OCT 18 2004

K042175

510(k) Summary

Date Prepared: September 28, 2004

Submitter: Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person: Dawn M. Stenstrom
Principal Regulatory Affairs Specialist
Phone: (763) 391-9604
Fax: (763) 391-9603

Device Name and Classification:

Trade Name:	CLOTtrac® HTC Control
Common Name:	Activated Whole Blood Clotting Time
Classification:	Class II
Predicate Devices:	Heparinase HR ACT Control K902081

Device Description:

The CLOTtrac® HTC Control is an *in vitro* diagnostic device. This control is intended to verify the performance of the ACT instrument and the Heparinase (HR HTC) cartridges. The cartridge is for use in the ACT (Automated Coagulation Timer) instrument.

Indication for Use

This product is intended to verify the performance of the ACT instrument and the Heparinase (HR HTC) cartridges

Comparison to Predicate Device

The predicate device, Heparinase HR ACT control is currently marketed. The CLOTtrac® HTC Control has the same indications for use and is the same in all aspects to the modified control with exception of the source of heparin.

Summary of Performance Data

Validation testing was used to establish the performance characteristic of the modifications of this device from the previously marketed device.

Conclusion

Medtronic has demonstrated that the CLOTtrac® HTC Control is substantially equivalent to the predicate device based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Dawn M. Stenstrom
Principal Regulatory Affairs Specialist
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, MN 55428-1088

OCT 18 2004

Re: k042175
Trade/Device Name: CLOTtrac® HTC Control
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: GGN, JBP
Dated: September 28, 2004
Received: September 29, 2004

Dear Ms. Stenstrom:

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 either class II (Special Controls) or class III (PMA), 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); 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., 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): K042175

Device Name:

CLOTtrac® HTC Control

Indications for Use:

To verify the performance of the ACT instrument and the Heparinase (HR HTC) cartridges

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 THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K042175