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**SUMMARY OF SAFETY AND EFFECTIVENESS
BIPORE BALLOON DILATATION CATHETER
May 15, 1996**

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: Medi-tech Ultra-Thin Balloon Dilatation Catheter
510(k): K897106 and K920547

Description of Device: The Bipore Balloon Dilatation Catheter is a double lumen balloon catheter for percutaneous transluminal angioplasty in peripheral vessels. One lumen is for inflation and deflation of the balloon; the other lumen is used to pass the catheter over a guidewire to locate the balloon at the site of stenosis.

The Bipore Balloon Dilatation Catheter will be offered in three balloon sizes and one shaft length, as follows:

Inflated Balloon Diameter (mm)	Balloon Length (cm)	Catheter Size (Fr)	Usable Length (cm)
6	4	5	100
8	4	5	100
10	4	5	100

Indications for Use: The Bipore Balloon Dilatation Catheter is indicated for Transluminal Percutaneous Angioplasty (PTA) of the iliac, femoral, and renal arteries, and for the treatment of obstructive lesions of autologous or synthetic arteriovenous dialysis fistulae.

Safety and Performance: The following *in vitro* functional tests were performed on the Bipore Balloon Dilatation Catheter:

- Balloon Burst
- Balloon Multiple Inflation
- Balloon Compliance
- Balloon Inflation/Deflation Time

The following biocompatibility tests were performed:

- Systemic Toxicity
- Intracutaneous Toxicity
- Implantation
- Hemolysis
- Cytotoxicity

Conclusion: Based on the indications for use, technological characteristics, and safety and performance tests, it has been demonstrated that the Bipore Balloon Dilatation Catheter is safe and effective for its intended use.