August 14, 2023

Boston Scientific Corporation
Stephanie Gorman
Sr. Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K232162
Trade/Device Name: Autotome Pro RX 39 Sphincterotome; Autotome Pro RX 44 Sphincterotome; Jagtome Pro RX 44 Sphincterotome; Jagtome Pro RX 39 Sphincterotome; Dreamtome Pro RX 44 Sphincterotome; Hydratome Pro RX 44 Sphincterotome; Jagtome Revolution Pro RX 39 Sphincterotome

Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: July 20, 2023
Received: July 21, 2023

Dear Stephanie Gorman:

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,

Glenn B. Bell -S

Glenn B.Bell, Ph.D.
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.

Submission Number *(if known)*

K232162

Device Name

Autotome Pro RX 39 Sphincterotome;
Autotome Pro RX 44 Sphincterotome;
Jagtome Pro RX 44 Sphincterotome;
Jagtome Pro RX 39 Sphincterotome;
Dreamtome Pro RX 44 Sphincterotome;
Hydratome Pro RX 44 Sphincterotome;
Jagtome Revolution Pro RX 39 Sphincterotome

Indications for Use *(Describe)*

The Autotome Pro RX Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the transendoscopic sphincterotomy of the Papilla of Vater and/or Sphincter of Oddi. The Sphincterotome can also be used to inject contrast medium.

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 (per 21 CFR 807.92)

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

Contact: Stephanie Gorman
Sr. Regulatory Affairs Specialist
508.382.0441
Stephanie.Gorman@bsci.com

Date Prepared: July 20, 2023

Proposed Device Information:

Trade Name:	Autotome Pro RX 39 Cannulating Sphincterotome Autotome Pro RX 44 Cannulating Sphincterotome Dreamtome Pro RX 44 Sphincterotome Hydratome Pro RX 44 Sphincterotome Jagtome Pro RX 39 Sphincterotome Jagtome Pro RX 44 Sphincterotome Jagtome Revolution Pro RX 39 Sphincterotome
Common Name:	Sphincterotome
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Class II
Panel:	Gastroenterology/Urology

Predicate Device Information:

Trade Name:	Autotome RX Sphincterotome
510(k) Number:	K013153
Common Name:	Sphincterotome
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Class II
Panel:	Gastroenterology/Urology

Reference Device Information:

Device Name:	Single Use Preloaded Sphincterotome V
510(k) Number:	K122505
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Class II
Panel:	Gastroenterology/Urology

Device Description:

The Autotome Pro RX Sphincterotome is used for cannulation of the bile duct when performing diagnostic and/or therapeutic endoscopic biliary procedures. The sphincterotome can deliver contrast medium to the distal tip via an injection channel to aid in fluoroscopic visualization. The sphincterotome consists of a cutting wire on the distal end to cut and cauterize the Papilla of Vater and/or Sphincter of Oddi when connected to a monopolar electrosurgical generator. The sphincterotome is designed for use with endoscopes that have a working channel of 2.8mm or larger.

The Autotome Pro RX Sphincterotome is a 200cm, triple lumen sphincterotome available in 2 sizes: 3.9Fr and 4.4Fr. The Autotome Pro RX 39 Sphincterotome is capable of accepting a 0.025" (0.64mm) guidewire and the Autotome Pro RX 44 Sphincterotome is capable of accepting a 0.035" (0.89mm) or 0.025" (0.64mm) guidewire. The Autotome Pro RX Sphincterotome includes insulation on the proximal end of the cut wire. The Autotome Pro RX Sphincterotome is also available with a pre-loaded guidewire.

Indications for Use:

The Autotome Pro RX Sphincterotome is indicated for use in the selective cannulation of the Common Bile Ducts (CBD) and the transendoscopic sphincterotomy of the Papilla of Vater and/or Sphincter of Oddi. The Sphincterotome can also be used to inject contrast medium.

Performance Data:

Non-clinical performance bench testing, simulated use testing and biocompatibility testing (per the requirements of ISO 10993-1) were completed to evaluate the design of the proposed Autotome Pro RX Sphincterotome.

Bench Testing included:

- Exposed Cut Wire Length
- Distal Shaft Drawdown Length
- Depth and Reference Markers
- Length of Rapid Exchange
- Non-Insulated Cut Wire Length
- Initial Tip Orientation
- Tip Rotation
- Tip Bowing
- Tip Bow Holding
- Injection Flow Rate
- Tissue Cutting
- System Leakage
- Insulation Durability
- Insulation Dielectric Strength
- Endoscope Capability
- Guidewire Passage/Compatibility
- Guidewire Exchangeability
- Biopsy Cap Compatibility
- In-Plane Bowing

Biocompatibility Testing included:

- Cytotoxicity
- Sensitization
- Irritation

All testing produced passing results and demonstrates the device's ability to fulfill non-clinical performance bench testing, simulated use testing, and biocompatibility requirements.

Conclusion:

Boston Scientific has demonstrated that the proposed Autotome Pro RX Sphincterotome is substantially equivalent to the currently marketed Autotome RX Sphincterotomes (K013153).