K982508
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OCT 16 1998

SECTION 9
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.

- COMMON/USUAL NAMES: Nasobiliary Catheter; Nasobiliary Tube
- TRADE/PROPRIETARY NAME: Flexima™
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Biliary Catheter and Accessories	78 FGE	876.5010

- DEVICE PANEL/BRANCH: Gastroenterology-Urology (GU)
  Gastro-Renal (GRDB)
- OWNER/OPERATOR: Boston Scientific Corporation
  One Boston Scientific Place
  Natick, MA 01760
  Owner/Operator No. 9912058
- CONTACT PERSON: Daniel J. Dillon, Regulatory Affairs Project Manager

INDICATIONS FOR USE

The Flexima™ Nasobiliary Catheter is indicated for prolonged access to the biliary ductal system via the nose, including:

- Decompression of an obstructed bile duct in acute suppurative cholangitis.
- Temporary or short-term decompression of the common bile duct, similar to that which follows unsuccessful stone extraction after endoscopic sphincterotomy.
- Prevention of stone impaction after endoscopic sphincterotomy.
- Infusion of contrast medium for repeat cholangiography.
- Instillation of various therapeutic solutions, including antibiotics (for acute bacterial cholangitis) or saline (to flush sludge or small stones after endoscopic sphincterotomy).
- Preoperative biliary decompression to decrease jaundice (thereby decreasing perioperative complications) in patients undergoing elective biliary tract surgery.

- Temporary biliary decompression in patients who are septic or who have severe coagulopathy. Once infection has been controlled or coagulopathy corrected, sphincterotomy can be performed, and a large stent can be inserted for long-term therapy.
- Access for intraluminal irradiation therapy, using iridium.
- Aspiration of bile for chemical and bacteriologic studies (e.g., to identify causative agents in bacterial cholangitis or to determine the lithogenicity of bile in patients with cholestasis).
- Facilitating the healing process in traumatic or surgical biliary fistulae.

CONTRAINDICATIONS

Patients with coagulopathy or any other contraindication to esophagogastroduodenoscopy are contraindicated for the Flexima™ Nasobiliary Catheter.

POTENTIAL COMPLICATIONS

Possible complications include, but may not be limited to: dislodgment of the catheter, nose and throat irritation, and excess bile loss due to external drainage.

SUBSTANTIAL EQUIVALENCE

Boston Scientific Corporation believes that the Flexima™ Nasobiliary Catheter is substantially equivalent to the currently-marketed Microvasive® Biliary Stent System, Medi-Tech® Flexima™ Biliary Drainage Catheter and the Wilson-Cook® Nasal Biliary Drainage Set.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on Flexima™ Nasobiliary Catheter to verify its safety and performance. A biocompatibility assessment was performed on the patient- and fluid-contact materials of the Flexima™ Nasobiliary Catheter with satisfactory results.

PACKAGING, STERILIZATION, AND PYROGENICITY

The Flexima™ Nasobiliary Catheter will be packaged in Tyvek® and extrusion coated-polyethylene on polyester. The Flexima™ Nasobiliary Catheter will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization. Pyrogenicity testing will be performed on a periodic basis to monitor bacterial endotoxin levels.

CONCLUSION

Boston Scientific Corporation believes that Flexima™ Nasobiliary Catheter is substantially equivalent to the currently-marketed Microvasive® Biliary Stent System, Medi-Tech® Flexima™ Biliary Drainage Catheter and Wilson-Cook® Nasal Biliary Drainage Set. Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Flexima™ Nasobiliary Catheter 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

OCT 16 1998

Mr. Daniel J. Dillon
Regulatory Affairs Project Manager
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K982508
Flexima™ Nasobiliary Catheter
Regulatory Class: II
Product Code: 78 FGE
21 CFR 876.5010
Dated: September 3, 1998
Received: September 4, 1998

Dear Mr. Dillon:

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 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 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, 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, the 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

SECTION 1
INDICATIONS FOR USE

510(k) Number: To Be Determined

Device Name: Flexima™ Nasobiliary Catheter

Indication for Use:

The Flexima™ Nasobiliary Catheter is indicated for prolonged access to the biliary ductal system via the nose, including:

- Decompression of an obstructed bile duct in acute suppurative cholangitis.
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- Facilitating the healing process in traumatic or surgical biliary fistulae.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Segner

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982508

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)