K122913

510(k) Summary of Safety and Effectiveness

Date Prepared: **September 17, 2012**

OCT 19 2012

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Brooklyn Park, MN 55428
Establishment Registration No. 2184009

Contact Person: Mary Donlin
Senior Regulatory Affairs Specialist
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Trade Name: Affinity Fusion® Recirculation Line
Common Name: Cardiopulmonary bypass tubing
Classification Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification: Class II, 21 CFR 870.4350

Product Code: DWF

Name of Predicate Device: Tubing, Connectors and Accessories with Balance® Biosurface (K113845)

Device Description:

The recirculation line consists of a 0.6 cm (1/4 in) flexible line with Y connector and female luer ports. The recirculation line provides a path from the recirculation port of the Affinity Fusion® Oxygenator with Integrated Arterial Filter to the venous reservoir. It is configured for maximum flexibility to facilitate ease of circuit set up and priming.

Intended Use:

The Affinity Fusion Recirculation Line is intended for use in connecting tubing and/or devices during cardiopulmonary bypass procedures up to 6 hours in duration.

Contraindications:

None.

Comparison to the Predicate Device:

A comparison of Affinity Fusion® Recirculation Line to the predicate device indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same materials
- Same shelf life.

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device. Clinical testing was not required to establish substantial equivalence with the predicate devices.

The following performance tests were conducted:

- Integrity Testing
- Burst Testing
- Dust Cap Pull-Off Testing
- Tube Pull-Off Testing

Conclusion:

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the Affinity Fusion® Recirculation Line is substantially equivalent to the legally marketed predicate device, Tubing, Connectors and Accessories with Balance® Biosurface (K113845).

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

OCT 19 2012

Medtronic, Inc.
c/o Ms. Mary Donlin
Senior Regulatory Affairs Specialist
7611 Northland Drive
Brooklyn Park, MN 55428

Re: K122913
Affinity Fusion® Recirculation Line
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: September 19, 2012
Received: September 21, 2012

Dear Ms. Donlin:

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,

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

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K122913

Device Name:

Affinity Fusion® Recirculation Line

Indications for Use:

The recirculation line is indicated for use in connecting tubing and/ or devices during cardiopulmonary bypass procedures up to 6 hours in duration.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K122913