

**Attachment VII**  
**510(k) SUMMARY**  
As of July 7, 1995

**Device Name**

Platinum™ Series of Diagnostic Electrophysiology Catheters

**Device Description**

The Platinum Series EP Diagnostic Catheter is an electrophysiology catheter with a range of two to ten platinum recording/stimulating electrodes arranged on its distal end. The distal band electrode is approximately .050" from the spherically molded Pebax tip. The distal band electrode serves as the tip electrode. The electrode bands are welded to electrical wires incorporated inside the shaft of the catheter that run from each platinum electrode to the electrical connector in the proximal end. The outside diameter of the catheter is 5 to 6 French and the usable length ranges from 60 to 125 cm.

**Intended Use**

A diagnostic electrophysiology catheter is used to record electrical activity from within the heart and coronary vessels and to stimulate the heart in accordance with various programmed electrical stimulation protocols incorporated into an EP diagnostic study. All catheters connect physician stimulator/recorder equipment to the desired region of the heart and carry analog signals. Data from the EP study is used to assess arrhythmia patient prognosis, guide therapy selection and evaluate the effectiveness of previously selected therapeutic interventions.

**Substantial Equivalence**

The Platinum series of EP catheters is substantially equivalent to the Medtronic CardioRhythm Torqr catheter and the Bard Intracardiac Electrode catheter.

**Catheter Testing Results and Conclusion**

The Platinum catheter is constructed of similar materials to those found in Medtronic CardioRhythm's Torqr catheter. All materials in the Platinum that are patient contacting are identical to those similarly exposed in the Torqr, therefore all biocompatibility testing was fulfilled.

The results of non-clinical and in-vivo testing quantitated and confirmed the adequacy of electrical and mechanical performance and reliability of the Platinum catheters. These tests support the equivalence of the Platinum catheters with the predicate device.