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**510(k) SUMMARY**

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## 510(k) Summary

### Classification Name

Common/Usual Name: Diagnostic electrophysiological catheter

Proprietary Name: T20 Diagnostic Deflectable Tip Catheter

### Name of Predicate Device

Cordis Webster Diagnostic 7F Deflectable Tip Catheter (primary)

Cordis Webster Orthogonal Catheter (secondary)

### Device Description

The Cordis Webster deflectable T20 electrode catheter has been designed for electrophysiological mapping of the tricuspid annulus. The catheter has a high-torque shaft with a halo-shaped tip section containing ten pairs of platinum electrodes that can easily be seen under fluoroscopy. The tip section also contains a radiopaque marker in the center of the electrode array. The tip section of the catheter has a halo-shaped preformed loop which can be positioned around the atrial aspect of the tricuspid annulus.

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

The Cordis Webster deflectable T20 electrode catheter facilitates simultaneously local electrograms spanning the tricuspid annulus, from midseptal to anterior to lateral to posterolateral. Recordings of the entire annulus can be obtained without repositioning the catheter tip.

### Intended Use

The Cordis Webster deflectable T20 electrode catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The preformed shape of the tip section is designed specifically for the tricuspid annulus.

## **510(k) Summary (Continued)**

### **Technological Characteristics**

The subject device is technologically similar to the predicate device, the Cordis Webster Diagnostic Deflectable catheter. The design of the *T20* electrode catheter, the subject device, includes a greater number of ring electrodes, 20, as compared to the Cordis Webster Diagnostic Deflectable catheter which has 4 and the Cordis Webster Orthogonal catheter which has 12 poles. The nominal width of each ring electrode used in the *T20* is 0.7mm compared to 1.3mm for the standard deflectable catheter. The distal tip of the *T20* electrode catheter has a "halo" shape as compared to A - F curve availability for distal tip deflection of the standard deflectable catheter. The differences indicated do not affect the safety or effectiveness of the device.

### **Performance Data (Nonclinical Testing)**

The nonclinical performance testing performed on the *T20* electrode catheter compared to the predicate device indicated that there were no statistically significant differences in the outcome of the tests for each of the devices that would affect the safety and effectiveness of the device. The tests on the following table were performed according to FDA's "Electrode Recording Catheter Preliminary Guidance". Certain tests were not applicable to this device and justifications are given for the absence of those particular tests.

### **Conclusions Drawn from the Nonclinical Tests**

The results of the nonclinical performance tests indicate that the *T20* electrode catheter performs as well as the predicate device (the standard Cordis Webster Diagnostic 7F Deflectable Catheter) and that the differences in testing outcome are not statistically significant; therefore, Cordis Webster concludes that the *T20* catheter is substantially equivalent to the predicate device.