APR 0 2 2002 K013363

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.

Date Prepared: August 1, 2001

510(k) Number: ~~To Be Determined~~

Applicant Information:	**Contact Person:**	**Device Information:**
TransVascular, Incorporated 1505-D Adams Drive Menlo Park, CA 94025	Steve Jwanouskos Vice President, Clinical & Regulatory Affairs Phone: (650) 473-4500 x105 Fax: (650) 473-4545	Classification: Class II Trade Name: CrossPoint™ TransAccess® Catheter Classification Name: Percutaneous Catheter (21 CFR 870.1250)

Equivalent Device:
The subject device (CrossPoint TransAccess Catheter) is substantially equivalent in intended use and/or method of operation to the Perclose Outback Catheter (K001577) and Endosonics' devices, Visions 2.9F Ultrasonic Imaging Catheter and Avanar F/X 2.9F Intravascular Ultrasound Imaging Catheter.

Intended Use:
The CrossPoint TransAccess Catheter is intended to facilitate the placement and positioning of catheters within the peripheral vasculature. The CrossPoint TransAccess Catheter also provides an intraluminal, cross-sectional ultrasound image of the area of interest. The CrossPoint TransAccess Catheter is not indicated for use in the coronary or cerebral vasculature.

Test Results:
Performance
Results of in-vitro testing and animal studies demonstrate that the CrossPoint TransAccess Catheter is safe and effective to allow the positioning and placement of catheters within the peripheral vasculature.

Biocompatibility
The materials used in the manufacture of the CrossPoint TransAccesss Catheter have been shown to be biocompatible when tested in accordance with ISO 10993-1 requirements.

Summary:
Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N								
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Prescription Use X
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013365

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Trans Vascular Incorporated
C/o Mr. Mark Job
TUV Product Service, Inc.
1775 Old Highway 8
New Brighton, MN 55112

APR 0 2 2002

Re: K013363
Trade Name: Crosspoint Transaccess Catheter
Regulation Number: 21 CFR 892.1570 and 21 CFR 870.1250
Regulation Name: Diagnostic Ultrasonic Transducer and Percutaneous Catheter
Regulatory Class: II (two)
Product Code: ITX and DQY
Dated: February 28, 2002
Received: March 1, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket 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 legally marketed predicate 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.

This determination of substantial equivalence applies to the following transducer intended for use with the Crosspoint Transaccess Catheter, as described in your premarket notification:

Transducer Model Number
0.014" Guidewire Compatible; 6.2 French

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4591. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Elisa Harvey at (301) 443-8262 extension 167.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Center for Devices and Radiological Health
Premarket Notification [510(k)]
Indications for Use Statement

K 013363

Date Prepared: August 1, 2001

Device Trade Name: **CrossPoint TransAccess Catheter**

Indications for Use:

The CrossPoint TransAccess Catheter is intended to facilitate the placement and positioning of catheters within the peripheral vasculature. The CrossPoint TransAccess Catheter also provides an intraluminal, cross-sectional ultrasound image of the area of interest. The CrossPoint TransAccess Catheter is not indicated for use in the coronary or cerebral vasculature.

Prescription Use X
(21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013363