December 29, 2022

Boston Scientific Corporation
Kerri Laplaca
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K223592
Trade/Device Name: Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter And Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: December 1, 2022
Received: December 1, 2022

Dear Kerri Laplaca:

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 An -S

Je Hi An, PhD
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)*
K223592

Device Name
Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers

Indications for Use *(Describe)*
The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers are intended for delivery of the stent to the pancreatic duct (PD):
• Used to drain pancreatic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Kerri LaPlaca
Principal Regulatory Affairs Specialist
Phone: (508) 382-0549
E-mail: kerri.laplaca@bsci.com

Date Prepared: December 2, 2022

2. Device

Trade Name:	Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Common Name:	Stents, Drains, and Dilators for the Biliary Ducts
Product Code:	FGE
Device Class:	Class 2
Device Panel:	Gastroenterology/ Urology
Classification Regulation:	21 CFR 876.5010, Biliary catheter and accessories

3. Predicate Device

Trade Name:	Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Clearance Number:	K133700
Common Name:	Stents, Drains, and Dilators for the Biliary Ducts
Product Code:	FGE
Device Class:	Class 2
Device Panel:	Gastroenterology/ Urology
Classification Regulation:	21 CFR 876.5010, Biliary catheter and accessories

4. Device Description

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers product consists of pancreatic stents and delivery systems or stent pushers.

The pancreatic stents are provided in straight or single pigtail shapes. The straight shape stents have trailing barbs and/or leading barbs depending on application, a rounded or tapered leading end tip to

facilitate access through the papilla, and a rounded trailing end to abut the push catheter portion of the delivery system or stent pusher. The single pigtail stent may or may not have leading end barbs depending on the application. Some stents have lateral drainage holes in the pigtails, a tapered or rounded leading end tip, and a rounded trailing end.

All stents have either an endoscopic marker, fluoroscopic marker, or both on the trailing or leading end of the stent to assist with depth of placement in the pancreatic duct. The location and presence of an endoscopic or fluoroscopic marker are dependent on the length and diameter size of the stent. Some codes have side port holes in the body of the stent.

5. Indications for Use

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers are intended for delivery of the stent to the pancreatic duct (PD):
• Used to drain pancreatic ducts

6. Technological Characteristics

The proposed Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers is identical to the predicate device.

7. Substantial Equivalence

The Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers is identical to the predicate device. The purpose of this Special 510(k) is to update the MRI safety information in the product labeling to align with FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (May 2021). The MRI safety status has not changed. The design requirements are not impacted by the labeling updates. Therefore, the subject is considered substantially equivalent to the predicate device.

8. Performance Data

Performance testing (bench) was completed to demonstrate compliance with the FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021. The testing included the following:

- **ASTM F2052**, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- **ASTM F2213**, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*
- **ASTM F2182**, *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging*
- **ASTM F2119**, *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

The performance (bench) testing demonstrated that the proposed Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers comply with the FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021, and are considered substantially equivalent to the predicate devices.

9. Conclusion

Boston Scientific has demonstrated that the proposed Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers with updated instructions for use are compliant with FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021, and is substantially equivalent to the currently marketed predicate device Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers (K133700).