K103386

FEB 11 2011

Special 510(k) Summary

Submitter:	Medtronic Vascular 35-37A Cherry Hill Drive Danvers, MA 01923-5186
Contact Person:	Anu Gaur Regulatory Affairs Specialist Phone: (978) 739-3080 Fax: (978) 739-7380
Alternate Contact	Fred Boucher Director of Regulatory Affairs Phone: (978) 739-3116 Fax: (978) 750-8204
Date Prepared:	November 17th, 2010
Trade Name:	Medtronic Vascular 5F Launcher® Guide Catheter Medtronic Vascular 8F Launcher® Guide Catheter
Common Name:	Guiding Catheter
Classification Name:	Catheter, Percutaneous 21CFR 870.1250, Product Code DQY
Predicate Devices:	K030779 - 5F Launcher® Guide Catheter. K023402 - 8F Launcher® Guide Catheter
Device Description:	The Medtronic Launcher Guide Catheter is constructed with an inner liner, stainless steel braid, outer shaft jacket, sleeve, marker band and a soft distal tip. The inner lumen of the Launcher Guide Catheter has a thin lubricious coating.
Statement of Intended Use:	The Medtronic Guide Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended for used in the coronary or peripheral vascular system.
Summary of Technological Characteristics:	The technological characteristics of the subject medical devices 5F and 8F Launcher Guide Catheters are identical to the predicate devices. **Luer hub:** The luer hub allows interfacing of the catheter with other devices. **Outer jacket:** The outer jacket provides the catheter with its ability to retain its curve, and also provides additional support.

Wire braided shaft: The wire braided shaft provides the catheter with torque response and crush resistance.
Inner liner: The inner liner provides sufficient lumen lubricity for therapeutic device to pass through.
Distal segments: The distal segments allow a transition of catheter stiffness from the proximal catheter shaft to the soft distal tip.
Soft tip: The soft tip minimizes the potential for vessel trauma when the catheter is advanced in the vasculature system.

Summary of Non-clinical Data:

The bench and biocompatibility testing were conducted in accordance with the recommendations from the relevant FDA guidance to demonstrate that the modified 5F and 8F Launcher Guide Catheters met the acceptance criteria and performed similarly to the predicate devices.

Bench Testing performed was specific to the luer hub due to the new material change. The tests performed included:

1. Visual Analysis - Sink Mark, Flash, Short Shot and Discoloration.
2. Visual Analysis – Luer Taper ISO 594-1 Gauge.
3. Dimensional Analysis – Hub Shaft ID.
4. Hub/Shaft Tensile.
5. Leak
6. Luer Hub Leak and Aspiration Test
7. Visual Analysis – Hub Inside Inspection for Exposed Wires.

Biocompatibility Testing: Cytotoxicity Testing was performed as a screening test for this device modification.

No new safety or effectiveness issues were raised during the testing.

Summary of Clinical Data:

No clinical investigation has been performed for these devices.

Conclusion from Data:

Medtronic Vascular has demonstrated that the modified 5F Launcher and 8F Launcher Guide Catheters are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 4 2011

Medtronic Vascular
c/o Anupama Gaur, Ph.D., MBA, MSRA
Regulatory Affairs Specialist
35-37 A Cherry Hill Drive
Danvers, MA 01923

Re: K103386
Trade/Device Name: Medtronic Vascular - Hub Material Modification to the 5F and 8F Launcher® Guide Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: January 11, 2011
Received: January 12, 2011

Dear Dr. Gaur:

This letter corrects our substantially equivalent letter of February 11, 2011.

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: K103386

Device Names: Medtronic Vascular 5F Launcher Guide Catheter and 8F Launcher Guide Catheter.

Indications for Use:

The Medtronic Guide Catheters are intended to be used in the coronary or the peripheral system; and are designed to provide a pathway through which therapeutic devices are introduced.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

:on Sign-Off)
:n of Cardiovascular Devices
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