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510(k) Summary

Classification

Common/Usual Name: Electrophysiology catheter

Proprietary Name: Deflectable braided-tip electrode catheter

Name of Predicate Device

Cordis Webster Diagnostic 7F Deflectable Tip Catheter (primary)
Cordis Webster Fixed Curve Catheter (secondary)
Cordis Webster Coronary Sinus Flow Catheter (tertiary)

Device Description

The Cordis Webster deflectable *braided-tip* electrode catheter has been designed for electrophysiological mapping of cardiac structures. The catheter has a high-torque shaft with an internal stainless steel braid and a tip section containing platinum electrodes that can easily be seen under fluoroscopy. The tip section also employs an internal braid to provide additional lateral stability during mapping procedures.

A piston in the handpiece is attached to an internal puller which changes the radius of curvature of the tip section. When the piston is pushed forward, the radius of curvature of the tip section is reduced; when the thumbknob is pulled back, the radius of curvature is increased until the tip section returns to its original state. The high-torque shaft allows the tip section to be maneuvered in order to facilitate accurate positioning within the heart.

Intended Use

The Cordis Webster deflectable *braided-tip* electrode catheter is indicated for electrophysiological mapping of cardiac structures; i.e., endocardial stimulation and recording within the right side of the heart.

Technological Characteristics

The *braided-tip* electrode catheter is technologically similar to currently marketed Cordis Webster deflectable catheters and to other manufacturers' deflectable curve catheters; e.g., Mansfield, Bard and Elecath. The design of the *braided-tip* electrode catheter, the subject device, includes a polyurethane tip section that contains an internal braid, as compared to the Cordis Webster deflectable catheter which has a polyurethane tip section without an internal braid. The catheter shaft is 8 French while the tip section is 6.5 French which is within the existing range of tip sizes for the currently marketed devices (6 and 7 French). The tip section internal braid design is identical to that of the currently marketed Cordis Webster fixed curve catheter. The number of electrodes and type of interface connectors are the same as currently marketed devices.

Performance Data (Non-clinical Testing)

Non-clinical performance testing was done to compare the *braided-tip* electrode catheter to the predicate devices indicated above and there were no significant differences in device performance. Basic electrical and mechanical characteristics are comparable and tip stiffness is no greater that that of other currently marketed devices. The side load capability of the *braided-tip* catheter is greater than that of the standard deflectable catheter and, as such, should provide a greater degree of stability in a beating heart during electrophysiological studies. Applicable tests were performed in accordance with the FDA's "Electrode Recording Catheter Preliminary Guidance".

Sterilization and Packaging

The sterilization and packaging of the *braided-tip* deflectable catheter is identical to that of the Cordis Webster standard deflectable and fixed curve catheters.

Conclusions

The results of the non-clinical performance tests indicate that the *braided-tip* electrode catheter performs as well as the predicate device, the standard Cordis Webster Deflectable Catheter. The braided-tip construction exhibits greater side load capability and thus may provide improved contact stability (as compared to the standard deflectable catheter) during use. Cordis Webster fixed curve catheters use the same braided tip construction; therefore, Cordis Webster concludes that the *braided-tip* catheter is substantially equivalent to the predicate devices. Because the 8 French shaft of the *braided-tip* catheter has greater pushability, it was deemed appropriate that it be contraindicated for left-sided applications; the catheter is available only in a 90 cm length which effectively precludes its use in other than the right side of the heart.