DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 17, 2016

Boston Scientific Corporation
Virginia Garcia, MPP, RAC
Principal, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K161003
Trade/Device Name: EndoVive™ One Step Button Low Profile Initial Placement PEG Kit with ENFit Connector, Endovive™ Low Profile Button Replacement Gastrostomy Tube Kit with ENFit Connector, Endovive™ Button Right Angle Feeding Set with ENFit Connector, Endovive Button Bolus Feeding Set with ENFit Connector, Endovive Button Decompression Tube with ENFit Connector
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: PIF
Dated: April 8, 2016
Received: April 11, 2016

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 One Step Button Low Profile Initial Placement Peg Kit with ENFit Connector and Endovive Low Profile Button Replacement Gastrostomy Tube 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 kits contain an antiseptic ointment packet and iodine swabs, 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:

Center for Drug Evaluation and Research
Office of Compliance
10903 New Hampshire Avenue
Bldg. 51, Rm 5271
Silver Spring, MD 20993-0002

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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161003

Device Name
EndoVive™ One Step Button Low Profile Initial Placement PEG Kit with ENFit Connector, Endovive™ Low Profile Button Replacement Gastrostomy Tube Kit with ENFit Connector, Endovive™ Button Right Angle Feeding Set with ENFit Connector, Endovive™ Button Bolus Feeding Set with ENFit Connector, Endovive™ Button Decompression Tube with ENFit Connector

Indications for Use *(Describe)*

The One Step Button device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

The EndoVive Low Profile Replacement Button Gastrostomy device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

The Right Angle Feeding Set is intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. It is indicated for use on patients who are unable to consume nutrition by conventional means.

The Bolus Feeding Set is intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. It is indicated for use on patients who are unable to consume nutrition by conventional means.

The Right Angle Decompression Tube is intended to provide stomach decompression through a gastrostomy tube. It is indicated for use on patients who require enteral feeding as a means of nutritional support

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.

SECTION 5 510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4430
Fax: 508-683-5939

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

Date Prepared: April 8, 2016

2. Devices

Trade Name:

EndoVive™ One Step Button Low Profile Initial Placement PEG Kit with ENFit Connector
Endovive™ Low Profile Button Replacement Gastrostomy Tube Kit with ENFit Connector
Endovive™ Button Right Angle Feeding Set with ENFit Connector
Endovive™ Button Bolus Feeding Set with ENFit Connector
Endovive™ Button Decompression Tube 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:	One Step Button, Low Profile Initial Placement PEG Kit	Low Profile Button Replacement Gastrostomy Tube Kit	Button Right Angle Feeding Set	Button Bolus Feeding Set	Button Decompression Tube
Manufacturer and Clearance Number:	Boston Scientific Corporation K910584	Boston Scientific Corporation K014297	Boston Scientific Corporation K014297	Boston Scientific Corporation K014297	Boston Scientific Corporation K920894
Product Code:	KGC	KNT	KNT	KNT	KNT
Classification Name:			Gastrointestinal tube and accessories		
Device Class and panel:			Class II, Gastroenterology/Urology		
Classification Regulation			21 CFR 876.5980		

4. Device Description

The purpose of this Traditional 510(k) is to demonstrate that the proposed changes to the Y-Port and Bolus/Decompression accessories that are included in the devices identified above do not raise new questions of safety or effectiveness and that the devices are substantially equivalent to the currently marketed EndoVive™ Button kit and Accessory products.

The Y-Port and Bolus/Decompression accessories that are included in the devices identified above have two connections. One is located the distal end and the other is at the proximal end. The connector on the proximal end is identical in design to the ENFit threaded connector of the Y-Port accessory which was cleared via K150679. The Y-Port and Bolus/Decompression accessories are also identical in materials to the Y-Port device which was cleared via K150679. All of the performance and biocompatibility testing that was presented in K150679 to support the ENFit threaded connector is applicable to the Y-Port and Bolus/Decompression accessories of the proposed device. The scope of this submission is to demonstrate that the changes to the distal end of the Y-Port and Bolus/Decompression accessories are substantially equivalent to the predicate device. Neither the Button feeding tube nor the accessories used for tube placement within these kits is changing. The Button feeding tube and placement accessories in the kits are identical to the predicates.

5. Indication for Use:

EndoVive™ One Step Button Low Profile Initial Placement PEG Kit with ENFit Connector
The One Step Button Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Endovive™ Low Profile Button Replacement Gastrostomy Tube Kit with ENFit Connector
The EndoVive Low Profile Replacement Button Gastrostomy Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Endovive™ Button Right Angle Feeding Set with ENFit Connector
The Right Angle Feeding Set is intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Endovive™ Button Bolus Feeding Set with ENFit Connector
The Bolus Feeding Set is intended to provide nutrition to a patient directly into the stomach through a gastrostomy tube. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Endovive™ Button Decompression Tube with ENFit Connector
The Right Angle Decompression Tube is intended to provide stomach decompression through a gastrostomy tube. It is indicated for use on patients who require enteral feeding as a means of nutritional support

6. Technological Characteristics:

The Y-Port and Bolus/Decompression accessories included in the initial placement kits, the replacement kits, and replacement accessory sets are the subject of this submission.

The initial placement kit 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 Button feeding tube. The feeding set accessories included in the kit are for use in connecting the feeding tube to nutrition.

The replacement kit contains a feeding tube that is used to replace an existing feeding tube using the accessories assembled in the kit. The feeding set accessories included in the kit are for use in connecting the feeding tube to nutrition.

The feeding set and decompression tube accessories that are included in the kits are also sold separately. The Y-Port and Bolus/Decompression accessory within the feeding and decompression tube sets is being modified to comply with the new AAMI/CN3 ISO/DIS 80369-3.2 standard requirements to reduce the risk of misconnection with non-enteral feeding devices. The AAMI/CN3 ISO/DIS 80369-3.2 ENFit thread design will be added to the connector and the connector will be made of a more rigid material. Other than the connector changes, the Button feeding tube and placement accessories in the kits are identical to the predicates.

7. Performance Data:

The EndoVive™ Button Kit with ENFit and Accessories have been tested according to the following standards:

- 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 Button Kit with ENFit and Accessory with ENFit Connector to the legally marketed predicate devices include: device description, indications for use, device comparison, material information, and labeling. Bench testing of the connector ISO/DIS 80369-3.2 ENFit thread design supports compliance to the material, mechanical, and non-interconnectability principles of the ISO 80369-1: 2010 standard. This performance assessment includes Risk analysis, Enteral Connector Misconnection Assessment, Enteral Connector Risk Management Report, Human Factors Validation Study, and ENFit Misconnection data with FMEA, tensile strength, flow rate, and liquid leakage.

Boston Scientific has assessed the similarities between the proposed EndoVive Button Kit with ENFit and Accessories with ENFit Connector 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 Button Kit with ENFit Connector and Accessories with ENFit Connector are substantially equivalent to the currently marketed EndoVive Initial Placement Button Kit (K910584), EndoVive Replacement Button Kit (K014297) and Decompression Tube (K920894).