October 8, 2020

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

Re: K202478
Trade/Device Name: Captivator Single-Use Polypectomy Snares (27mm, 30mm, 33mm), Captiflex Single-Use Polypectomy Snares (27mm)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: August 27, 2020
Received: August 28, 2020

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 and Part 809 ); 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,

For 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)*
K202478

Device Name
Captivator Single-Use Polypectomy Snares (27mm, 30mm, 33mm)
Captiflex Single-Use Polypectomy Snares (27mm)

Indications for Use *(Describe)*
The Captivator and Captiflex Polypectomy Snares are used endoscopically in the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

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
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| | |
|---|---|
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| | |
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Date Prepared: August 27, 2020

### 2. Proposed Device

| | |
|---|---|
| Trade Name: | Captivator Single-Use Polypectomy Snares (27mm, 30mm, 33mm)<br>Captiflex Single-Use Polypectomy Snares (27mm) |
| Common Name: | Polypectomy Snares |
| Product Code: | FDI, FGX |
| Regulation Class: | Class II |
| Regulation Number: | 876.4300 |
| Regulation Name: | Endoscopic Electrosurgical Unit and accessories |

### 3. Predicate Device

| | |
|---|---|
| Trade Name: | Captivator Single-Use Polypectomy Snares<br>Captivator II Single-Use Polypectomy Snares<br>Captiflex Single-Use Polypectomy Snares<br>Profile Single-Use Polypectomy Snares<br>Sensation Single-Use Polypectomy Snares<br>Rotatable Single-Use Polypectomy Snares |
| Manufacturer: | Boston Scientific Corporation |
| Clearance Number: | K131700 |
| Common Name: | Polypectomy Snares |
| Product Code: | FDI, FGX |
| Regulation Class: | Class II |
| Regulation Number: | 876.4300 |
| Regulation Name: | Endoscopic Electrosurgical Unit and accessories |

## 4. Device Description

The Captivator and Captiflex Single-Use Polypectomy Snares consist of a flexible wire cable and loop which can be extended and retracted from the snare's flexible outer sheath using a three-ring handle. When passed through an endoscope the snare can be activated to deliver a monopolar electrical current to cut and cauterize tissue with the loop.

Table 5-1 lists the Captivator and Captiflex Single-Use Polypectomy Snares within scope of this 510(k).

**Table 5-1. Impacted Captivator and Captiflex Single-Use Polypectomy Snares**

| Sellable UPN/Product Code (Box Quantity) | UPN/Product Code (Single Unit) | Product Description | Loop Size |
|---|---|---|---|
| M00562371 (Box 10) | M00562370 | Captivator Medium Crescent Stiff | 27mm |
| M00562401 (Box 10)<br><br>M00562402 (Box 40) | M00562400 | Captiflex Medium Oval Flexible | 27mm |
| M00561311 (Box 10) | M00561310 | Captivator Large Oval Medium Stiff | 30mm |
| M00562341 (Box 10) | M00562340 | Captivator Medium Hexagonal Stiff | 27mm |
| M00562321 (Box 10) | M00562320 | Captivator Medium Oval Stiff | 27mm |
| M00561291 (Box 10) | M00561290 | Captivator Extra Large Round Stiff | 33mm |
| M00562391 (Box 10) | M00562390 | Captivator Large Oval Thin Wire Flex | 30mm |

## 5. Indications for Use

The Captivator and Captiflex Polypectomy Snares are used endoscopically in the removal and /or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.

## 6. Technological Characteristics

The modified Captivator (27mm, 30mm and 33mm) and Captiflex (27mm) Polypectomy Snares share the same intended use, indications for use, and fundamental scientific technology as the predicate devices (K131700).

## 7. Performance Data

Bench testing has been performed on the Captivator (27mm, 30mm, 33mm) and Captiflex (27mm) Single-Use Polypectomy Snares to demonstrate that the modified handle design meets required performance specifications and has restored performance to that of the predicate Captivator and Captiflex Snares (K131700). The testing included the following:

- Loop Extension Functionality
- Loop Retraction Functionality
- Snare Actuation Force

- Maximum Cutting Force

The modified Captivator and Captiflex Snares met all pre-defined specifications identified for snare loop extension functionality, retraction functionality, and actuation force in a simulated-use tortuous path. All snare configurations were tested for loop extension and retraction functionality. For snare actuation force, the largest snare (M00561290) was tested to represent all snares within scope of the change as a worst-case with regards to friction and resistance.

In addition, comparative maximum cutting force testing was performed on the predicate Captivator, Captiflex and Sensation Single-Use Polypectomy Snares and the modified snares. This bench testing was performed by measuring the maximum allowable force that could be applied by the snare on a non-compressible pin gauge. A summary of the maximum cutting force test results can be found in Table 5-2 and Table 5-3 below.

**Table 5-2. Predicate Captivator (27mm, 30mm, 33mm), Captiflex (27mm) and Sensation (30mm) Single-Use Polypectomy Snares Maximum Cutting Force**

| UPN | Description | Mean (lbf) | Standard Deviation (lbf) |
|---|---|---|---|
| M00562400 | Captiflex Medium Oval Flexible – 27mm | 5.4 | 0.54 |
| M00562390 | Captivator Large Oval Thin Wire Flexible – 30mm | 4.4 | 0.38 |
| M00561310 | Captivator Large Oval Medium Stiff – 30mm | 5.0 | 0.34 |
| M00561290 | Captivator II Extra Large Rounded Stiff – 33mm | 5.7 | 0.36 |
| M00562650 | Sensation Large Oval Medium Stiff – 30mm | 12.0 | 0.55 |

**Table 5-3. Modified Captivator (27mm, 30mm, 33mm) and Captiflex (27mm) Single-Use Polypectomy Snares Maximum Cutting Force**

| UPN | Description | Mean (lbf) | Standard Deviation (lbf) |
|---|---|---|---|
| M00562400 | Captiflex Medium Oval Flexible | 6.4 | 0.47 |
| M00562390 | Captivator Large Oval Thin Wire Flexible | 6.2 | 0.39 |
| M00561310 | Captivator Large Oval Medium Stiff | 6.7 | 0.85 |
| M00561290 | Captivator II Extra Large Rounded Stiff | 7.1 | 0.77 |
| M00562320 | Captivator Medium Oval Stiff | 7.4 | 0.81 |
| M00562340 | Captivator Medium Hexagonal Stiff | 6.2 | 0.57 |
| M00562370 | Captivator Medium Crescent Stiff | 6.8 | 0.45 |

All sizes of the modified Captivator and Captiflex Snares within scope of the 510(k) were tested.

The bench testing performed demonstrates that the modified Captiflex and Captivator Snares are substantially equivalent to the predicate snares (K131700).

**8. Conclusion**

The modified Captivator (27mm, 30mm, 33mm) and Captiflex (27mm) Polypectomy Snares met all bench testing acceptance criteria. Boston Scientific has demonstrated that the modified Captivator (27mm, 30mm, 33mm) and Captiflex (27mm) Polypectomy Snares are substantially equivalent to the predicate devices (K131700).