

JAN 28 1996

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510(k) Premarket Notification  
BSC Transend Guidewire

November 15, 1996

**ATTACHMENT K**

**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 **Transend Guidewire** is as follows:

- Trade Name:** Transend Guidewire
- Manufacturer:** BSC/SciMed Life Systems, Inc.  
6655 Wedgwood Road  
Maple Grove, MN 55311-3636
- Device Generic Name:** Guidewire
- Classification:** According to Section 513 of the Federal Food, Drug and Cosmetic Act, the device classification is Class II, Performance Standards (CFR 870.1330).
- Predicate Devices:** BSC Transend Guidewire  
Target Therapeutics Dasher-10 and Seeker-Lite Guidewires  
Terumo Corporation's Glidewire Gold Guidewire  
Micro Interventional Systems Quicksilver Guidewire

**Product Description:**

The BSC Transend Steerable Guidewire with hydrophilic coating and accessories are intended for general intravascular use including the peripheral and neurovasculature. The devices will be provided sterile, and are intended for one procedure use only. Testing and evaluation included tip tensile, tip flexibility, torque strength, torque response, coating adherence, coating extraction, lubricity testing, biocompatibility and in vivo testing.

**Conclusion:**

Based on the Indication for Use, technological characteristics and safety and performance testing, the **Transend Guidewire** has been shown to be safe and effective for its intended use.

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