K974788

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510(K) SUMMARY

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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: Balloon Dilatation Catheter
- TRADE/PROPRIETARY NAME: Modified CRE™ Balloon Dilatation Catheter
- CLASSIFICATION NAME & DEVICE CLASSIFICATION: Class II

Name	Number	21 CFR Ref.
Dilator, Esophageal	78 KNQ	876.5365
Endoscope & Accessories	78 KOG	878.1500

- 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, Senior Regulatory Affairs Specialist

INDICATIONS FOR USE

The Modified CRE™ Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label.

CONTRAINDICATIONS

None known.

POTENTIAL COMPLICATIONS

Possible complications that may result from an alimentary tract procedure include, but may not be limited to; perforation; hemorrhage; hematoma; septicemia/infection; allergic reaction to contrast medium.

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DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

Boston Scientific Corporation believes that the Modified CRE™ Balloon Dilatation Catheter is substantially equivalent to the current CRE™ Balloon Dilatation Catheter and the Vector TTS™ Balloon Dilatation Catheter.

PERFORMANCE CHARACTERISTICS

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

PACKAGING, STERILIZATION, AND PYROGENICITY

The Modified CRE™ Balloon Dilatation Catheter will be packaged both sterile and non-sterile in a Tyvek-Mylar pouch. The Modified CRE™ Balloon Dilatation Catheter, when sterilized, will be sterilized using ethylene oxide gas using the AAMI protocol for ethylene oxide sterilization. Because the Modified CRE™ Balloon Dilatation Catheter will not normally contact blood, pyrogenicity testing will not be performed.

CONCLUSION

Boston Scientific Corporation believes that Modified CRE™ Balloon Dilatation Catheter is substantially equivalent to the current CRE™ Balloon Dilatation Catheter and the Vector TTS™ Balloon Dilatation Catheter. Boston Scientific Corporation has presented laboratory testing and biocompatibility information. The information presented provides assurance that the Modified CRE™ Balloon Dilatation 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

MAR 20 1998

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

Re: K974788
Modified CRE™ Balloon Dilatation Catheter
Dated: December 19, 1997
Received: December 22, 1997
Regulatory Class: II
21 CFR 876.1500/Procode: 78 KOG
21 CFR 876.5365/Procode: 78 KNQ

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 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. 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 Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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,

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:

Device Name: Modified Balloon Dilatation Catheter

Indication for Use:

The Modified Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. The recommended application is printed on the package label.*

* The recommended application on the label may refer to any combination of esophageal, pyloric, and colonic dilatation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert D. Watkins
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974788

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