May 6, 2021

Boston Scientific Corporation
Kyra McNamara
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K210353
Trade/Device Name: AutoCap RX
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODC
Dated: February 5, 2021
Received: February 8, 2021

Dear Kyra McNamara:

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,

Shanil P. Haugen, Ph.D.
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)*
K210353

Device Name
AutoCap RX

Indications for Use *(Describe)*
The AutoCap RX Integrated Biopsy Cap and Guidewire Locking Device is intended to facilitate placement of the guidewire and lock it into place during ERCP procedures. The device also provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the ERCP procedure, and provides access for irrigation.

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

1. **Submitter:**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Kyra McNamara
Regulatory Affairs Specialist II
Telephone: (508) 382-0375

Date Prepared: 27 April 2021

2. **Device:**

Trade Name:	AutoCap™ RX
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	ODC
Regulatory Class:	Class II

3. Predicate Device:

Trade Name:	RX Locking Device & Biopsy Cap
Manufacturer:	Boston Scientific
510(k) Number:	K010610
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	ODC
Regulatory Class:	Class II

4. Device Description

The AutoCap RX is an integrated biopsy cap and guidewire locking device that fits on the biopsy port of an endoscope. The device is an accessory to be used with endoscopic devices to facilitate device passage, maintain insufflation, and lock the guidewire(s) in place during ERCP procedures. The AutoCap RX combines the locking device and the biopsy cap of the predicate, RX Locking Device and Biopsy Cap (K010610), into one integrated unit.

Materials and patient contact potential of the AutoCap RX components are provided below.

Component	Material Name	Patient Contacting
Housing	Plastic	No
Biopsy Cap	Silicone	Yes-Indirect
Foam Insert	Polyurethane Foam	Yes-Indirect

Testing was conducted per the requirements of 1SO 10993-1 based on the biocompatibility classification of the device (category: surface, contact duration: limited (<24 hours), and body contact: mucosal membrane). Testing performed per ISO 10993-1 confirmed that the AutoCap RX is biocompatible for its intended use.

5. Indications for Use:

The AutoCap RX Integrated Biopsy Cap and Guidewire Locking Device is intended to facilitate placement of the guidewire and lock it into place during ERCP procedures. The device also provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the ERCP procedure, and provides access for irrigation.

The AutoCap RX and the predicate, RX Locking Device and Biopsy Cap (K010610), share the same intended use, to facilitate placement of the guidewire and lock it into place during ERCP procedures. Although the Indications for Use of the AutoCap RX specifically identify its use to maintain insufflation and minimize leakage of biomaterial, these are not new uses. Maintaining Insufflation and minimizing leakage of biomaterials are generally established performance requirements of a biopsy cap. The RX Locking Device and Biopsy Cap was designed to meet these same performance capabilities per K010610.

6. Comparison of Technological Characteristics with the Predicate Device

The device consists of a plastic housing that holds a silicone biopsy cap with a foam insert. The plastic housing has molded guidewire locking slots to hold up to two guidewires. The plastic housing fits directly onto the biopsy port of the endoscope. The AutoCap RX is compatible with Olympus ERCP scopes. The AutoCap RX is substantially s equivalent to the predicate, RX Locking Device and Biopsy Cap (K010610), in terms of technological characteristics. Both have two guidewire locking slots and a silicone biopsy cap to facilitate device passage. Both devices attach to the scope via a press fit.

The AutoCap RX device combines the functionality of the RX Locking Device and Biopsy Cap (K010610) into an integrated unit allowing for a single attachment mechanism. The AutoCap RX secures directly around the scope and the housing will sit flush with the scope port.

Both the AutoCap RX and the RX Locking Device and Biopsy Cap (K010610) incorporate a silicone cap with a foam insert to minimize leakage of fluid and air while allowing for device exchange. The AutoCap RX incorporates additional molded silicone features within the cap to minimize leakage of fluid and air while allowing for device passage during endoscopic procedures.

Comparative bench testing confirms the ability of both AutoCap RX and predicate RX Locking Device and Biopsy Cap (K010610) to meet its intended use. The AutoCap RX is substantially equivalent to the predicate, RX Locking Device and Biopsy Cap (K010610), in terms of performance and technological characteristics.

7. Performance Data

Non-clinical performance bench testing, simulated use testing, biocompatibility per the requirements of ISO 10993, packaging, and sterilization validation per the requirements of ISO 11135 were completed to evaluate the design of the AutoCap RX for its indications for use.

Bench Testing included:

- Scope Attachment and detachment
- Biopsy Cap Bile Leakage
- Insufflation Ability
- Device Passability
- Guidewire Slippage
- Scope Suction Ability
- Simulated Use testing

All testing was passing and demonstrates the device's ability to fulfill non-clinical performance bench testing, biocompatibility, packaging, and sterilization requirements. The results of the predicate device are also included in the performance section and are comparable to the proposed device.

Both the AutoCap RX and the predicate RX Locking Device and Biopsy Cap (K010610) are provided sterile with a labeled shelf life. Aging testing on both the packaging and device confirm performance over the labeled shelf life.

Conclusion

The information provided in this submission demonstrates that the proposed AutoCap RX is substantially equivalent to the RX Locking Device and Biopsy Cap (K010610).