



Food and Drug Administration
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July 7, 2017

Boston Scientific Corporation
Tara Paul
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K171454
Trade/Device Name: Interject Injection Therapy Needle Catheter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: May 16, 2017
Received: May 17, 2017

Dear Tara Paul:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K171454

Device Name

Interject Injection Therapy Needle Catheter

Indications for Use (Describe)

The Interject Injection Therapy Needle Catheter is used for endoscopic injection into gastrointestinal mucosa and submucosa to:

- introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system
- aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures
- control non-variceal hemorrhage

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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SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. SUBMITTER:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4296
Fax: 508-683-5939

Contact: Tara Paul
Regulatory Affairs Specialist II
Date Prepared: May 16, 2017

2. DEVICE:

Name of Device: Interject™ Injection Therapy Needle Catheter
Common Name: Injection Therapy Needle Catheter
Classification Name: Endoscopic Injection Needle, Gastroenterology- Urology
Regulation Number: 876.1500
Product Code: FBK
Classification: Class II

2. PREDICATE DEVICES:

Name of Device: Interject™ Injection Therapy Needle Catheter
Manufacturer: Boston Scientific
Common Name: Injection Therapy Needle Catheter
510(k) Number: K012864
Classification Name: Biopsy Needle
Regulation Number: 876.1075
Product Code: FCG
Classification: Class II

Name of Device: InjectorForce Max Single-Use Injection Needle
Manufacturer: Olympus Medical Systems Corp.
510(k) Number: K902736
Classification Name: Endoscopic Injection Needle, Gastroenterology- Urology
Regulation Number: 876.1500
Product Code: FBK
Classification: Class II

Name of Device: Wilson-Cook Variable Length GI Injection Needle
Manufacturer: Wilson-Cook Medical, Inc.
510(k) Number: K941305
Classification Name: Endoscopic Injection Needle, Gastroenterology- Urology
Regulation Number: 876.1500
Product Code: FBK
Classification: Class II

4. DEVICE DESCRIPTION:

The Interject™ Injection Therapy Needle Catheter is a catheter that consists of a handle with a hub for injection, a catheter sheath, and a needle. It is available in a variety of configurations with varying needle lengths, gauges, and catheter lengths.

5. INDICATIONS FOR USE:

The Interject™ Injection Therapy Needle Catheter is used for endoscopic injection into gastrointestinal mucosa and submucosa to:

- introduce a sclerosing agent, vasoconstrictor, or other solutions into selected sites to control actual or potential bleeding lesions in the digestive system
- aid in Endoscopic Mucosal Resection (EMR), Endoscopic Submucosal Dissection (ESD), or polypectomy procedures
- control non-variceal hemorrhage

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The proposed Interject Injection Therapy Needle Catheter device has identical technological characteristics as the predicate Interject Injection Therapy Needle Catheter (K012864) and similar technological characteristics as the predicate Olympus InjectorForce Max (K902736) and predicate Wilson-Cook Variable Length GI Injection Needle (K941305). The proposed device and the predicate Olympus and Cook devices have a minor difference in sheath outer diameter. This minor dimensional difference does not alter the suitability of the proposed device for its intended use.

7. PERFORMANCE DATA:

The proposed Interject Injection Therapy Needle Catheter is identical to the predicate Interject Injection Therapy Needle Catheter (K012864). The proposed device meets the requirements of ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing”, ISO 11135 “Sterilization of health care products - Ethylene oxide - Requirements for the development, validation, and routine control of a sterilization process for medical devices”, and ISO 10993-7 “Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals”, as the design and materials remain unchanged from that of the predicate Interject Injection Therapy Needle Catheter (K012864).

8. CONCLUSION:

Boston Scientific Corporation has demonstrated that the proposed Interject™ Injection Therapy Needle Catheter is substantially equivalent to the currently marketed Interject™ Injection Therapy Needle Catheter (K012864), the Olympus InjectorForce Max (K902736), and the Wilson-Cook Variable Length GI Injection Needle (K941305).