JUN 2 7 2003

510(K) SUMMARY

SPONSOR:	Boston Scientific Corporation (BSC) Microvasive Endoscopy Division One Boston Scientific Place Natick, MA 01760
CONTACT/SUBMITTER:	Paige Sweeney Senior Regulatory Affairs Specialist
DATE OF SUBMISSION:	May 14, 2003
DEVICES:	EndoVive™ Initial Placement PEG Kit EndoVive™ Initial Placement Direct PEJ Kit EndoVive™ Initial Placement PEG Safety Kit
TRADE NAME: **COMMON NAME:** **CLASSIFICATION:**	EndoVive™ Initial Placement PEG Kit Gastrostomy Tube Tubes, Gastrointestinal & Accessories Tube, Gastro-Enterostomy Classified Under 21 CFR Part 876, §5980. Classified as a Class II Device
TRADE NAME: **COMMON NAME:** **CLASSIFICATION:**	EndoVive™ Initial Placement Direct PEJ Kit Jejunostomy Tube Tube, Feeding Classified Under 21 CFR Part 876, §5980. Classified as a Class II Device
TRADE NAME: **COMMON NAME:** **CLASSIFICATION:**	EndoVive™ Initial Placement PEG Safety Kit Gastrostomy Tube Tubes, Gastrointestinal & Accessories Tube, Gastro-Enterostomy Classified Under 21 CFR Part 876, §5980. Classified as a Class II Device
PREDICATE DEVICES:	EndoVive™ Initial Placement PEG Kit (K030855) EndoVive™ Initial Placement Direct PEJ Kit (K030855) EndoVive™ Initial Placement PEG Safety Kit (K030855)
DEVICE DESCRIPTIONS:	The proposed EndoVive™ Initial Placement PEG Kit, the proposed EndoVive™ Initial Placement Direct PEJ Kit, and the EndoVive™ Initial Placement

PEG Safety Kit are used during initial placement for direct feeding.

INTENDED USES:

EndoVive™ Initial Placement PEG Kit 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 EndoVive™ Initial Placement Direct PEJ Kit is indicated for use for enteral nutritional support and decompression directly into the jejunum when feeding via the upper gastrointestinal tract is contraindicated.

The EndoVive™ Initial Placement PEG Safety Kit is indicated for providing nutrition directly into the stomach in patients who are unable to consume nutrition by conventional means. The safety components of the kit are designed to reduce the potential for inadvertent sharps injury to medical personnel during and after the procedure.

COMPARISON OF CHARACTERISTICS:

The proposed devices are substantially equivalent to currently marketed devices, as they are identical with the exception of the proposed domed PEG/PEJ material.

PERFORMANCE DATA:

The proposed devices are substantially equivalent to currently marketed devices in terms of performance characteristics and were tested for biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

Ms. Paige Sweeney
Senior Regulatory Affairs Specialist
Boston Scientific Corporation
One Boston Scientific Place
NATICK MA 01760

Re: K031538
Trade Name: EndoVive™ Initial Placement PEG Kit, Direct PEJ Kit, and PEG Safety Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: May 15, 2003
Received: May 30, 2003

Dear Ms. Sweeney:

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 (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were 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. 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.

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); 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 antibiotic ointment, iodine swabs and xylocaine 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:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(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, please contact the Office of Compliance at (301) 594-4616. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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 (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENTS

510(k) Number (if known) To be determined

Device Names EndoVive™ Initial Placement PEG Kit
EndoVive™ Initial Placement Direct PEJ Kit
EndoVive™ Initial Placement PEG Safety Kit

Indications for Use EndoVive™ Initial Placement PEG Kit 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 EndoVive™ Initial Placement Direct PEJ Kit is indicated for nutritional support and decompression directly into the jejunum when feeding via the upper gastrointestinal tract is contraindicated.

The EndoVive™ Initial Placement PEG Safety Kit is indicated for providing nutrition directly into the stomach in patients who are unable to consume nutrition by conventional means. The safety components of the kit are designed to reduce the potential for inadvertent sharps injury to medical personnel during and after the procedure.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031538