

K964272

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SECTION 6. 510(k) SUMMARY

The following 510(k) Summary of Safety and Effectiveness information is provided per 21 CFR §807.92.

Device Name

Performr Series of Diagnostic Electrophysiology Catheters

Device Description

The Performr Series Catheter is a closed-lumen diagnostic electrophysiology catheter with a variable number of platinum alloy recording/stimulating electrodes (2-11) fixed around the catheter shaft. The most distal electrode is located at the catheter tip. The electrode bands are welded to electrical wires incorporated inside the shaft of the catheter that run from each electrode to the electrical connector at the proximal end of the catheter. The outside diameter of the catheter is 5 to 7 French and the usable length ranges from 60 to 125 cm. A manipulator handle at the proximal end of the catheter permits the physician to vary the angle of curve of the catheter tips. Some models have controls in the handle to vary the radius of curvature, and the distal end of some models may be laterally deflected.

Intended Use

A diagnostic electrophysiology catheter is used to record electrical activity from within the heart 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 Performr series of EP catheters is substantially equivalent to the Medtronic CardioRhythm Mariner EP catheter, as well as the Bard EP-XT Steerable and Elecath Genesis catheters.

Catheter Testing Results and Conclusion

The Performr catheter is constructed of similar materials to those found in the Medtronic CardioRhythm Mariner catheter. All materials in the Performr that are patient contacting are identical to those similarly exposed in the Mariner. Therefore, all biocompatibility testing was fulfilled via the predicate device.

The non-clinical and *in-vivo* testing were conducted in accordance with applicable FDA guidance and per GLP. The tests quantified and confirmed the adequacy of electrical and mechanical performance and reliability of the Performr catheters. These tests support the substantial equivalence of the Performr catheters with the predicate device.