K960501

ATTACHMENT H

APR - 9 1996

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation is required to submit with this Premarket Notification either an "... adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Boston Scientific Corporation choose to submit a summary of information respecting safety and effectiveness. According to §513(i)(3)(B), "Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concearning adverse health effects..."

The summary regarding the adverse health effects of the proposed **Diamond™ Balloon Dilatation Catheter** is as follows:

Trade Name: Diamond™ Balloon Dilatation Catheter

Manufacturer: Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760

Device Generic Name: Balloon Dilatation Catheter

Classification: According to Section 13 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards.

Predicate Devices:

The following devices are referenced in this premarket notification as predicate devices for the **Diamond™ Balloon Dilatation Catheter:**

BSC -- Blue Max Balloon Dilatation Catheter
BSC -- Ultra-thin™ Balloon Catheter
BSC -- Symmetry™ Small Vessel Balloon Dilatation Catheter
BSC -- Courier™ Balloon Dilatation Catheter

All of the devices mentioned above have been determined substantially equivalent by FDA.

Device Description:

The proposed **Diamond™ Balloon Dilatation** catheter is an over-the-wire catheter indicated for percutaneous transluminal angioplasty of the iliac, femoral and renal arteries and for treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The proposed device is designed to be placed over guidewires which have outer diameters of .035" or smaller. The device is offered with and without Glidex™ and Medi-Glide™ coatings.

Indications for Use:

The Diamond™ Vessel Balloon Dilatation Catheter is indicated for PTA of the iliac, femoral and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

Safety and Performance:

The following in vitro frunctional tests were performed on the **Diamond™ Balloon Dilatation Catheter:**

- Balloon Burst Testing
- Multiple Inflation Testing
- Inflation/Deflation Time Testing
- Balloon Compliance Testing
- Balloon Proximal Bond Testing
- Sheath Withdrawal Testing
- Wingfolded Balloon Profile Testing
- Coating Slip/Adhesion Testing
- Coating Coefficient of Friction Testing
- Particulate Analysis Testing
- Solvent Residual Testing

The following biocompatibility tests were performed:

- Cytotoxicity
- Hemolysis
- U.S.P. Class IV
- Mutagenicity
- Sensitization
- Thrombogenicity
- Pyrogenicity
- 90-Day Muscle Implantation

Conclusion:

Based on the Indication for Use, technological characteristics and safety and performance testing, the **Diamond™ Balloon Dilatation Catheter** has been shown to be safe and effective for its intended use.