



October 23, 2014

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
Jessica Sixberry
Senior Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K133157

Trade/Device Name: Tri-optic Measurement Cell with Balance Biosurface
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary Bypass In-Line Blood Gas Monitor
Regulatory Class: II
Product Code: DRY
Dated: September 18, 2014
Received: September 19, 2014

Dear Ms. Jessica Sixberry:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

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)
K133157

Device Name
Tri-Optic Measurement Cells

Indications for Use (Describe)

The BioTrend oxygen saturation and hematocrit system measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed-chest support, and limb perfusion.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: February 11, 2014

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establish Registration Number: 2184009

Contact Person: Jessica Sixberry
Senior Regulatory Affairs Specialist
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Device Name and Classification:

Trade Name: Tri-optic Measurement Cell with Balance™ Biosurface
Common Name: Cardiopulmonary bypass in-line blood gas monitor
Regulation Number: 21 CFR 870.4330
Product Code: DRY
Classification: Class II

Predicate Devices

Medtronic MX2 Oxygen Saturation and Hematocrit Monitoring System (K910421)
Medtronic BioTrend Oxygen Saturation and Hematocrit System (K093650)
Medtronic Tri-optic Measurement Cell with Trillium Biosurface (K012743)

Device Description

The Medtronic Tri-optic Measurement Cell is a sterile, single-use cell used with the BioTrend Oxygen Saturation and Hematocrit System. This 510(k) premarket notification was submitted to add Balance Biosurface to the disposable cell as well as update the labeling information for all Tri-optic Measurement Cell versions. The disposable cell is coated on its blood contacting surfaces with Balance Biosurface. Previously cleared disposable cells are also available in uncoated form, and with Carmeda BioActive Surface coating or Trillium Biosurface coating. A list of the models and descriptions is included in **Table 5-1**.

Table 5-1: Model Descriptions

Models	Description
BBTMC25, BBTMC38, BBTMC50	Tri-optic Measurement Cell with Balance Biosurface
CB4714R1, CB4715R1, CB4716R1	Tri-optic Measurement Cell with additional tubing extension with Carmeda BioActive Surface
TMC25T, TMC38T, TMC50T	Tri-optic Measurement Cell with Trillium Biosurface
TMC25, TMC38, TMC50	Tri-optic Measurement Cell
1473R1, 1474R1, 1475R1	Tri-optic Measurement Cell with additional tubing extension

Indications for Use

The BioTrend Oxygen Saturation and Hematocrit System measures percent oxygen saturation and hematocrit of the blood in the extracorporeal circuit. The extracorporeal circuit is used for, but is not limited to, cardiopulmonary bypass, closed-chest support, and limb perfusion.

Comparison to Predicate Devices

The Tri-optic Measurement Cells have the same intended use, design and materials, and principles of operation and technology when compared to the predicate devices.

- Intended Use: The Tri-optic Measurement Cells have the same intended use as the currently marketed Tri-optic Measurement Cells.
- Design and Materials: The design and the materials of the Tri-optic Measurement Cells are the same as the predicate devices. The devices are available uncoated and three coating options, Carmeda, Trillium and Balance, which are biocompatible surface coatings that increase the thromboresistance of the blood contact surfaces. Carmeda and Trillium are available coatings on the predicate Tri-optic Measurement Cell devices. Balance is a heparin-free version of Trillium coating. Balance is available on the Affinity Pixie Arterial Filter as well as numerous other previously cleared Medtronic devices.

- Principles of Operation and Technology: The technology of the subject device and the predicate devices are identical. The disposable cells are included within the cardiopulmonary bypass circuit. The disposable cells are connected to a sensor cable connected to the BioTrend instrument that reads the oxygen saturation and hematocrit of the blood going through the circuit.
- Performance: The performance of the Tri-optic Measurement Cells remains unchanged and continues to meet the performance specifications.

Summary of Performance Data

Bench testing was used to demonstrate the performance characteristics of the Tri-optic Measurement Cells with Balance Biosurface coating. The testing summarized in **Table 5-2** was performed to demonstrate substantial equivalence:

Table 5-2: Testing Summary

Test	Description	Results
Coverage Testing	Ensures the coating has been applied successfully	Pass
Leaching Testing	Ensures the coating adheres properly	Pass
Accuracy	Ensures coating does not interfere with the accuracy of reading the flow rate	Pass

Clinical testing was not required to establish substantial equivalence. Performance testing was deemed unnecessary for the labeling changes related to the remainder of the models described in this 510(k).

Conclusion

Medtronic has demonstrated that the Tri-optic Measurement Cells are substantially equivalent to the predicate devices based upon design, test results, and indications for use.