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SECTION 8
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- COMMON/USUAL NAMES: Snare, Flexible
- TRADE/PROPRIETARY NAME: Retrieval Snare
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

| Name | Number | 21 CFR Ref. |
|-----------------|--------|-------------|
| Snare, Flexible | 78 FDI | 876.4300 |

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
Gastro Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

- CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Specialist

INDICATIONS FOR USE

The Retrieval Snare is indicated for use in grasping and retrieval of foreign body within the alimentary tract. These foreign bodies may include guidewires, pullwires, or plastic stents.

CONTRAINDICATIONS

There are no known contraindications for this device.

POTENTIAL COMPLICATIONS

Possible complications include, but may not be limited to: inadvertent perforation during retrieval.

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FIGURE 8-1: SIMILARITIES AND DIFFERENCES BETWEEN RETRIEVAL SNARE, BOSTON SCIENTIFIC'S SNARE, PROFILE POLYPECTOMY SNARE, AND RETRIEVAL LOOP

| | <i>Microvase Retrieval Snare</i> (This 510(k)) | <i>BSC's Snare</i> (K950496) | <i>BSC's Profile Polypectomy Snare</i> (K941750) | <i>BSC's Retrieval Loop</i> (K860269) |
|---------------------------|---|---|--|---|
| USE | | | | |
| <i>Indication</i> | Retrieval of foreign body such as guidewires, pullwires, or plastic stents. | Resection, removal and cauterization of structures such as polyps, tissue, lesions or small tumors. | Removal and cauterization of sessile, diminutive, and pedunculated polyps. | Removal of foreign bodies, stones, PEG tubes, and stents. |
| <i>Catheter</i> | | | | |
| <i>Usable Length (cm)</i> | 180 | 40 to 240 | 240 | 190 |
| <i>Sheath OD (mm)</i> | 1.9 or 2.3 | 1.9 or 2.3 | 1.9 | 1.7 |
| | | | | |
| <i>Handle Type</i> | Plastic Three-Ring | Plastic Three-Ring | Plastic Three-ring | Plastic Three-Ring |
| <i>Loop Diameter</i> | 11 - 33 mm | 11 - 33 mm | 11-33 mm | 3/8" |
| <i>Loop Shapes</i> | Oval, Crescent, or Hexagonal | Oval, Crescent, or Hexagonal | Oval, Crescent, or Hexagonal | Oval |

BSC = Boston Scientific Corporation