K022648
1 of 1

SEP 5 2002

Section 10
510(K) SUMMARY

SPONSOR:	Boston Scientific Corporation (BSC) Microvasive Endoscopy Division One Boston Scientific Place Natick, MA 01760
CONTACT/SUBMITTER:	Paige Sweeney Regulatory Affairs Specialist
DATE OF SUBMISSION:	August 8, 2002
DEVICE:	EndoVive™ Initial Placement Direct PEJ Kit
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.
PREDICATE DEVICE:	EndoVive™ Initial Placement Direct PEJ Kit (K020120)
DEVICE DESCRIPTION:	The proposed EndoVive™ Initial Placement Direct PEJ Kit is used during initial placement for direct feeding.
INTENDED USE:	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.
COMPARISON OF CHARACTERISTICS:	The proposed device is substantially equivalent to currently marketed devices, as they are identical with the exception of a modified kit component.
PERFORMANCE DATA:	The proposed device is substantially equivalent to currently marketed device in terms of performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Paige Sweeney
Regulatory Affairs Specialist
Boston Scientific Corporation
Microvasive Endoscopy
One Boston Scientific Place
NATICK MA 01760-1537

SEP 5 2002

Re: K022648
Trade/Device Name: EndoVive™ Initial Placement
Direct PEJ Kit
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: 78 KNT
Dated: August 8, 2002
Received: August 9, 2002

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 (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 (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 iodine swabs, lubricating jelly, antibiotic ointment, and 1% Xylocaine®, which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug component[s] of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component[s]. For information on applicable Agency requirements for marketing this [these] drug[s], 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 (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act, may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Nancy C Brogdon

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

Enclosure

K022648

Indications for Use Statement

510(k) Number (if known) K022648

Device Name EndoVive™ Initial Placement Direct PEJ Kit

Indications for Use 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.

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022648