

MAY 28 1997

K964881

510(k) SUMMARY of SAFETY AND EFFECTIVENESS

2380 Tedlo Street
Mississauga, Ontario
Canada, L5A 3V3

FOR THE

ULTRAVERSE™ PTA BALLOON DILATATION CATHETERS

Tel. (905) 848-5800
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- A. Submitter Information:** Vas-Cath Incorporated
Address: 2380 Tedlo Street
Mississauga, Ontario L5Z 3V3
Canada
Telephone Number: (905) 848-5800
Fax Number: (905) 848-6638
Contact Person: Dolores McGirr
Date of Preparation: August 23, 1996
- B. Device Name:** Ultraverse™ Angioplasty Catheter
3.5F Opti-Plast Catheter
Common/Usual Name: Peripheral Angioplasty Catheter
Classification Name: Surgical Vessel Dilator
- C. Predicate Device Name:** Ultraverse™ Angioplasty Catheter (K925485)
Trade Name: Ultraverse

D. Device Description:

The Vas-Cath Ultraverse™ PTA Catheter is a dual lumen catheter with a balloon mounted on its distal tip. One lumen accommodates the insertion guidewire and the second provides a channel for inflation on the balloon with contrast media. The catheters were designed to be used in conjunction with a 0.016 inch diameter guidewire. There are two radiopaque marker bands placed beneath the balloon to indicate its position within the vasculature. The balloon inflates to the stated diameter and length at an 8 atmosphere operating pressure.

E. Intended Use:

The Ultraverse™ Small Vessel Peripheral Balloon Dilatation Catheters are recommended for use in the peripheral vascular system, in the following vessels: renal, tibial, popliteal, femoral, and peroneal. This catheter is not for use in coronary arteries. The device is for single use only and must not be resterilized or reused.

F. Technological Characteristics Summary: Summarized in Table 1.

TABLE 1 : COMPARISON OF DEVICES

Characteristics	Predicate K925485 Vas-Cath Ultraverse™ PTA Catheter	Proposed New Sizes for Vas-Cath Ultraverse™ PTA Catheter
Similarities		
Intended Use	PTA of renal, tibial, popliteal, femoral, and peroneal vessels	PTA of renal, tibial, popliteal, femoral, and peroneal vessels
Catheter Shaft Material	Nylon	Nylon
Catheter Shaft Diameter	3.5 French	3.5 French
Inflated Balloon Diameters	2, 3, 4, 5 mm	2, 3, 4, 5 mm
Balloon Material	Nylon	Nylon
Maximum Recommended Inflation Pressure	8 atmospheres	8 atmospheres
Guidewire Capability	0.016 inch diameter	0.016 inch diameter
Shaft configuration	Double lumen	Double lumen
Radiopaque	Yes	Yes
Marker Bands	Yes	Yes
Balloon Leg Length	7 cm	7 cm
Distal Leg Length	5.5 cm	5.5 cm
Rated Burst Pressures	2mm by 2cm is 15atm 3mm by 2cm is 15atm 4mm by 2cm is 12 atm 5mm by 2cm is 12 atm	2mm by 6cm is 15 atm 3mm by 6cm is 15 atm 4mm by 6cm is 12 atm 5mm by 3,4,5 or 6cm is 10 atm
Differences		
Inflated Balloon Length	2 cm	3, 4, 5, 6 cm
Catheter Shaft Length	75, 100 cm	75 - 150 cm

G. Performance Data

The design, materials and manufacturing processes for the predicate and proposed devices are the same. The additional balloon and shaft sizes proposed in this submission were tested for the following characteristics: balloon minimum burst strength, balloon distensibility, balloon inflation/deflation time, balloon fatigue, joint strength, catheter shaft and balloon profile, introducer sheath compatibility, catheter flow/maximum pressure, trackability/ deflatability, and tip torque. The proposed product is substantially equivalent to the current Ultraverse™ Catheters marketed under 510(k) concurrence K925485.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 1997

Ms. Dolores McGirr
Vas-Cath, Inc.
2380 Tedlo Street
Canada, L5A 3V3

Re: K964881
Ultraverse™ 3.5F PTA Catheters
Regulatory Class: II (two)
Product Code: 74 LIT
Dated: April 2, 1997
Received: April 15, 1997

Dear Ms. McGirr:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



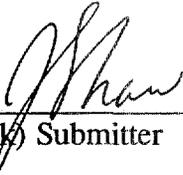
Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 1. D INDICATION(S) STATEMENT*

I state in my capacity as Manager of Quality Assurance and Regulatory Affairs of Vas-Cath Inc. that this premarket notification 510(k) for the Ultraverse™ 3.5 French Angioplasty Catheter is indicated for the following.

The Ultraverse™ Small Vessel PTA Balloon Dilatation Catheter is recommended for use in angioplasty of the peripheral vascular system. The catheter is recommended for use in the following vessels: renal, tibial, popliteal, femoral, and peroneal. The catheter is not for use in coronary arteries.



Signature of 510(k) Submitter

Janet Shaw

Printed Name of Submitter

96/11/15

Date

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the code of Federal Regulations, Title 21.

CONCURRENCE OF OFFICE OF DEVICE EVALUATION

K964881

510(k) Number



Division Sign-Off

Office of Device Evaluation