K113235
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510(k) Summary

Date Prepared October 28, 2011

Submitter

Medtronic, Inc.
Medtronic Perfusion Systems
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Establish Registration Number: 2184009

Contact Person

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Device Name and Classification

Trade Name:	Pressure Display Box DLP® Disposable Pressure Display Set
Common Name:	Cardiopulmonary bypass coronary pressure gauge
Regulation Number:	Box: 21 CFR 870.4310
Product Code:	DXS
Classification:	Class II

Predicate Device

Pressure Display Box and Pressure Tubing Set (K852232 – Cleared August 09, 1985)

Comparison to Predicate Device

A comparison of the modified device and the currently marketed Pressure Display Box and DLP Disposable Pressure Display Sets show the following similarities:

- Same intended use since the proposed labeling changes.
- Same operating principle.
- Same technological characteristics.
- Same performance claims.

Description of Device Modification and the Reasons for Implementation

No modifications have been made to the Devices as a result of this change. This submission is a result of a change to the labeling. The devices operating principle and technological characteristics are remaining the same.

As described in this submission, minor modifications since the original submission have been made to the Devices Directions for Use and the device packaging labels for the convenience of the user.

Intended Use

The intended use remains unchanged for both devices from the current version of the IFU.

Pressure Display Box

This product is intended for use in displaying line pressures during cardiopulmonary bypass surgery.

DLP® Disposable Pressure Display Set

This product is intended for use in monitoring catheter, cannula, or line pressures associated with cardiopulmonary bypass equipment and/or related products.

Conclusion

The modifications to the Pressure Display Box and the DLP Disposable Pressure Display Set described in this submission result in a substantially equivalent device because the fundamental scientific technology and the intended use are unchanged since the proposed labeling change.

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

DEC - 2 2011

Medtronic, Inc.
c/o Ms. Amra Racic
Regulatory Affairs Specialist
Medtronic Cardiovascular MVS83
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K113235
Trade/Device Name: Medtronic Pressure Display box and DLP Disposable Pressure Display
Regulation Number: 21 CFR 870.4310
Regulation Name: Cardiopulmonary bypass coronary pressure gauge
Regulatory Class: Class II
Product Code: DXS
Dated: October 28, 2011
Received: November 2, 2011

Dear Ms. Racic:

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,

M. A. Hillebrenner

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

Enclosure

K113235

Indications for Use

510(k) Number (if known): K113235

Device Name: **Pressure Display Box**

DLP® Disposable Pressure Display Set

Pressure Display Box
Indications for Use:

This product is intended for use in displaying line pressures during cardiopulmonary bypass surgery.

DLP® Disposable Pressure Display Set
Indications for Use:

This product is intended for use in monitoring catheter, cannula, or line pressures associated with cardiopulmonary bypass equipment and/or related products.

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)

M. J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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