

**510(k) SUMMARY of SAFETY AND EFFECTIVENESS
FOR THE
NIAGARA™ DUAL LUMEN CATHETER**

2380 Tedlo Street
Mississauga, Ontario
Canada, L5A 3V3

Tel. (905) 848-5800
Fax (905) 848-6638

A. Submitter Information:

Submitter's Name: Vas-Cath Incorporated
Address: 2380 Tedlo Street
Mississauga, Ontario
Canada, L5A 3V3
Telephone Number: (905) 281-7745
Fax Number: (905) 848-6638
Contact Person: Dolores McGirr
Date of Preparation: November 15, 1996

B. Device Name: Niagara™ Dual Lumen Catheter
Trade Name: Niagara™
Common/Usual Name: Hemodialysis Catheter
Classification Name: Subclavian Catheter

C. Predicate Device Name: Permanent Dual Lumen Catheter
Trade Name: Soft-Cell™

D. Device Description:

The Vas-Cath Niagara™ catheter is a polyurethane catheter which allows for dialysis, hemoperfusion or apheresis. The Niagara™ catheter contains two clear polyurethane clamping extensions with luer connectors at the ends and atraumatic nylon clamps. The arterial and venous extensions are identified with red and blue luer connectors. The two extensions merge into a tapered bifurcation joint or hub molded to the catheter body tubing. Both a fixed and a removable suture wing are provided for securing the catheter after initial placement.

The cross-section of the oval shaft contains two round arterial and venous lumens. The arterial lumen exit is bevelled and is perforated with two holes. The venous lumen extends beyond the arterial lumen and ends with a soft atraumatic black tip. The Niagara™ catheters are available in a straight configuration with 15cm, 20cm, and 24cm insertion lengths; as well as in a pre-curved configuration with 12.5 cm, 15 cm and 20 cm insertion lengths.

E. Intended Use:

The Niagara™ Dual Lumen Catheter is indicated for use in attaining short term vascular access for hemodialysis, hemoperfusion, or apheresis therapy via the jugular, subclavian or femoral vein.



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F. Technological Characteristics:

Characteristic	Niagara™ Catheter	Vas-Cath Soft-Cell™ Catheter (K871488)
Shaft Diameter	13.5 French	12.5 French
Materials	Polyurethane body and extensions, PVC connectors	Polyurethane body and extensions, PVC connectors
Priming Volume (arterial lumen)	15cm: 1.3cc 20cm: 1.5cc 24cm: 1.6cc	12cm: 1.3cc 19cm: 1.5cc 23cm: 1.7cc
Priming Volume (venous lumen)	15cm: 1.4cc 20cm: 1.6cc 24cm: 1.7cc	12cm: 1.4cc 19cm: 1.6cc 23cm: 1.8cc
Shape of arterial/venous lumens	two round lumens	"Double-D" lumens
Indications	hemodialysis, hemoperfusion, apheresis,	hemodialysis, hemoperfusion, apheresis
Catheter Insertion lengths	15cm, 20cm, and 24cm	12 cm, 19 cm, 23 cm
Tip Characteristic	soft black tip	45° bevelled tip
Manufacturing Process	Injection Molded bifurcation onto Body and Extensions. Catheter is one piece	Injection Molded bifurcation onto Body and Extensions. Catheter is one piece

G. Performance Data:

In vitro performance data shows the Niagara™ catheter to be substantially equivalent to the predicate catheter in regard to elongation, tensile strength of molded joints, leakage, recirculation, as well as maximum pressure and vacuum. The flow rate of the Niagara™ catheter is greater than the Soft-Cell™ catheter as determined by bench testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Dolores McGirr
Regulatory Affairs
Vas-Cath, Inc.
2380 Tedlo Street
Mississauga, Ontario L5A 3V3
CANADA

Re: K965178
Niagara™ Dual Lumen Catheter
Dated: July 2, 1997
Received: July 10, 1997
Regulatory class: II
21 CFR §876.5540
Product code: 78 MPB

AUG 19 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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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.

FDA notes that your device will contain sutures for which you have provided evidence that the suture characteristics are not altered by the sterilization process used for the device. However, you should be aware of the following additional information regarding the inclusion of a suture as a component of your device:

1. The labeling, packaging and method of sterilization of the suture cannot be changed without prior notification, review and clearance by FDA.
2. The supplier of the sutures used in your device cannot be changed without prior notification, review and clearance by FDA.

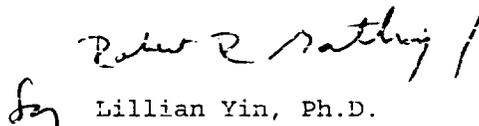
In addition, we have determined that your device kit contains 1% xylocaine, povidone iodine swabsticks, and povidone iodine ointment which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0063

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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. 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,

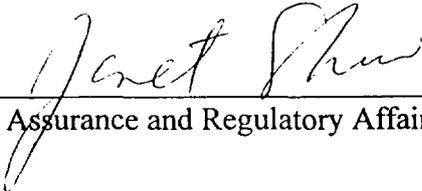

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

I.D Indication(s) Statement

I state in my capacity as Manager of QA/RA of Vas-Cath that this 510(k) premarket notification for the Niagara™ Dual Lumen catheter is indicated for the following:

The Niagara™ Dual Lumen Catheter is indicated for use in attaining short term vascular access for hemodialysis, hemoperfusion or apheresis therapy via the jugular, subclavian or femoral vein.



Manager of Quality Assurance and Regulatory Affairs, (signature)

Janet Shaw

Manager of Quality Assurance and Regulatory Affairs, (printed)

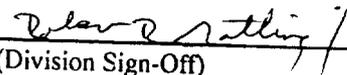
96/12/20

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

510(K) Number



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K965178

Division Sign-Off, Office of Device Evaluation

Prescription Use _____
(Per 21 CFR 801.109)

Over-the-Counter Use _____