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Summary of Safety and Effectiveness

General Provisions	**Trade Name:** Equalizer Balloon Catheter **Classification Name:** Catheter, Angioplasty, Peripheral, Transluminal
Name of Predicate Devices	Large Occlusion Balloon Catheter Blue Max Balloon Catheter
Classification	Class II
Performance Standards	Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act
Intended Use and Device Description	The Equalizer Balloon is indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. The Equalizer Balloon Catheter is designed for temporary occlusion of vessels up to 40mm in diameter. To allow for large inflation diameters, the balloons are mounted on a non-tapered catheter shaft. All Equalizer Balloon Catheters have two lumens that are marked. The tubing, marked BALLOON, is the balloon inflation lumen. The tubing 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 Equalizer Balloon Catheter is constructed of a soft compliant latex balloon mounted on the tip of a multi-lumen nylon catheter shaft. Radiopaque markers are placed adjacent to the balloon segment of the catheter to provide visual reference points for balloon positioning within the vessel. Catheter shafts are radiopaque, maximizing fluoroscopic visibility.
Biocompatibility	No new materials have been introduced during this modification as compared to the predicate devices. The predicate devices have been tested for biocompatibility. All data demonstrate this device is biocompatible for its intended use.
Summary of Substantial Equivalence	The Equalizer Occlusion Balloon Catheter has been tested and compared to the predicate devices. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Corporation
c/o Jennifer Bolton, RAC
Senior Regulatory Affairs Specialist
One Boston Scientific Place
Natick, MA 01760-1537

JUN 2 0 2002

Re: K021721
Device Name: Equalizer Occlusion Balloon Catheter
Regulation Number: 21 CFR 1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: May 23, 2002
Received: May 24, 2002

Dear Ms. Bolton:

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.

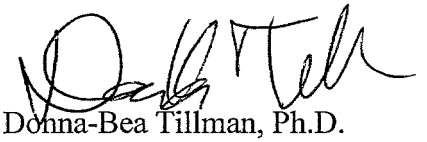
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) 594-4646. 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,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known)	Unknown
Device Name:	Equalizer Balloon Catheter
Indications for Use	The Equalizer Balloon is indicated for use for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K021721