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August 28, 1996

Medi-tech Ultra-thin™ Diamond™
Balloon Dilatation Catheter

ATTACHMENT H

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 concerning 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 -- PEMT-5 Balloon Dilatation Catheter
- BSC -- Ultra-thin™ Diamond Balloon 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 designed to be placed over guidewires which have outer diameters of .035" or smaller.

Indications for Use:

The **Diamond™ 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. In addition, certain sizes of the Diamond balloon catheter are indicated for stent deployment / optimization of the J&J Palmaz Biliary Stent into the biliary ducts.

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Safety and Performance:

Functional and integrity bench testing and biocompatibility testing (according to the FDA guidance document, ODE Blue Book Memorandum #G95-1, May 1, 1995, *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"*) were performed, and the data supported the substantial equivalence of the Ultra-thin™ Diamond™ Balloon Dilatation Catheter to the PEMT-5 Balloon Dilatation Catheter.

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.

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