



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 29, 2015

Boston Scientific Corporation
Virginia Garcia
Principal, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01756

Re: K150679
Trade/Device Name: EndoVive™ Initial Placement Standard PEG Kit with ENFit Connector, EndoVive™ Initial Placement Safety PEG Kit with ENFit Connector
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: March 17, 2015
Received: March 18, 2015

Dear Virginia Garcia,

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. However, you are responsible to determine that the medical devices you use as components in the EndoVive™ Initial Placement Standard PEG Kit with ENFit Connector and EndoVive™ Initial Placement Safety PEG Kit with ENFit Connector 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); 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.

In addition, we have determined that your device kit contains iodine swabs, safety xylocaine, standard lidocaine, Chloraprep triple swab sticks, triple antibiotic ointment packets, and antiseptic ointment, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Ave.
Silver Spring, MD 20993
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 yours,


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)

K150679

Device Name

EndoVive™ Initial Placement Standard PEG Kit with ENFit Connector

EndoVive™ Initial Placement Safety PEG Kit with ENFit Connector

Indications for Use (Describe)

The Initial Placement PEG is indicated for enteral nutrition directly into the stomach in both pediatric and adult patients who are unable to consume nutrition by conventional means.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION 5 510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
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Fax: 508-683-5939

Contact: Virginia Garcia, MPP, RAC
Principal, Regulatory Affairs Specialist

Date Prepared: 26 May 2015

2. Devices

Trade Name:	EndoVive™ Initial Placement Standard PEG Kit with ENFit Connector EndoVive™ Initial Placement Safety PEG Kit with ENFit Connector
Common Name:	Gastrointestinal tube and accessories
Product Code:	PIF
Device Class and panel:	Class II, Gastroenterology and Urology
Classification Regulation:	21 CFR 876.5980

3. Predicate Devices

Trade Name:	EndoVive™ Initial Placement Standard PEG Kit, EndoVive™ Initial Placement Safety PEG Kit
Manufacturer and Clearance Number:	Boston Scientific Corporation, K031538
Classification Name:	Gastrointestinal tube and accessories
Product Code:	78 KNT
Device Class and panel:	Class II, Gastroenterology and Urology
Classification Regulation:	21 CFR 876.5980

4. Device Description

The EndoVive Standard Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit and Safety PEG Kit with ENFit are single-use, sterile, disposable kits. These kits contain a feeding tube, accessories used during initial placement of the tube, and accessories used after placement to aid in the provision of nutrition and medication directly into the stomach of adult and pediatric patients who are unable to consume nutrition by conventional means. In addition to the accessories packaged with the kits, replacement Y-Ports, c-clamps and round external bolsters are also available separately.

The Y-Port accessory, which is attached to the external end of the feeding tube to allow connection with other enteral feeding devices, is being modified to comply with the new ISO/DIS 80369-3.2 standard requirements to reduce the risk of misconnection with non-enteral feeding devices. The change to the Y-Port is to add the ISO/DIS 80369-3.2 ENFit thread design and to manufacture it in a more rigid material. Neither the feeding tube nor the accessories used for tube placement within these kits is changing. Other than the Y-Port, all other accessories in the Standard and Safety PEG Kits with ENFit are identical to the predicates.

5. Indication for Use:

The Initial Placement PEG is indicated for enteral nutrition directly into the stomach in both pediatric and adult patients who are unable to consume nutrition by conventional means. The Safety and Standard kit configurations are comprised of accessories assembled for the preference of the physician placing the PEG tube and contain the identical initial placement tube.

6. Technological Characteristics:

The Kit that is the subject of this submission contains a feeding tube that is placed via a procedure called Percutaneous Endoscopic Gastrostomy (PEG). It also contains accessories assembled for the preference of the physician placing the PEG tube. This placement procedure inserts a feeding tube into the stomach, through the abdominal wall, to the outside of the body under the visual guidance of an endoscope (a lighted instrument). After placement, the feeding tube extends from inside the stomach to approximately 12-15 inches from the skin outside the patient, with a Y-Port on the end of it. To keep the tube in place, an external bolster is placed near the skin level at the stoma (the tract from the outside skin to the stomach).

The Y-Port accessory, which is attached to the external end of the feeding tube to allow connection with other enteral feeding devices, is being modified to comply with the new ISO/DIS 80369-3.2 standard requirements to reduce the risk of misconnection with non-enteral feeding devices. The change to the Y-Port is to add the ISO/DIS 80369-3.2 ENFit thread design and to manufacture it in a more rigid material. Neither the feeding tube nor the accessories used for tube placement within these kits is changing. Other than the Y-Port, all other accessories in the Standard and Safety PEG Kits with ENFit are identical to the predicates.

7. Performance Data:

The EndoVive™ Initial Placement Standard PEG Kit with ENFit and EndoVive™ Initial Placement Safety PEG Kit with ENFit have been tested according to the following standards:

- EN ISO 10993-1:2009/AC 2010 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing
- EN ISO 10993-3:2009 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- EN ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity

- EN ISO 10993-6:2009 Biological evaluation of medical devices - Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- EN ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10 : Tests for irritation and delayed-type hypersensitivity
- EN ISO 10993-11:2009 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- EN ISO 10993-7:2008:AC 2009 Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals
- AAMI CN3:2014 (PS)/ ISO/DIS 80369-3.2 Small bore connectors for liquids and gases in healthcare applications – Part 3: Connectors for enteral applications
- AAMI CN20:2014 (PS)/ ISO 80369-20 Small bore connectors for liquids and gases in healthcare applications – Part 20: Common test methods

The information presented in this submission to support substantial equivalence of the EndoVive Initial Placement Standard PEG Kit with ENFit and EndoVive Initial Placement Safety PEG Kit with ENFit devices to the legally marketed predicate devices include: device description, indications for use, device comparison, material information, and labeling. Bench testing of the Y-Port ISO/DIS 80369-3.2 ENFit thread design supports compliance to the material, mechanical, and non-interconnectability principles of the ISO ISO/DIS 80369-3.2 standard. Specifically, the following bench tests were used to establish substantial equivalence: ENFit Performance (Resistance to separation from unscrewing, Resistance to overriding, Disconnection by unscrewing, Stress cracking, Positive pressure drop liquid leakage, Resistance to separation from axial load), Tensile strength, Liquid leakage, Flow rate, Y-port bifurcation, Shelf life testing, Risk analysis, Enteral Connector Misconnection Assessment, Enteral Connector Risk Management Report, Human Factors Validation Study, and ENFit Misconnection data with FMEA.

Boston Scientific has assessed the similarities between the proposed EndoVive Initial Placement Standard PEG Kit with ENFit and EndoVive Initial Placement Safety PEG Kit with ENFit and its predicates in terms of intended use and technological characteristics. The differences in the technological characteristics are minor and do not present any new issues of safety or effectiveness. This evidence supports a finding of substantial equivalence between the products.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed EndoVive Initial Placement Standard PEG Kit with ENFit and EndoVive Initial Placement Safety PEG Kit with ENFit are substantially equivalent to the currently marketed EndoVive Initial Placement Standard PEG Kit and EndoVive Initial Placement Safety PEG Kit (K031538).