



K960806

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY - 2 1996

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.

CONTACT PERSON:

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DEVICE NAME:

TurboTRACKER; Class II

DEVICE DESCRIPTION:

TurboTRACKERS are single lumen devices designed to aid the physician in the access of distal vasculature when used with a guiding catheter and steerable guidewire. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section aids the physician in tracking over the selectively placed guidewire. TurboTRACKERS are externally coated with Hydrolene™, a hydrophilic surface that reduces friction during manipulation. TurboTRACKERS are available in one and two tip marker versions.

INDICATIONS FOR USE:

TurboTRACKERS are intended to assist in the delivery of diagnostic agents such as contrast media and therapeutic agents such as occlusion coils into the peripheral, coronary, and neuro vasculature.

PREDICATE DEVICE:

Target Therapeutics' Hydrophilic Tracker Infusion Catheter

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:

The results of bench testing (Tensile Test, Tip Flexibility Test, Static Pressure Strength Test, Post Steam Shaping Outer Diameter Hydrophilic Coating Durability Test, Forces Required to Deliver Occlusion Coils Test, Flow Rate Test, Forces Required to Withdraw the Catheter Through a Guiding Catheter Test, Tip Buckling Test, Coefficient of Friction Test - O.D., Minimum Bend Radius Test, and Steam Shaping Shrinkage Test) and biocompatibility testing support the substantial equivalence claims of the TurboTRACKER for its intended use in the peripheral, coronary, and neuro vasculature. Results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the TurboTRACKER's substantial equivalence to the predicate device.

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

Substantial equivalence is based on the fact that the TurboTRACKER has the same intended use and similar technological characteristics as the predicate device. 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 TurboTRACKER. Therefore, it can be concluded that the TurboTRACKER is substantially equivalent to the predicate device.