K091340
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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: 508-683-4454
Fax: 508-683-5939

Contact: Marybeth Gamber
Regulatory Affairs Manager
Date Prepared: May 5, 2009

JUN - 9 2009

2. Device:

Trade Name: EndoVive™ Through-The-PEG (TTP) Jejunal Feeding Tube Kit
Classification Name: Tube, Gastrointestinal (and Accessories)
Regulation Number: 876.5980
Product Code: KNT
Classification: Class II

3. Predicate Device:

Through-The-PEG (TTP) Jejunostomy Tube Kit K072476
Manufactured by Boston Scientific, Inc.

4. Device Description:

The TTP Jejunal Feeding Tube consists of a three-port device designed to be placed through a Boston Scientific gastrostomy tube to provide enteral access for decompression and delivery of nutrition and/or medication. The TTP Jejunal Feeding Tube Kit is available in two tip configurations, a pigtail tip and a bent tip. It may be placed by either the tether or guidewire techniques.

5. Intended Use:

The Through-the PEG (TTP) Jejunal Feeding Tube Kit is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

6. Technological Characteristics:

The proposed TTP Jejunal Feeding Tube Kit is similar in design, materials, and manufacturing processes to the predicate 3-Port TTP Jejunal Feeding Tube Kit (K072476).

7. Performance Data:

In-vitro testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Through-The-PEG (TTP) Jejunal Feeding Tube Kit is substantially equivalent to Boston Scientific Corporation's currently marketed Through-The-PEG (TTP) Jejunostomy Tube Kit (K072476).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2009

Ms. Marybeth Gamber
Manager Regulatory Affairs
Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
MALBOROUGH MA 01752

Re: K091340
Trade/Device Name: Through-The-Peg (TTP) Jejunal Feeding Tube Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT and FPD
Dated: May 5, 2009
Received: May 12, 2009

Dear Ms. Gamber:

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 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). 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 [kit/tray] 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, and labeling, and prohibitions against misbranding and adulteration.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	This application
Device Name:	Through-The-PEG (TTP) Jejunal Feeding Tube Kit
Indications for Use:	The Through-The-PEG (TTP) Jejunal Feeding Tube Kit is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091340