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K955712



6.0 510(k) SUMMARY FOR THE USCI® BIPOLAR PACING ELECTRODE

As required under Section 12, part (a)(i)(3A) of the Safe Medical Device Act of 1990, an adequate summary of any information respecting safety and effectiveness follows.

6.1 General Information

- ◆ Name and address of submitter: USCI, Div. of C.R. Bard, Inc.
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Date of Preparation: December 11, 1995

- ◆ Device Names:
 - Trade Name(s): USCI® Bipolar Balloon
Pacing Electrode
USCI® Special Care Electrode
 - Common Name: Temporary Transvenous Pacing
Electrode
 - Classification Name: Temporary Pacemaker Electrode

- ◆ Predicate Device Name:
 - Trade Name: USCI® Bipolar Balloon Pacing
Electrode

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6.1 General Information con't

◆ Device Description and Intended Use:

The USCI® Balloon Bipolar Pacing Electrodes and USCI® Special Care Electrodes (temporary pacing leads) are flexible, insulated conductors, constructed of a woven filament and a polyurethane base with Benzalkonium Heparin coating and stainless steel electrodes.

The USCI® Balloon Bipolar Pacing Electrodes and the USCI® Special Care Electrodes are used to transmit an electrical stimulus from the pulse generator to the heart and/or to transmit an electrical signal from the heart to a recording device. These devices are sold sterile and are for one time use only. In addition to the pacing electrode with BH coating, each catheter is packaged with a needle cannula, an EKG clip, and a syringe to assist in the use of the pacing electrode.

6.2 Summary of Similarities and Differences

The coated USCI Bipolar Pacing Electrode is substantially equivalent to the uncoated USCI® Bipolar Balloon Pacing Electrode (covered under #K800298).

The similarities between the current devices, the USCI Bipolar Pacing Electrodes and the predicate device, the USCI® Bipolar Balloon Pacing Electrode, include identical materials: a latex balloon, a polyurethane shaft, and stainless steel electrodes.

The difference between the two devices is that the current USCI® Bipolar Pacing Electrode has been coated with benzalkonium heparin, which is identical to the coating used on the USCI® Safe-T-Cath Thermodilution catheter (#K791873), and the USCI® Temporary Atrio-Ventricular Electrode, (#K830094).

Results from bench test data demonstrate that the BH coated USCI Bipolar Pacing Electrodes perform similar to the predicate device, the uncoated USCI® Bipolar Balloon Pacing Electrode. Electrical continuity tests demonstrated that the BH coated Bipolar Pacing Electrodes does not affect the ability of the catheter to pace. The inflated balloon diameter test confirms that the BH coated Bipolar Pacing Electrode is within the recommended diameter range.

In conclusion, results from all the bench test data demonstrate that the BH coated Bipolar Pacing Electrodes perform similar to the predicate device, the uncoated Bipolar Balloon Pacing Electrode, therefore, a determination of substantial equivalence can be claimed.