MAY 1 8 2000

K992320

510(k) Summary

Date Prepared February 18, 2000

Submitter

Address: Boston Scientific Corporation
Schneider (USA) Inc
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Minneapolis, MN 55442

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Contact Person Ronald W. Bennett
Regulatory Affairs Project Manager

Device Name and Classification

Trade Name: Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter

Common Name: Percutaneous Transluminal Angioplasty (PTA) Catheter

Classification: Class II

Predicate Device SMASH ™ Percutaneous Transluminal Angioplasty (PTA) Catheter - K972512

Device Description

The Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter consists of a multilumen catheter with a controlled-compliance balloon mounted at the distal tip. The balloon is designed to inflate to a known diameter and length at a specific pressure and is inflated and deflated via the side port. A second lumen allows access to the distal tip of the catheter for guidewire insertion. Two marker bands are positioned under the balloon at the proximal and distal tapers to aid in accurate placement.

Intended Use

Megabello Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty (PTA) of the iliac and femoral vessels whose lumens are obstructed by atherosclerotic plaque. Megabello catheters are not indicated for use in coronary arteries nor in the neurovasculature. Any other use than those indicated is not recommended.

Technical Characteristic Comparison to Predicate

The Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter has the same intended use and basic construction as the predicate device, the SMASH™ Percutaneous Transluminal Angioplasty (PTA) Catheter. The following table compares the technical characteristics of the two devices:

Feature	MEGABELLO Percutaneous Transluminal Angioplasty (PTA) Catheter	Smash™ Percutaneous Transluminal Angioplasty (PTA) Catheter
Configuration	Multilumen	Multilumen
Shaft Length (cm)	75 –120	60-120
Shaft French Size	7	5
Balloon Length (mm)	20-40	20-80
Balloon Diameter (mm)	12, 14	3-12
Rated Burst Pressure (atm)	7	7-15
Guidewire Size (inches)	0.035	0.035
Balloon Markers	2 (90/10 Platinum/ Iridium)	2 (Gold)
Balloon Material	Nylon	Nylon
Manifold Material	Pebax	ABS
Shaft Material	Pebax 6333	Nylon

Performance Data

The Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter had non-clinical performance testing, as did the predicate device, the SMASH™ Percutaneous Transluminal Angioplasty (PTA) Catheter.

Testing of the Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter generally followed the PTCA Balloon Catheters section in Part II of the "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices", May 1994. The following types of tests were performed similar to those in the guidance:

Balloon Minimum Burst Strength
Balloon Compliance (Distensibility)
Balloon Inflation/Deflation Performance
Balloon Fatigue (Repeated Balloon Inflation)
Bond Strength
Catheter Diameter and Balloon Profile
Catheter Body Burst Pressure

The following additional evaluations were also performed:

Sheath Removal
Profile

The biocompatibility of the catheter was also tested and found acceptable.

Summary
In summary, Boston Scientific Corporation has demonstrated the Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter is substantially equivalent to the SMASH™ Percutaneous Transluminal Angioplasty (PTA) Catheter based on design and test results for the indications for use given, and is therefore acceptable for commercialization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Mr. Ronald W. Bennett
Regulatory Affairs Project Manager
Boston Scientific Corporation
Scneider (USA) Inc.
5905 Nathan Lane
Minneapolis, MN 55442

Re: K992320
Megabello Balloon Dilatation Catheter
Regulatory Class: II (two)
Product Code: LIT
Dated: February 18, 2000
Received: February 22, 2000

Dear Mr. Bennett:

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. 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) 594-4648. 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 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

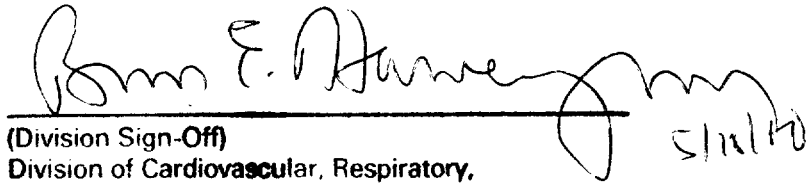
Enclosure

510(k) Number (if known):

Device Name: **Megabello Percutaneous Transluminal Angioplasty (PTA) Catheter**

Indications for Use:

Megabello Balloon Dilatation Catheters are recommended for percutaneous transluminal angioplasty (PTA) of the iliac and femoral vessels whose lumens are obstructed by atherosclerotic plaque. Megabello catheters are not indicated for use in coronary arteries nor in the neurovasculature. Any other use than those indicated is not recommended.



5/12/10

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992320

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)