AUG 20 1997

SECTION 10
510(K) SUMMARY

FOI RELEASABLE

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation chooses to submit a summary of information respecting safety and effectiveness.

- DATE: May 21, 1997
- COMMON/USUAL NAMES: Jejunostomy Feeding Tube
- TRADE/PROPRIETARY NAME: Unknown this time
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Tube, Feeding	78 FPD	876.5980

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
- CONTACT PERSON: Lisa M. Quaglia, Regulatory Affairs Manager

DESCRIPTION OF DEVICE

The Microvasive *TTP J-Tube* is a three port device designed to be placed through a Microvasive gastrostomy tube to provide gastric decompression and jejunal feeding. The Microvasive TTP J-Tube is available in two tip configurations (pigtail, & bent tip), and may be placed by either tether (pull), or guidewire techniques.

INDICATIONS FOR USE

The TTP J-Tube is indicated for enteral nutritional support and decompression where feeding via the upper gastrointestinal tract is contraindicated. This includes, post upper G.I. tract surgery,

radiation therapy, chemotherapy, reflux and other conditions associated with nausea, vomiting and possible aspiration.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the TTP J-Tube is substantially equivalent to currently-marketed devices such as Bard's Jejunal Feeding/Gastric Decompression Tube and Corpak's Corflo-Ultra Jejunostomy Tube. The major components of the TTP J-Tube are the shaft and the Y-Adapter. Both predicate devices as well as the TTP J-Tube are used for the same indicated use and are constructed with similar features. A thorough comparison of the descriptive characteristics between the TTP J-Tube and the predicate devices show equivalence.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the TTP J-Tube to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the TTP J-Tube with satisfactory results.

CONCLUSION

Boston Scientific Corporation believes that TTP J-Tube is substantially equivalent to the currently-marketed TTP J-Tube. Comparison of the descriptive characteristics of these products demonstrate the TTP J-Tube is equivalent in its indications for use, while being very similar in design and materials as the predicate devices. In addition, Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the TTP J-Tube will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa M. Quaglia
Regulatory Affairs Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

AUG 20 1997

Re: K971906
TTP Jejunostomy Feeding Tube
Regulatory Class: II
21 CFR §876.5980/Product Code: 78 FPD
Dated: May 21, 1997
Received: May 23, 1997

Dear Ms. Quaglia:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 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. 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 (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 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 the labeling regulation (21 CFR Part 801 and additionally 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Robert R Gatlin

for Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Health
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K971906

SECTION 1
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Name: TTP J-Tube

Indication for Use:

The *TTP J-Tube* is indicated for enteral nutritional support and decompression where feeding via the upper gastrointestinal tract is contraindicated. This includes, post upper G.I. tract surgery, radiation therapy, chemotherapy, reflux and other conditions associated with nausea, vomiting and possible aspiration.

Robert P. Rathbun

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971906

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____