K123448

DEC 1 3 2012

510(k) Summary

Date Prepared: **September 28, 2012**

Applicant:
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Device Name and Classification:

Trade Name:	Affinity® Flexible Luer Lock Adapters with Carmeda BioActive Surface **(Model CBPT1830)** or Balance Biosurface **(Model BBPT1830)**
Common Name:	Adapter, stopcock, manifold or fitting; cardiopulmonary bypass
Regulation Number:	21 CFR 870.4290
Product Code:	DTL
Classification:	Class II
Classification Panel:	Cardiovascular

Predicate Device

The predicate device is the Affinity® Flexible Luer Lock Adapters, accessory packaged with the Affinity Pixie® Cardiotomy/Venous Reservoir (CVR) (K100645).

Device Description

The flexible luer lock adapters are single use only devices that consist of a flexible tubing segment with an inner diameter of 0.32 cm (0.125 in) with a male luer adapter on one end and a female luer adapter on the other end. This device is currently packaged with the Affinity Pixie® Cardiotomy/Venous Reservoir device. This device is currently packaged

with the Affinity Pixie® Cardiotomy/Venous Reservoir device. It is also available as a standalone device (subject of this submission).

Product Family	Model	Description
Adapters	CBPT1830	Flexible Luer Lock Adapter with Carmeda BioActive Surface
	BBPT1830	Flexible Luer Lock Adapter with Balance Biosurface

Intended Use

Affinity® Flexible Luer Lock Adapters are indicated for use in connecting tubing and/or devices during cardiopulmonary bypass procedures up to 6 hours in duration.

Comparison to Predicate Devices

The Affinity Flexible Luer Lock Adapters has the same intended use, design and materials, and principles of operation and technology when compared to the predicate devices.

- Intended Use: Flexible Luer Lock Adapters are indicated for use in connecting tubing and/or devices during cardiopulmonary bypass procedures up to 6 hours in duration.
- Design: There is no change in the device design of the Affinity Luer Lock Adapters as compared to the predicate, only the packaging has changed.
- Materials: There are no changes to the device design, additional materials are included in the Affinity Luer Lock Adapters in comparison to the predicate devices as it is packaged in a different configuration.
- Principles of Operation and Technology: The flexible luer lock adapters are for connecting tubing and or components together in an extracorporeal circuit which is used in the same manner of operation as the predicate connectors.
- Performance: The performance of the adapters did not change from the predicate device.

The Affinity Flexible Luer Lock Adapters are identical to the predicate device, with the exception of packaging. The predicate device is currently an accessory which is packaged and sterilized with the Affinity Pixie Cardiotomy/Venous Reservoir.

The stand-alone flexible luer lock adapters will be sold as a ten (10) pack of Tyvek lidded sealed blister trays in a paperboard carton with 1 Instruction For Use (IFU). These trays are overpacked in a corrugated shipper box.

Summary of Performance Data

The packaging for these products was tested to demonstrate compliance to ISO 11607-1 and 11607-2, 2006.

The packaged samples were sterilized twice and subjected to climactic conditioning prior to testing. After being subjected to the distribution simulation and testing (ASTM D4169-08), the packaging was visually inspected. The seals are then subjected to the dye penetration test to ensure integrity of the seals. In addition, seals then undergo a peel test to ensure the proper level of adherence between the Tyvek lid and the blister tray.

Conclusion

Medtronic has demonstrated that the Affinity Flexible Luer Lock Adapters are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

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

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Medtronic, Inc.
c/o Ms. Julia A. Nelson, MS, RAC
Principal Regulatory Affairs Specialist
8200 Coral Street NE
Mailstop MVS83
Mounds View, MN 55112

Re: K123448
Trade/Device Name: Affinity Flexible Luer Lock Adapters
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting
Regulatory Class: Class II
Product Code: DTL
Dated: November 7, 2012
Received: November 8, 2012

Dear Ms. Nelson:

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,

Matthew G. Hillebrenner

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 Statement

510(k) Number (if known): K123448

Device Name:

Affinity® Flexible Luer Lock Adapters with Balance™ Biosurface
Affinity® Flexible Luer Lock Adapters with Carmeda® BioActive Surface

Indications for Use:

Flexible Luer Lock Adapters are 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 K123448