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**SUMMARY OF SAFETY AND EFFECTIVENESS**

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

**A. GENERAL INFORMATION**

Submitter's Name: Boston Scientific Corporation  
Address: One Boston Scientific Place  
Natick, MA 01760-1537 U.S.A.  
Date of Preparation: October 6, 1995  
Contact Person: Wanda M. Carpinella  
Device Generic Name: Electrode Recording Catheter  
Device Classification: 74DRF Catheter, Electrode Recording

**B. INDICATIONS**

The electrode catheter is intended for temporary use in electrophysiologic procedures for intracardiac stimulation and/or recording potentials.

**C. DESCRIPTIVE CHARACTERISTICS**

The catheters are typically placed percutaneously through femoral or jugular access sites and directed through the vasculature into the cardiac chambers. The catheter is composed of a wire-reinforced, polyurethane shaft and a soft, distal tip. The distal end of the catheter is fitted with three ring electrodes and one tip electrode. No new electrode geometries are introduced. Catheters with various tip lengths are available to meet anatomical constraints as well as physician preference and technique.

Substantial equivalence for the proposed catheter is based on similarities in design, materials and dimensions to Boston Scientific's currently-marketed Polaris catheter and Medtronic's CardioRhythm Voyagr catheter.

**D. PERFORMANCE CHARACTERISTICS**

The structural strength of each bond in the catheter was determined. The results demonstrated functional integrity and performance characteristics that were substantially equivalent and acceptable for the device's intended use and do not affect safety and effectiveness. Biocompatibility tests demonstrated that materials used in the proposed device are suitable for short-term, human intravascular use.

**E. STERILIZATION, PACKAGING and PYROGENICITY**

The electrode recording catheter is packaged in an inner Tyvek-lidded blister pack and an outer Tyvek®/mylar pouch. The device is sterilized using ethylene oxide gas. Ethylene oxide gas residuals were shown to be less than the acceptable maximums. All testing was performed on sterilized samples and no detrimental effects from the sterilization process were noted.

**F. CONCLUSIONS**

Mechanical, electrical and biological tests verify that the electrode recording catheter meets the essential requirements that are considered necessary for its intended use.

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