

OCT 5 2007
510(k) Summary

This summary of 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: 31 July 2007

Applicant Information	Contact Person	Device Information
Medtronic Vascular	Catherine Priestley	Classification:
3576 Unocal Place	Regulatory Affairs Specialist	Class II
Santa Rosa, CA 95403	3576 Unocal Place	
USA	Santa Rosa, CA 95403	Trade name:
	707.591.7205	Pioneer Catheter
	707.591.7138	
	catherine.priestley@medtronic.com	Classification Name:
		Diagnostic Ultrasound
		Transducer <u>and</u>
		Percutaneous Catheter

Predicate Device: Pioneer Catheter (formerly known as CrossPoint TransAccess Catheter) K013363 (April 2, 2002) and K031920, (July 28, 2003).

Equivalent Device Pioneer Catheter, formerly known as the CrossPoint TransAccess Catheter. The proposed and predicate Pioneer Catheter products are identical in terms operation, biocompatibility characteristics, performance characteristics, materials, and sterilization process. The purpose of the submission is to clarify the indication to include appropriate applications.

Statement of Intended Use: The Pioneer Catheter is designed to facilitate the placement and positioning of catheters within peripheral vasculature. The Pioneer Catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e., PTCA, stent, etc.). The Pioneer Catheter is not indicated for use in coronary or cerebral vasculature.

Summary of Technological Characteristics: No technological changes have been made to the proposed Pioneer Catheter. This submission covers an update to the indication for use to include appropriate applications. Therefore, the predicate and proposed products are equivalent in terms of technological characteristics.

Summary of Non-clinical Data: No technological changes have been made to the proposed Pioneer Catheter. The purpose of the submission is to clarify the indications to include appropriate applications as supported by prior testing and published literature.

Conclusion from No technological changes have been made to the proposed Pioneer

Data:

Catheter. The purpose of the submission is to clarify the indications to include appropriate applications as supported by prior testing and published literature. Therefore, the proposed and predicate Pioneer Catheter products are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 2007

Medtronic Vascular
c/o Ms. Catherine Priestley
Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, CA 95043

Re: K072155
Pioneer Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: II (Two)
Product Code: ITX, DQY
Dated: July 31, 2007
Received: August 3, 2007

Dear Ms. Priestley:

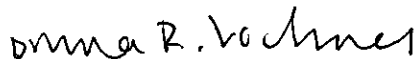
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

Indication for Use

510(k) Number (if known): K072155

Device Name: Pioneer Catheter

Proposed Indications For Use (changes in red):

"The Pioneer catheter is intended to facilitate placement and positioning of catheters within the peripheral vasculature. The Pioneer catheter also provides an intraluminal cross-sectional ultrasound image of the area of interest to facilitate placement of guidewires beyond stenotic lesions (e.g., sub-total, total or chronic total occlusions) prior to additional intervention (i.e. PTCA, stent, etc.). The Pioneer catheter is not indicated for use in the coronary or cerebral vasculature."

Prescription Use X
Use _____
(Part 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-Counter
(21 CFR 807

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

Sumner D. Kochner
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072155