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510(k) SUMMARY STATEMENT of SAFETY AND EFFECTIVENESS

FOR THE

OPTI-PLAST® XL 5.5F PTA CATHETER

- A. Submitter Information:** Vas-Cath Incorporated
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Canada
Telephone Number: (905) 281-7745
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Contact Person: Dolores McGirr
Date of Preparation: January 24, 1997
- B. Device Name:** Opti-Plast® XL 5.5 F PTA Catheter
XL (Xtra-Large)
Common/Usual Name: Peripheral Angioplasty Catheter
Classification Name: Surgical Vessel Dilator
- C. Predicate Device :** Opti-Plast® PTA Catheter (K933483)
Trade Name: Opti-Plast
Predicate Device for the Indications for Use: Medi-tech® XXL™ Balloon Dilatation Catheter (K952063)

D. Device Description:

The Vas-Cath Opti-Plast® XL 5.5 F PTA Catheter is a dual lumen catheter with a balloon mounted on its distal end. One lumen accommodates the insertion guidewire and the other provides a channel for inflation and deflation of the balloon with contrast media. The catheters were designed to be used in conjunction with a 0.035 inch diameter guidewire. There are two radiopaque marker bands secured on the catheter body to indicate the position of the balloon within the vasculature. The balloon inflates to the labelled diameter and length at a 5 atmosphere operating pressure.

E. Indicated Use:

The Opti-Plast® XL 5.5 F PTA Catheter is recommended for use in the Percutaneous Transluminal Angioplasty of the Iliac and Femoral vessels. This catheter is not for use in coronary arteries. The device is indicated for single use only and indicated not to be resterilized nor reused.

F. Technological Characteristics Summary: Summarized in Table 6.1.

TABLE 6.1 : Technological Characteristics Summary

Features	Proposed Vas-Cath Opti-Plast® XL 5.5 F PTA Catheter	Vas-Cath Opti-Plast® PTA Catheter (K933483)	Medi-tech® XXL™ Balloon Dilatation Catheter (K952063)
Indicated Use	PTA of Iliac and Femoral vessels	PTA of vessels of the peripheral vascular system	PTA of the Iliac and Femoral arteries in the peripheral vasculature
Balloon Material	Nylon	Nylon	NA
Inflated Balloon Diameters	12 mm	10 mm*	12, 14 mm
Inflated Balloon Length	4 cm	4 cm*	2, 4, 6 cm
Recommended Operating Pressure	5 atmospheres	6 atmospheres*	NA
Rated Burst Pressure	8 atmospheres	8 atmospheres*	8 atmospheres
Catheter Shaft Material	Nylon	Nylon	NA
Radiopaque	Yes	Yes	NA
Shaft Diameter	5.5 French	5.5 French	5.8 French
Shaft Length	75, 100, 120 cm	75, 100, 120 cm	75, 120cm
Shaft configuration	Double lumen	Double lumen	Double lumen
Marker Bands	Yes, Tantalum	Yes, Tantalum	Yes
Tip Length	5 mm	5 mm	5 mm
Tip Inner Diameter	0.037 inch	0.037 inch	0.037 inch
Guidewire Capability	0.035 inch diameter	0.035 inch diameter	0.035 inch diameter

NA- Not available from promotional literature

* Note that there are many other sizes of balloons in this product line. However, the comparison here is made with the 10 mm x 4 cm balloon since this is the closest size to the proposed catheter.

G. Performance Data

Bench testing was conducted for the following characteristics: balloon burst strength, balloon distensibility, balloon inflation/deflation time, balloon fatigue, joints and material test, catheter shaft and balloon profile, introducer sheath compatibility, catheter flow/maximum pressure, trackability/ deflatability, and tip torque. The test results indicate that the proposed Opti-Plast® XL 5.5 F PTA Catheter is substantially equivalent to the current Opti-Plast® PTA Catheter marketed under 510(k) concurrence K933483. There are no new safety or effectiveness issues.