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Medi-tech Channel™ Balloon
Catheter

January 31, 1997

ATTACHMENT I

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 Channel™ Balloon Catheter is as follows:

Trade Name: Channel™ Balloon 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 Channel™ Balloon Dilatation Catheter:

BSC -- Courier Balloon Dilatation Catheter
BSC -- Ultra-thin Diamond Balloon Catheter
BSC -- Katzen Thrombolysis Guidewire
LocalMed Inc. - Kaplan Simpson InfusSleeve Catheter

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

Device Description:

The proposed Channel™ Balloon catheter is an over-the-wire balloon catheter with four lumens indicated for percutaneous transluminal angioplasty of the iliac, femoral and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.. A secondary function is the controlled selective regional infusion of contrast or therapeutic agents nto the peripheral vasculature.

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Safety and Performance:

The following in vitro functional tests were performed on the Channel™ Balloon Catheter:

1. Balloon Burst Testing
2. Multiple Inflation Testing
3. Balloon Compliance Testing
4. Inflation / Deflation Time Testing
5. Sheath Withdrawal Testing
6. Proximal Bond Tensile Testing
7. Shaft Tensile Testing
8. Flow Rate Testing
9. Outer Sleeve Distal and Proximal Bond Testing
10. Flow Uniformity Testing

In addition, the following Biocompatibility Testing was performed:

1. Intracutaneous Reactivity
2. Sensitization
3. Cytotoxicity
4. Acute Systemic Toxicity
5. Haemocompatibility (completed as Hemolysis)
6. Pyrogenicity
7. Mutagenicity

Animal testing was also conducted to establish the Vessel Depth of Penetration for the proposed device.

Conclusion:

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