K965189 MAR 24 1997

TARGET THERAPEUTICS

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:
SPINNAKER™ Infusion Catheter, Class II

DEVICE DESCRIPTION:
Spinnaker Infusion Catheter is a single lumen device with a graded shaft stiffness, ranging from a highly flexible tip to a semi-rigid proximal section that allows ease of advancement by the physician. A lure fitting located on the catheter hub is used for the attachment of accessories. Spinnaker is manufactured with HYDROLENE®, a hydrophilic surface coating that reduces friction during manipulation in the vessel.

The Spinnaker Infusion Catheter will be made available as a system consisting of a Spinnaker Infusion Catheter, a stylet with a torque device attached, and a steam shaping mandrel.

INDICATIONS FOR USE:
The Spinnaker is indicated for use in facilitating access through distal, tortuous vasculature, and may be used for the controlled, regional infusion of diagnostic agents, such as contrast media and Target Therapeutics' Berenstein Liquid Coil -10 in the peripheral and neuro vasculature. It is not intended for use in the coronary vasculature.

The Spinnaker Infusion Catheter in Contraindicated for use with any other occlusion oils.

Note: Compatibility testing has been conducted with the Berenstein Liquid Coil -10 only.

PREDICATE DEVICE:
Balt Magic Infusion Catheter, K923368
Zephyr Infusion Catheter, K921247

TESTING in SUPPORT of SUBSTANTIAL EQUIVALENCE DETERMINATION:
Substantial equivalence is based on the fact that the Spinnaker has similar technological characteristics and intended use as the predicate devices. The results of performance testing (flow rates, tip flexibility, tensile, static rupture, and coefficient of friction) and Biocompatibility testing support the claim of substantial equivalence to the predicate device. Results of the performance and Biocompatibility testing in conjunction with the substantial equivalence claims as outlined in this premarket notification, effectively demonstrate that the Spinnaker is substantially equivalent to the predicate devices.

DEVICE DESCRIPTION

SPINNAKER with HYDROLENE Infusion Catheter (SPINNAKER) is a single lumen device designed to aid the physician in accessing distal vasculature when used with a guiding catheter. Graded shaft stiffness ranging from a highly flexible tip to a semi-rigid proximal section allows ease of advancement by the physician. A luer fitting located on the catheter hub is used for the attachment of accessories. A radiopaque tip and body facilitate fluoroscopic visualization. SPINNAKER is manufactured with HYDROLENE, a hydrophilic surface that reduces friction during manipulation in the vessel. The stylet accompanying the SPINNAKER is used to increase rigidity of the distal section during introduction into the guiding catheter. The steam shaping mandrel packaged with the SPINNAKER is used when the physician desires to shape the catheter's distal end.

INTENDED USE

The Spinnaker is indicated for use in facilitating access through distal, tortuous vasculature, and may be used for the controlled, regional infusion of diagnostic agents, such as contrast media and Target Therapeutics' Berenstein Liquid Coil -10 in the peripheral and neuro vasculature. It is not intended for use in the coronary vasculature.

The Spinnaker Infusion Catheter ~~is~~ is Contraindicated for use with any other occlusion oils.

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Table 1
SPINNAKER Infusion Catheter

	SPINNAKER Catheter Lengths (cm)				*Approximate Flow Rates at 100 psi (690 kPa) (cc/sec)*			
SPINNAKER Catalog No.	*Proxi. Section (cm)*	*Mid Section (cm)*	*Distal Section (cm)*	*Total Length (cm)*	*Dead Space Volume (cc)*	*Water*	*60% Ionic Contrast*	*76% Ionic Contrast*
191601	30	20	10	60	.17	.75	.23	.11
191010	120	25	10	155	.37	.37	.10	.05
191020	120	25	20	165	.40	.42	.11	.05

POTENTIAL COMPLICATIONS

Potential complications include, but are not limited to: hematoma at the site of entry, vessel perforation, emboli, hemorrhage, ischemia, vasospasm, neurological deficits including stroke and death.