K122811

Medtronic

510(k) Summary

OCT 12 2012

Date Prepared: September 12, 2012

Submitter:
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Device Name and Classification

Trade Name: Tubing, Connectors and Accessories with Balance® Biosurface

Common Name: Cardiopulmonary bypass adapter, tubing, connector, stopcock, manifold or fitting

Regulation Number: 21 CFR 870.4290

Product Codes: DTL and DWF

Product Classification: Class II

Predicate Device

K113845 Tubing, Connectors and Accessories with Balance® Biosurface

Device Description

Medtronic Connector Components with Balance Biosurface are intended for use in the extracorporeal circuit during cardiopulmonary bypass surgery. These components are primarily used to interconnect tubing and the primary devices of the bypass circuit. The lumen of the Connector Components with Balance Biosurface consist of smooth blood-contacting surfaces which provide a continuous pathway for the flow of blood and/or other fluids during cardiopulmonary bypass surgical procedures. The Connector Components with Balance Biosurface are comprised of polycarbonate and Balance Biosurface materials and provided in Y-type, straight, reducer and adapter (luer) configurations.

Intended Use

Medtronic Connector Components with Balance Biosurface are intended for use in the extracorporeal cardiopulmonary perfusion bypass circuit to interconnect tubing and the primary devices of the bypass circuit.

Comparison to Predicate

When compared to the predicate device (K113845), the Medtronic Connector Components with Balance Biosurface presented in this submission have the same:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biological safety
- Base materials prior to coating
- Coating materials
- Packaging materials and configurations
- Method of sterilization and sterility assurance level
- Shelf life

Conclusion

Medtronic has demonstrated that Connector Components with Balance Biosurface for use in extracorporeal cardiopulmonary bypass perfusion systems (tubing sets/packs) are substantially equivalent to the predicate device based upon design, test results, and indications for use. The fundamental scientific principle, labeling and intended use are unchanged from the predicate device.

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 12 2012

Medtronic, Inc.
c/o Ms. Jacqueline Hauge
Senior Regulatory Affairs Specialist
7611 Northland Dr.
Minneapolis, MN 55428

Re: K122811
Trade/Device Names: Connector Components with Balance Biosurface
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II
Product Code: DTL
Dated: September 12, 2012
Received: September 13, 2012

Dear Ms. Hauge:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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" (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

Indications for Use

510(k) Number (if known):

Device Name: Connector Components with Balance™ Biosurface

Indications For Use:

Medtronic Connector Components with Balance™ Biosurface are indicated for use in the extracorporeal circuit during cardiopulmonary bypass surgical procedures.

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 LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122811