K973563

SUMMARY OF SAFETY AND EFFECTIVENESS
BIPORE BALLOON DILATATION CATHETER
March 24, 1998
Ref: 510(k) K973563

Trade Name: Bipore Balloon Dilatation Catheter

Manufacturer:
Bipore, Inc.
31 Industrial Parkway
Northvale, NJ 07647
Tel (201)767-1993 Fax (201) 767-0435

Device Generic Name: Balloon Dilatation Catheter

Classification: Class II, Performance Standards

Predicate Devices: Bipore Balloon Dilatation Catheter
510(k) K961980

Description of Device: The Bipore Balloon Dilatation Catheter is a double lumen balloon catheter for percutaneous transluminal angioplasty in peripheral vessel. One lumen is for inflation and deflation of the balloon; the other lumen is used to pass the catheter over a guide wire to locate the balloon at the sire of stenosis. This submission adds ~~two~~ four balloon sizes to the existing product line, as follows, and does not affect the safety or effectiveness of the device.

Inflated Balloon Diameter (mm)	Balloon Length (Cm)	Catheter Size (Fr)	Usable Length (cm)
4	4	5	100
5	4	5	100
5	10	5	100
6	10	5	100

Indications for Use: The Bipore Balloon Dilatation Catheter is recommended for percutaneous transluminal angioplasty of the iliac, femoral, and renal arteries, and for the treatment of obstructive lesions of autologous or synthetic arteriovenous dialysis fistulae.

14

The Bipore PTA Balloon Dilatation Catheter is also indicated for post deployed stent expansion. Use of the Bipore Balloon Dilatation Catheter for post-deployed stent expansion was demonstrated on the bench within Cardis Palmaz™ stent.*

All stents must be implanted and deployed according to the stent manufacturer's indications, contraindications, and instructions for use.

*Testing included: Rated Burst Pressure within the Stent
Balloon Fatigue within the Stent

Safety and Performance: The following *in vitro* function tests were performed on the Bipore Balloon Dilatation Catheter product line extensions:

Balloon Burst
Balloon Multiple Inflation
Balloon Compliance
Balloon Inflation/Deflation Time
Rated Burst pressure within the Stent
Balloon Fatigue within the Stent

The following biocompatibility tests were performed on the Bipore Balloon Dilatation Catheter; 510(k) K961980:

Systemic Toxicity
Intracutaneous Toxicity
Implantation
Hemolysis
Cytotoxicity
Sensitization

Conclusions: Based on the indications for use, technological characteristics, and safety and performance tests, it has been demonstrated that the Bipore Balloon Dilatation Catheter product line extensions are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 1998

Mr. Durmus Koch
President
Bipore, Inc.
31 Industrial Parkway
Northvale, NJ 07647

Re: K973563
Trade Name: Bipore Balloon Dilatation Catheter
Regulatory Class: II
Product Code: LIT
Dated: January 6, 1998
Received: January 7, 1998

Dear Mr. Koch:

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 to 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) 594-4618 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" (21 CFR 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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K973563

Device Name: Bipore Balloon Dilatation Catheter

Indications For Use:

The Bipore PTA catheters are indicated for percutaneous transluminal angioplasty of the iliac, femoral, and renal arteries, and for the treatment of obstructive lesions of autologous or synthetic arteriovenous dialysis fistulae.

The Bipore Inc. PTA Balloon Dilatation Catheter is also indicated for post-deployed stent expansion. Use of the Bipore Dilatation Catheter for post-deployment sten expansion was demonstrated on the bench with the CordisPalmaz™ stent*.

All stents must be implanted and deployed according to the stent manufacturer's indications, contraindications, and instructions for use.

Testing included: Rated Burst Pressure within the Stent
Balloon Fatigue within the Stent

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973563

✓ prescription use only

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

Concurrence of CDRH, Office of Device Evaluation (ODE)