July 3, 2025

Boston Scientific
Yanine Garcia-Quezada
Principle Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K251291
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: April 25, 2025
Received: April 25, 2025

Dear Yanine Garcia-Quezada:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ANTHONY LEE -S

Anthony C. Lee, Ph.D., M.B.A.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251291

Please provide the device trade name(s).

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

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-06-26

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Boston Scientific
Applicant Address	300 Boston Scientific Way Marlborough MA 01752 United States
Applicant Contact Telephone	508-382-0240
Applicant Contact	Yanine Garcia-Quezada
Applicant Contact Email	yanine.garcia-quezada@bsci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers
Common Name	Biliary catheter and accessories
Classification Name	Stents, Drains And Dilators For The Biliary Ducts
Regulation Number	21 CFR 876.5010
Product Code(s)	FGE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223592	Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pusher	FGE

Device Description Summary

21 CFR 807.92(a)(4)

The Advanix™ Pancreatic Stent and NaviFlex™ RX Pancreatic Delivery System and Pushers is a plastic pancreatic stent designed for the delivery of the stent to the pancreatic duct and used to drain pancreatic ducts.

The pancreatic stents are provided in straight or single pigtail shape. 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 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 is dependent on the length and diameter size of the stent. Some codes have side port holes in the body of the stent.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the proposed Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers device are identical to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed Advanix™ Pancreatic Stent and NaviFlex™ Rapid Exchange (RX) Pancreatic Delivery System and Pushers is identical to the predicate's design, intended use, fundamental technology, operating principle, manufacturing process and all materials with the exception of the stent material for the 4F and 5F sizes listed in this submission.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

This 510(k) notification includes testing for the following:
-Performance Bench Testing
- -Stent Corrosion Testing
- -Stent Tensile Testing
- -Lumen Patency Testing
- -Side Drainage Hole Testing
- -Stent Integrity Testing
- -Stent Length Testing
- -Stent Outer Diameter Testing
- -Pigtail Stent Shape and Diameter Testing
- -Stent Endoscopic Marker Location Testing
- -Pusher Deployment Force Testing
- -Pusher Trackability Force Testing

-Biocompatibility Testing:
- -Cytotoxicity Testing
- -ISO Guinea Pig Maximization Sensitization Testing
- -ISO Intracutaneous Reactivity Study in Rabbits
- -ISO Acute Systemic Toxicity Study in Mice
- -USP Rabbit Pyrogen Study, Materials Mediated
- -Genotoxicity: Bacterial Reverse Mutation Study
- -Genotoxicity: Mouse Lymphoma Assay
- -Implantation & Systemic Toxicity
- -Chemical Characterization

The results of the testing listed above demonstrate that the proposed Advanix Pancreatic Stent and NaviFlex RX Pancreatic Delivery System and Pushers is considered safe and effective for its intended use. The data also demonstrates its substantially equivalent to the predicate device (K223592).