K041293

JUL - 9 2004

510(k) Summary

Submitted by:

Keith Paluch
Consultant
Bipore, Inc.
31 Industrial Parkway
Northvale, NJ 07647

Proposed Device:

Bipore Balloon Dilation Catheter

Product Classification:

Class II C.F.R. 880.5025 Product code: LIT

FDA registration number:

2248069

Predicate Devices:

510(k)	Name	Manufacturer
K961980	Balloon Dilation Catheter	Bipore, Inc.

Device Description:

The Bipore Inc. Balloon Dilation Catheter is an over-the-wire double lumen balloon catheter designed for percutaneous transluminal angioplasty (PTA) in peripheral arteries, including iliac, femoral, and renal arteries. The catheter consists of a 5 French nylon-based shaft with two lumens. One lumen is for inflation and deflation of the balloon. The other lumen accepts a guidewire for manipulation of the catheter to the site stenosis. Guidewires up to 0.035" diameter may be used. There is a bifurcated proximal juncture that provides access to each lumen.

A non-compliant dilation balloon of nylon (11) is at the distal end of the catheter. When inflated, the balloon exerts a controlled radial pressure.

Located under the proximal and distal ends of the balloon are radiopaque markers, which provide a reference point for locating the balloon within the vessel.

A Teflon™ sleeve is placed over the deflated balloon prior to shipping. This sleeve is designed to protect the balloon in storage and is removed prior to use.

Information on proposed change to the device:

The currently cleared device uses a polyethylene terephthalate (PET) balloon. The rated pressure for 3mm through 8mm balloons is 12 atmospheres. (Atm.) The rated pressure for the 10mm balloon is 10 atmospheres. (Atm.) And, the rated pressure for the 12mm balloon is 8 atmospheres. (Atm.) The change from PET to Nylon balloon construction material improves the burst resistance of the device. Because of the improved properties of the Nylon polymer rated burst pressures increase to 15 atmospheres for 3mm through 8mm balloons, 12 atmospheres for the 10mm balloon and 10 atmospheres for the 12mm balloon size.

The material is nylon 11 manufactured by ELF Atochem designated Besvo A. This material is known to be commonly used in the manufacture of similar type medical devices.

All materials and assembly processes except for the balloon are identical to the original 510(k) submission. Newly performed FMEA identified seven items that were evaluated to access the suitability of material change to nylon.

1. Balloon pressure to yield (burst test).
2. Balloon multiple inflations (to access the element of fatigue)
3. Balloon compliance (ability of the balloon to expand to a predetermined diameter at a specified pressure).
4. Balloon inflation and deflation time.
5. Tensile strength at the catheter shaft connection.
6. Balloon pressure to burst when placed within stent (expansion)
7. Shelf life at simulated three-year period.

Acceptance Criteria:

All tests conducted on radiation-sterilized units exposed to a minimum of 40 kilo gray dosage representative of worst-case exposure. Tests performed at 37°C, water bath immersed to simulate actual use conditions.

1. The device must not yield (burst) at pressures of less than 15 atmospheres for 3mm, 3.5mm, 4mm, 5mm, and 6mm 7mm and 8mm balloons. The 10mm balloon must withstand 12 atmospheres. The 12mm balloon size must withstand 10 atmospheres. The sample size must be sufficiently large enough to yield data that is 95% confident that 99.9% of the balloons will not fail at or below specification.

2. The device must not yield (burst) at pressures of less than 15 atmospheres for 3mm, 3.5mm, 4mm, 5mm, and 6mm 7mm and 8mm balloons. The 10mm balloon must withstand 12 atmospheres. The 12mm balloon size must withstand 10 atmospheres. All sizes must withstand at least 40 individual pressurization cycles. This test accesses the element of fatigue. The sample size must be sufficiently large enough to yield data that is 95% confident that 99.9% of the balloons will not fail at or below specification.

3. The Balloon must expand to a predetermined diameter at a pressurization range of between 4 and 15 atmospheres for 3.5mm through 8mm sized balloons and 4 to 10 atmospheres for the 10mm and 12mm balloon. The test result must be no less than 1% under the nominal rated size and no greater than 14% at the highest pressurization (+14%/-1%).

4. The Balloon must be capable of inflating to the specified size within 60 seconds after setup and air purge.
   The Balloon must be capable of completely deflating within 60 seconds of the initiation of test.

5. The Balloon must withstand a straight-line pull force of greater than 5 pounds for one minute. No leakage or separation of the junction or joint is permitted.

6. A non-compliant hollow tube is used to simulate stent expansion. Each French sized balloon is placed inside of the stent simulator and pressurized until burst. The test results must be as follows: The device must not yield (burst) at pressures of less than 15 atmospheres for 3mm, 3.5mm, 4mm, 5mm, and 6mm 7mm and 8mm balloons. The 10mm balloon must withstand 12 atmospheres. The 12mm balloon size must withstand 10 atmospheres.

7. Shelf life at simulated three-year period was performed by elevated temperature and time. Test units were placed in an incubator at 51°C for a period of 17 weeks. A calculation of the 3-year period is based upon "Shelf Life Extension of Medical Devices dated April 1991 (DSMA of FDA). Aged units must meet original specification.

Comparison to predicate device:

Similarities:

Proposed and predicate devices have the same indications for use.

The proposed device modification meets Bipore, Inc. original device specification.

The modified device is fully reverse compatible with the originally cleared device.

Proposed modification and predicate devices are sterile and non-pyrogenic.

Burst ratings are within the range of competitors advertised claims.

Differences:

Modified device have a greater burst pressure rating than the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2004

Bipore, Inc.
c/o Mr. Keith Paluch
Consultant for Bipore, Inc.
31 Industrial Parkway
Northvale, NJ 07647

Re: K041293
Bipore Balloon Dilation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: May 11, 2004
Received: May 14, 2004

Dear Mr Paluch:

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 Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.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

510(k) Number (if known): K041293

Device Name: Bipore Balloon Dilation Catheter

Indications For Use: The Bipore Balloon Dilation Catheter is intended to be used for percutaneous transluminal angioplasty of the iliac, femoral and renal arteries, and for the treatment of obstructive lesions of the autologous or synthetic arteriovenous dialysis fistulae.

Prescription Use: Yes 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 K041293