Medtronic

K102953

NOV - 4 2010

510(k) Summary

Date Prepared October 1, 2010

Submitter

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

Contact Person

Jeffrey L. Koll
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Device Name and Classification

Trade Name:	Heparin Dose Response (HDR) Cartridge
Common Name:	Automated Heparin Analyzer
Regulation Number:	21 CFR 864.5680
Product Code:	JOX
Classification:	Class II

Predicate Device

Heparin Dose Response (HDR) Cartridge (K042070) cleared on October 1, 2004.

Comparison to Predicate Device

A comparison of the modified device and the currently marketed Heparin Dose Response (HDR) Cartridge shows the following similarities:

- Same intended use.
- Same operating principle.
- Same technological characteristics.
- Same performance claims.

Description of Device Modification

Heparin

- The modification to the current device is to replace old USP heparin with revised USP heparin. The heparin concentrations have been increased by 13.6% for heparinized channels (ch 1 & 2 and ch 3 &4). The source of the heparin remains porcine.

Intended Use

The intended use is unchanged.

Labeling

The current labels and IFU are being updated to reflect the revised USP heparin concentrations in heparinized channels (ch.1& 2 and ch.3 & 4). The current IFU also includes updates for style, grammar and readability. Applicable tables have also been updated with data generated from the verification testing with modified cartridges using revised USP heparin.

- Appendix A contains the current IFU.
- Appendix B contains the draft IFU.
- Appendix C contains the current and draft labels

Conclusion

The modifications to the Heparin Dose Response (HDR) Cartridge described in this submission result in a substantially equivalent device because the fundamental scientific technology and the intended use are unchanged.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Medtronic, Inc.
Medtronic Perfusion Systems
c/o Mr. Jeffrey Koll
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

NOV 0 4 2010

Re: k102953
Trade/Device Name: Heparin Dose Response (HDR) Cartridge
Regulation Number: 21 CFR 864.5680
Regulation Name: Automated heparin analyzer
Regulatory Class: Class II
Product Code: JOX
Dated: October 28, 2010
Received: November 1, 2010

Dear Mr. Koll:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102953

Device Name: Heparin Dose Response Cartridge

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Indications for Use:

For determining in vitro individual responses to heparinization using whole blood on the HMS Plus instrument.

For in Vitro Diagnostic Use.

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

Office of In Vitro Diagnostic
Device Evaluation and Safety

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