JUL 2 3 2003

510(k) Safety and Effectiveness Information Summary

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: June 20, 2003.

510(k) Number:_____

Applicant Information:	**Contact Person:**	**Device Information:**
TransVascular, Incorporated 1505-D Adams Drive Menlo Park, CA 94025-1439	Richard E. Anderson Phone: (650) 473-4500 X124 Fax: (650) 473-4545 Email: randerson@transvascular.com	Classification: Class II Trade Name: CrossPoint® TransAccess® Catheter Classification Name: Percutaneous Catheter (21 CFR 870.1250) and Diagnostic Ultrasound Transducer (21 CFR 892.1570)

Equivalent Device:
The subject device (CrossPoint TransAccess Catheter) is substantially equivalent in intended use and/or method of operation to the original CrossPoint TransAccess Catheter (K013363).

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:
Results of *in-vitro* testing demonstrate that the modified design of the CrossPoint TransAccess Catheter is safe and effective to allow the positioning and placement of catheters within the peripheral vasculature.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 3 2003

TransVascular, Inc.
c/o Mr. Richard E. Anderson
1505-D Adams Drive
Menlo Park, CA 94025-1439

Re: K031920
CrossPoint® TransAccess® Catheter
Regulation Number: 21 CFR 870.1250, 892.1570
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: ITX, DQY
Dated: June 20, 2003
Received: June 23, 2003

Dear Mr. Anderson:

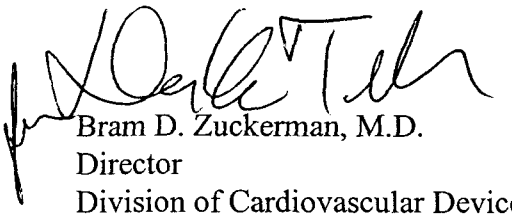
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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) that do not require approval of a premarket approval application (PMA). 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 (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 letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Indications for Use

510(k) Number (if known): This application

Device 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 intra-luminal, cross-sectional ultrasound image of the area of interest. The CrossPoint TransAccess Catheter is not indicated for use in the coronary or cerebral vasculature.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ___ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031920