K023337

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SECTION 14

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:	October 4, 2002
Common/Usual Names:	Balloon Dilatation Catheter
Trade/Proprietary Names:	CRE™ Pulmonary Balloon Dilatation Catheter

Classification Name & Device Classification: Class II

Name	Number	21CFR Ref.
Bronchoscope & Acc.	77 KTI	874.4680

Device Panel/Branch: Ear, Nose and Throat (ENT)

Owner/Operator:
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Contact Person:
Paige Sweeney
Regulatory Affairs Specialist

K023337

Description of Devices

The CRE™ Pulmonary Balloon Dilatation Catheter is used to access the airway tree via a bronchoscope for the purpose of dilating strictures. It consists of an inflatable balloon on a catheter shaft with lumens for inflation and guidewire.

Indications for Use

The CRE™ Pulmonary Balloon Dilatation Catheter is intended to be used endoscopically to dilate strictures of the airway tree.

Descriptive and Technological Characteristics of Proposed and Predicate Devices

Boston Scientific Corporation believes that the CRE™ Pulmonary Balloon Dilatation Catheter is substantially equivalent to the currently marketed CRE™ Balloon Dilatation Catheter. The major components of these devices are the balloon, catheter shaft, and proximal hub. A thorough comparison of the descriptive characteristics between the proposed devices and the predicate devices show equivalence.

Conclusion

Boston Scientific Corporation has demonstrated that the CRE™ Pulmonary Balloon Dilatation Catheter is substantially equivalent to the currently marketed CRE™ Balloon Dilatation Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 8 2002

Boston Scientific, Corp.
c/o Paige Sweeney
Regulatory Affairs Specialist
Microvasive Endoscopy
One Boston Scientific Place
Natick, MA 01760

Re: K023337
Trade/Device Name: CRE™ Pulmonary Balloon Dilation Catheter
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: KTI
Dated: October 4, 2002
Received: October 7, 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 (Act) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 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.

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 21 CFR Part 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" (21CFR 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/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION 3
INDICATIONS FOR USE

510(k) Number: To Be Determined K023337

Device Name: - CRE™ Pulmonary Balloon Dilatation Catheter

Indication for Use: **The CRE™ Pulmonary Balloon Dilatation Catheter** is intended to be used endoscopically to dilate strictures of the airway tree.

(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 21CFR 801.1091) **(Optional Format 1-2-96)**

Karen A. Baker

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023337