

OCT 5th 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	Trade name:
USA	Santa Rosa, CA 95403	Pioneer Catheter
	707.591.7205	Classification Name:
	707.591.7138	Diagnostic Ultrasound
	catherine.priestley@medtronic.com	Transducer and
		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
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic Vascular Inc.
Ms. Catherine Priestley
Regulatory Affairs Specialist
3576 Unocal Place
Santa Rosa, CA 95403

SEP 18 2013

Re: K072155
Trade/Device Name: Pioneer Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU, ITX
Dated: July 31, 2007
Received: August 3, 2007

Dear Ms. Priestly:

This letter corrects our substantially equivalent letter of October 5, 2007.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for 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): A.072155

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 _____

AND/OR

Over-The-Counter

(Part 21 CFR 801 Subpart D)
Subpart C)

(21 CFR 807

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

Summer D. Kochner

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K072155