

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: August 9, 1995
 Contact Person: Wanda M. Carpinella
 Device Generic Name: Electrode Recording Catheter
 Device Classification: 74DRF Catheter, Electrode Recording

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B. INDICATIONS

The electrode catheter is intended for intracardiac electrogram recording and pacing for the purpose of determining conduction times from one cardiac location to another, to localize aberrant conduction pathways and to test for the susceptibility of the cardiac chambers to arrhythmias.

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 reinforced with a stainless steel braid to enhance torque control and allow easier maneuverability and has a soft tip to reduce the potential for vessel trauma during placement of the catheter. The tip of the catheter is fitted with up to ten platinum electrodes. No new electrode geometries are introduced. Catheters with various curve styles are also available to meet anatomical constraints as well as physician preference and technique.

The catheters described in this submission are substantially equivalent to Elecath's Investigator and Daig's Response electrophysiology catheters. Descriptive characteristics between the proposed catheter and the Investigator and Response catheters are compared in **Table 1**.

D. PERFORMANCE CHARACTERISTICS

The strength of each bond in the catheter was determined. Tensile testing evaluated the strength of the following joints: tip electrode/tubing; shaft/tip tubing and connector/shaft. In addition, the tip electrode was fixed in a chuck and the catheter was rotated until failure occurred. Other testing included an evaluation of recording and pacing capabilities and torque performance testing conducted in bench top models. The testing 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 conducted according to the Tripartite and ISO Guidelines for Medical Devices demonstrated that materials used in the proposed device are suitable for short-term, human intravascular use.

E. STERILIZATION, PACKAGING and PYROGENICITY

The electrode recording catheters are packaged in an innerTyvek-lidded blister pack and an outer Tyvek®/mylar pouch. The device is sterilized using ethylene oxide gas. Ethylene oxide gas residuals and bacterial endotoxin levels are monitored for compliance to maximum releasable limits. 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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TABLE 1. SUBSTANTIAL EQUIVALENCE COMPARISON CHART			
CHARACTERISTIC	PROPOSED ELECTRODE CATHETER	ELECATH'S INVESTIGATOR SERIES	DAIG'S RESPONSE SERIES
Distal Tip Design	Soft, non-braided atraumatic tip	Soft, non-braided atraumatic tip	Soft, non-braided atraumatic tip
Tip Curve Styles	Cournand Josephson Damato Multipurpose Special Procedure Conduction Study	Cournand Josephson Damato	Cournand Josephson Damato CRD-1 JSN-1 DAO-1
Shaft Materials	Polyurethane/Wire Braid Construction	Nylon/Wire Braid Construction	Not Specified
Electrode Material	Platinum	Platinum	Platinum
Useable Length	100 cm	105 cm	120 cm 65 cm
French Size	6F	6F	6F
Electrode Spacing	2 to 10 mm	1 to 5 mm	2 to 10 mm
Connector Type	Quick	Quick	Quick Connect
Tip Electrode Length	1 mm	2 mm	Not Specified
Electrode Number	2, 4, 6, 8, 10	4	2, 4, 6, 8, 10
Proximal Electrode Length	1 mm	2 mm	Not Specified

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