July 25, 2019

Boston Scientific Corporation
Laura Kuroski
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K191789
Trade/Device Name: Stonetome Stone Removal Device
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: LQR
Dated: July 2, 2019
Received: July 3, 2019

Dear Laura Kuroski:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Daniel Walter
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)*

Device Name
Stonetome Stone Removal Device

Indications for Use *(Describe)*
The Stonetome Stone Removal Device is indicated for use in diagnostic or therapeutic endoscopic retrograde cholangiopancreatography (ERCP), transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi, to remove stones from the biliary system, and to facilitate injection of contrast medium while occluding the duct with the balloon.

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.

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Date Prepared: July 2, 2019

2. Proposed Device

Trade Name:	Stonetome Stone Removal Device
Common Name:	Biliary Stone Dislodger
Product Code:	LQR
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.5010

3. Predicate Device

Trade Name:	Endoscopic Biliary Catheter
Manufacturer:	Boston Scientific Corporation
Clearance Number:	K946358
Common Name:	Biliary Stone Dislodger
Product Code:	LQR
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.5010

4. Device Description

The Stonetome Stone Removal Device is a 200 cm tapered 7F (2.3 mm) to 5.5F (1.8 mm) triple lumen catheter that incorporates a sphincterotome with a latex retrieval balloon. The Stonetome Stone Removal Device is available in several configurations: (1) with the latex balloon mounted distal or proximal to the cutting wire, (2) with a 20- or 30-mm wire, and (3) with a 5 mm or 20 mm distal tip. See Stonetome Stone Removal Device configuration summary table below:

Stonetome Stone Removal Device Configurations Table

UPN*	Mounted Balloon Location	Distal Tip Length	Cut Wire Length
M005**3511**0	Above Cut Wire (Distal)	20mm Long Nose	20mm Cut Wire
M005**3513**0	Above Cut Wire (Distal)	20mm Long Nose	30mm Cut Wire
M005**3515**0	Below Cut Wire (Proximal)	5mm Short Nose	20mm Cut Wire
M005**3517**0	Below Cut Wire (Proximal)	20mm Long Nose	20mm Cut Wire
M005**3519**0	Below Cut Wire (Proximal)	5mm Short Nose	30mm Cut Wire
M005**3521**0	Below Cut Wire (Proximal)	20mm Long Nose	30mm Cut Wire

*Note: Bolded numbers within UPN are Catalog Numbers referenced within predicate 510(k), K946358

The Stonetome Stone Removal Device is capable of accepting a 0.035 in (0.89 mm) guidewire in one lumen while inflating the balloon via a second lumen. When connected to a monopolar electrosurgical generator, passed through a duodenoscope and activated, it will deliver a monopolar current to incise the Papilla of Vater and/or the Sphincter of Oddi. After sphincterotomy, the balloon may be passed beyond the stone, inflated, and withdrawn to remove the stone.

5. Indications for Use

The Stonetome Stone Removal Device is indicated for use in diagnostic or therapeutic endoscopic retrograde cholangiopancreatography (ERCP), transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi, to remove stones from the biliary system, and to facilitate injection of contrast medium while occluding the duct with the balloon.

6. Technological Characteristics

The modified Stonetome Stone Removal Device shares the same intended use, indications for use, and fundamental scientific technology as the predicate Endoscopic Biliary Catheter (K946358), (the current trade name had not been finalized at the time of the original submission). The modified device and the predicate device share nearly identical technological characteristics, with the modified device incorporating new retrieval balloon material.

7. Performance Data

Non-clinical testing was successfully performed on the modified Stonetome Stone Removal Device.

Performance testing (bench) was successfully completed to establish substantial equivalence between the modified Stonetome Stone Removal Device and the predicate device. This testing included the following:

- Balloon Inflation (OD)
- Balloon Inflation (Leakage)
- Simulated Stone Retrieval
- Balloon Distensibility

Biocompatibility of the Stonetome Stone Removal Device was evaluated in accordance with a risk management process, ISO 10993-1:2009 Biological evaluation of medical devices Part 1: Evaluation and the FDA Guidance for Industry and Food and Drug Administration Staff titled Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" dated June 16, 2016. The following tests were performed: Cytotoxicity, Irritation, Sensitization, and Acute Systemic Toxicity. All acceptance criteria were met.

The results of non-clinical testing demonstrate that the modified Stonetome Stone Removal Device is considered safe and effective for its intended use.

8. Conclusion

The modified Stonetome Stone Removal Device met all acceptance criteria for design verification as specified by applicable standards, guidance, and test protocols. Boston Scientific has demonstrated that the modified Stonetome Stone Removal Device is substantially equivalent to the predicate Endoscopic Biliary Catheter (K946358).