K071309

510(k) Summary

Per 21 CFR §807.92

JUL 13 2007

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311
Contact Name and Information	Kari Christianson Regulatory Affairs Specialist Phone: (763) 494-1969 Fax: (763) 494-2222
Date Prepared	May 07, 2006
Proprietary Name(s)	**Blue Max™** Balloon Dilatation Catheter
Common Name	Balloon Dilatation Catheter
Product Code	LIT
Classification of Device	Class II, 21 CFR Part 870.1250
Predicate Device	Blue Max™ Balloon Dilatation Catheter — K000570 — April 13, 2000
Device Description	The Blue Max™ Balloon Dilatation Catheter, styled after the Gruentzig technique, is a double lumen catheter with a non-compliant balloon mounted at the distal tip. Dilatation balloon catheters are used to exert radial force to dilate narrow vessel segments. The Blue Max™ balloon dilation catheter is designed to deliver maximum force in calcified or fibrotic lesions, or in lesions or strictures that are resistant to dilatation. **Balloon Construction** Each balloon inflates to its stated diameter and length over a range of 4 atm (405 kPa) to its rated burst pressure. The minimal dilating force required to dilate should be applied, minimizing risks of balloon over-inflation or rupture.

Device Description (continued)	**Catheter Construction** The Catheter body has two lumens. The lumen marked "distal" is the central lumen of the catheter which terminates at the distal tip. This lumen is used to pass the catheter over a guidewire. The lumen can also be used for infusion of contrast medium. The lumen marked "Balloon" is the balloon inflation lumen. The catheter shaft tapers beneath the balloon segment to achieve the lowest possible deflated profile. Radiopaque markers are placed under the balloon segment of the catheter to provide visual reference points for balloon positioning within the vessel.
Intended Use of Device	Blue Max™ Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty of the Iliac, Femoral, and Renal Arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Comparison of Technological Characteristics	The materials and design of the Blue Max™ Balloon Dilatation Catheter are equivalent to the predicate Blue Max Balloon Dilatation Catheter.
Support of Substantial Equivalence	Boston Scientific Corporation considers the proposed Blue Max™ Balloon Dilatation Catheter to be substantially equivalent to the existing Blue Max™ Balloon Dilatation Catheter (K000570 cleared April 13, 2000). This assessment is based upon identical device materials and design characteristics. The only change being initiated is to add a contraindications section to the Directions for Use, and move three existing precautions to this new section.
Conclusion	Based on the indications for use and the technological characteristics, the Blue Max™ Balloon Dilatation Catheter has been shown to be equivalent in intended use and is considered to be substantially equivalent to the Blue Max™ Balloon Dilatation Catheter (K000570; cleared April 13, 2000).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2007

Boston Scientific Corp.
c/o Ms. Kari Christianson
One Scimed Place A380
Maple Grove, MN 55311-1566

Re: K071309
Trade/Device Name: Blue Max™ Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Transluminal Angioplasty Balloon Dilatation Catheter
Regulatory Class: Class II (Two)
Product Code: LIT
Dated: May 7, 2007
Received: May 9, 2007

Dear Ms. Christianson:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K071309

Device Name: Blue Max™ Balloon Dilatation Catheter

Indications for Use:

Balloon Dilatation Catheters are recommended for Percutaneous Transluminal Angioplasty of the Iliac, Femoral and Renal Arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071309