OCT 2 2 2013

Special 510(k) Summary

Submitter: Medtronic Vascular
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Danvers, MA 01923-5186

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Date Prepared: August 23, 2013

Trade Name: 5F Launcher® Guide Catheter
6F Launcher® Guide Catheter
5F Sherpa® Active NX Guide Catheter
6F Z4 (Sherpa) Guiding Catheter

Common Name: Guiding Catheter

Classification Name: Catheter, Percutaneous
21CFR 870.1250, Product Code DQY

Predicate Devices:

Device	510(k)	Clearance Date
5F Launcher® Guide Catheter	K103386	02/11/2011
6F Launcher® Guide Catheter	K021256	05/17/2002
5F Sherpa® Guide Catheter	K062420	09/08/2006
6F Sherpa® (Z4) Guiding Catheter	K042489	12/13/2004

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 lubricious coating. The inner lumen of the Sherpa Guide Catheters is an HDPE liner.

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 6F Launcher and Sherpa 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 support and contributes to the shaft stiffness and kink resistance.

Wire braided shaft: The wire braided shaft provides the catheter with torque response and crush resistance.

Inner liner: Provides smooth, low friction surface for therapeutic device passage.

Distal segments: The distal segments allow a transition of catheter stiffness from the proximal catheter shaft to the soft distal tip.

i. **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: No new safety or effectiveness issues were raised during the evaluation and testing. Current testing demonstrates that the 5F and 6F Launcher and Sherpa Guide Catheters are safe, effective and are substantially equivalent to the predicate devices.

Biocompatibility Testing: The current biocompatibility testing supports the biological safety, as no new materials or processes are being introduced into the design, and no additional biocompatibility tests were deemed necessary. Therefore, the modified 5F and 6F Launcher and Sherpa Guide Catheters remain biocompatible and compliant to ISO 10993

Summary of Clinical Data: No clinical investigation has been performed on the modified device.

Conclusion from Data: Medtronic Vascular has demonstrated that the modified 5F and 6F Launcher and Sherpa Guide Catheters are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 22, 2013

Medtronic Inc.
C/O Heather Morose
Regulatory Affairs Specialist
37a Cherry Hill Drive
Danvers, MA 01923 US

Re: K132673
Trade/Device Name: 5F Launcher Guide Catheter, 6F Launcher Guide Catheter, 5F Sherpa Guide Catheter and 6F Sherpa Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 20, 2013
Received: September 23, 2013

Dear Ms. Morose:

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

Indications for Use

510(k) Number (if known): K132673

Device Name: Medtronic 5F and 6F Launcher™ Guide Catheters and Medtronic 5F and 6F Sherpa™ 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 ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

M A Hillebrenner

PAGE 1 OF __