510(k) Summary

K101885

Date Prepared: July 02, 2010

Applicant:
Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

SEP 09 2010

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Proprietary Name: Medtronic C315 Delivery Catheter

Common Name:	C315 Delivery Catheter
Device Classification Name:	Catheter, Percutaneous Class II, 21 CFR 870.1250
Product Code:	DQY
Device Description:	The Medtronic C315 Delivery Catheter contains one catheter and one dilator constructed of Polyether Block Amide and Polyethylene respectively. It is designed to aid in the introduction of various types of pacing or defibrillator leads and catheters. There are seven models in the Medtronic C315 Delivery Catheter product family, all of which have the same inner and outer diameter (5.4Fr and 7.0Fr respectively). The models differ in useable length, which varies from 20cm to 43cm. Proximally, the C315 is equipped with a hemostatic valve, and the distal tip is radiopaque to facilitate imaging under fluoroscopy. The C315 is designed to be slittable, thereby allowing its removal after device placement. A variety of curves are available to accommodate various anatomies and different lead locations.
Indications For Use:	The C315 is indicated for the introduction of various types of pacing or defibrillator leads and catheters. This is identical to the predicate Acumen Single Lumen Delivery Sheath (510(k) cleared K080500).
Substantially Equivalent Devices:	The Medtronic C315 Delivery Catheter product family uses similar technology and has similar intended uses, function, materials and method of operation to the predicates Acumen Single Lumen Delivery Sheath (510(k) K080500) and Attain Command™ 6250 product family (510(k) K090659).
Summary of Technological Characteristics:	The Medtronic C315 Delivery Catheter consists of a hydrophilic coated inner liner to aid lubricity, and an outer jacket, with a wire braid encapsulated between the inner liner and outer layers. The distal tip is radiopaque to facilitate imaging under fluoroscopy and the hub at the proximal end of the shaft consists of an integrated valve and flushing side port. The catheter is packaged with a dilator. The technological characteristics of the Medtronic C315 Delivery Catheter are identical to the predicate Acumen Single Lumen Delivery Sheath (510(k) K080500).

Summary of Studies:

Device integrity testing was performed to support the equivalency of the Medtronic C315 Delivery Catheter product family to the predicates. The following in-vitro bench tests were completed using C315 devices:

- Dimensional Measurement
- Catheter Tensile Strength
- Curve Stiffness
- Straight Shaft Distal Segment Compression
- Radiopacity
- Curve Retention
- Manual Slitting of Catheter
- Guide Catheter Leakage Test (Catheter Shaft Related)
- Guide Catheter Leakage Test (Valve Related)
- Torsional Strength
- Chemical Compatibility
- Straight Shaft Kink Resistance
- Guide Catheter Interface Testing
- Transport Simulation
- Seal Strength
- Pouch Seal Area
- Dye Penetration Test

The Medtronic C315 Delivery Catheter product family met all specified design and performance requirements.

Summary of Clinical Data: No clinical investigation has been performed for this device.

Biocompatibility Information:

The testing which supports the biocompatibility of the Medtronic C315 Delivery Catheter product family is consistent with International Standard ISO10993-1:2009 "Biological Evaluation of Medical devices- Part 1: Evaluation and Testing."

When classified according to this standard, the catheter and dilator included in the Medtronic C315 Delivery Catheter product family are categorized as external communicating devices with limited exposure i.e. whose contact with circulating blood is ≤ 24 hours.

The following Biocompatibility tests were performed:

- Cytotoxicity Using ISO Elution Method
- ASTM Hemolysis Study
- Material Mediated Pyrogen
- ISO Maximization Sensitization Study
- ISO Intracutaneous Study
- ISO Systemic Toxicity Study
- C3a and SC5b-9 Complement Activation Assay Study
- Physicochemical Tests for Plastic
- ASTM Partial Thromboplastin Time Study (PTT)
- In Vivo Thromboresistance Study in the Dog, Jugular Vein

The biocompatibility evaluation completed verifies that the Medtronic C315 Delivery Catheter product family is biocompatible.

Sterilization Validation:

The Medtronic C315 Delivery Catheter product family will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:

Through the data and information presented, Medtronic Ireland considers the Medtronic C315 Delivery Catheter product family to be 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

Medtronic, Inc.
c/o Ms. Elaine O'Connor
Primary Regulatory Affairs Specialist
Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

SEP 09 2010

Re: K101885
Trade/Device Name: Medtronic C315 Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: August 19, 2010
Received: August 23, 2010

Dear Ms. O'Connor:

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.

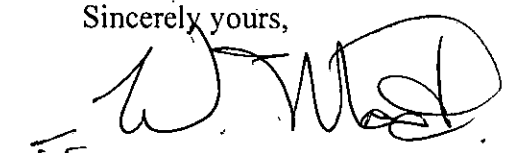
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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" (21CFR 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, Zuckerman, MD
Division Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

K101885

510(k) Number (if known): K101885

SEP 09 2010

Device Name: Medtronic C315 Delivery Catheter

Indications for Use: The C315 is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101885