DEC 1 2 1996

K963988

510(k) Premarket Notification
Medi-tech Intravascular Infusion Device
October 3, 1996

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 Intravascular Infusion Device is as follows:

Trade Name: **Intravascular Infusion Device**

Manufacturer:
BSC/SciMed Life Systems
6655 Wedgewood Road
Maple Grove, MN 55311-3646

Device Generic Name: Diagnostic Intravascular Catheter

Classification: According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 870.1200)

Predicate Device:

Balt Magic Infusion Catheter
Manufactured by:
Target Therapeutics, Inc.
130 Rio Robles
San Jose, CA 95134

Transend Steerable Guidewire
Manufactured by:
BSC/Scimed
6655 Wedgwood Road
Maple Grove, MN 55369

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Product Description:

The Intravascular Infusion Device is a single lumen device constructed with progressively softer characteristics from proximal to distal end to aid in selective placement in the vasculature.

Indications for Use:

The Intravascular Infusion Device is indicated for the infusion of diagnostic agents into the general vasculature including the peripheral, coronary and neurovasculature.

Safety and Performance:

The following Functional Testing was performed on the proposed device:

1. Infusion Rate Testing
2. Dynamic Infusion Testing
3. Static Burst Testing
4. Tip Flexibility Testing
5. Torque Response Testing
6. Torsion Strength Testing
7. Tensile Strength Testing
8. Coatings Testing
9. *In vivo* Testing

In addition, the following Biocompatibility Testing was performed:

1. Cytotoxicity
2. Hemolysis
3. Acute Systemic Toxicity
4. Intracutaneous Toxicity
5. Sensitization
6. Pyrogenicity
7. USP Physiochemical Testing

Conclusion:

Based on the Indications for Use, technological characteristics and safety and performance testing, the Intravascular Infusion Device has been shown to be safe and effective for its intended use.