2/17/99

K983650

Summary of Safety and Effectiveness
Bipore Balloon Dilatation Catheter

Trade Name:	Bipore Balloon Dilatation Catheter
Manufacturer:	Bipore, Inc. 31 Industrial Parkway Northvale, New Jersey 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
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 and deflation of the balloon; the other lumen is used to pass the catheter over a guide wire to locate the balloon at the site of stenosis. This submission adds two balloon sizes to the existing product line, as follows, and does not affect the safety or effectiveness of the device.
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. 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 Cordis Palmaz™ stent.
*Testing included:	Rated Burst pressure within the stent Balloon Fatigue within the stent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 1999

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

Re: K983650
Trade Name: Bipore Balloon Dilatation Catheter
Regulatory Class: II
Product Code: LIT
Dated: January 28, 1999
Received: January 29, 1999

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 (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) 594-4586. 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,

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

Enclosure

510(k) Number (if known): K983650

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____