

K962307

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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DEVICE NAME

Rhyder Diagnostic Catheter; Class II

DEVICE DESCRIPTION

The Fidus Rhyder Diagnostic Catheter is a flexible catheter with two pairs of electrodes at the distal tip. One pair of electrodes consisting of tip (active) and side (indifferent) electrodes is used for recording ECG signals. The second pair of electrodes, located adjacent to the catheter's tip, are used for pacing. The Rhyder Diagnostic Catheter is available with three distal tip designs.

INDICATIONS FOR USE

The Fidus Rhyder Diagnostic Catheter is intended to simultaneously pace and record monophasic action potentials (MAPs) from the endocardial surface of the heart. The combined capabilities of this catheter obviate the need to insert a separate catheter for stimulation in MAP studies.

PREDICATE DEVICES

- EP Technologies, Inc. Franz™ Combination Map Catheter (K900452)
- Daig Response™ Electrophysiology Catheter (K894500, K942379)

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION

The results of bench testing (thermal cycling test, impedance testing, tensile test, tip buckling test, deflection test, torsional test, connector test, leakage current test, joint seal test, radiopacity) and biocompatibility testing support the substantial equivalence claims of the Rhyder Diagnostic Catheter for its intended use in the coronary vasculature. Results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the Rhyder Diagnostic Catheter's substantial equivalence to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS

Substantial equivalence is based on the fact that the Rhyder Diagnostic Catheter is substantially equivalent in regard to intended use and technological characteristics as the predicate devices. In instances where the technological characteristics are different, it has been demonstrated that there are no new questions raised regarding safety or efficacy of the Rhyder Diagnostic Catheter. Therefore, it can be concluded that the Rhyder Diagnostic Catheter is substantially equivalent to the predicate devices.