

JUL 30 1998

K981815

**510(k) SUMMARY**

**Submitted by:** Medtronic Blood Management  
18501 E. Plaza Drive  
Parker, Colorado 80134

**Manufacturing Facility:** Medtronic Blood Management  
18501 E. Plaza Drive  
Parker, Colorado 80134

**Submitted Device:** Trade Name: HEPtrac Electronic Quality Control  
Common Name: Electronic Quality Control

**Device Classification:** Class II

21 CFR § 864.5425 "A multipurpose system for *in vitro* coagulation studies is a device consisting of one automated or semiautomated and its associated reagents and controls. The system is used to perform a series of coagulation studies and coagulation factor assays." The HEPtrac is a Electronic Control for such a device.

**Product Description:** The HEPtrac is an electronic control that has been developed to assist users of the Hepcon Hemostasis Management (HMS) Instrument (K894317) and associated cartridges and controls (K894317), to perform control testing as required under 42CFR493.1253. Sec. ( c ) "for all automated coagulation testing systems, the laboratory must include two levels control each eight hours of operation and each time a change in reagents occurs". The HEPtrac, electronic quality control is designed to minimize the use of liquid based controls by providing the operator a means to determine the operating condition of the instrument.

**Intended Use:** The HEPtrac Electronic Quality Control, manufactured by Medtronic Blood Management, is an interactive mechanical and software controlled verification cartridge for use with instruments that utilize the Hepcon Hemostasis Management cartridges. The purpose of the HEPtrac is to provide a means for performing quality control of the instruments in the clinical testing environment.

**Performance Standards:** Per section 514 of the Food, Drug and Cosmetic Act, there are no specific performance standards for this device.

**Statement of substantial equivalence-**

The HEPtrac electronic control for the HMS instrument is very similar to the ACTtrac electronic control for the ACT instrument in the following areas; intended use, operation, and function. The HEPtrac and the ACTtrac are both used to assess the operating condition of automated coagulation timers. The HEPtrac has been designed to function with a six channel instrument rather than the predicate device that was designed to function in a two channel device.

A summary of the essential features between the ACTtrac (predicate device) and HEPtrac is contained in *Table 1.1*

**Table 1.1**  
**Comparison between the ACTtrac and HEPtrac Electronic Quality Control tests**

Control Test Type	Predicate device	
	ACTtrac	HEPtrac
Number of channels	2	6
Reagent delivery check	yes	yes
Flag Sensor check	yes	yes
Clot detection	yes	yes
Flag release test	no	yes

From Table 1.1 it can be seen that the two types of devices share the same basic features for testing automated coagulation timers. The primary difference between these two devices lies in the model number of coagulation timer it is designed to test.

**Testing:**

Laboratory testing was done to confirm the devices performance in relation to the predicate device.

Performance testing was done to verify the HEPtrac's ability to check the condition of the HMS instrument for the following functions:

1. Flag release force
2. Reagent delivery
3. Flag lift wire height
4. Flag sensors



JUL 30 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Karl Steineck  
.Regulatory Affairs Specialist  
Medtronic Blood Management  
18501 E. Plaza Drive  
Parker, Colorado 80134-9061

Re: K981815  
HEPtrac  
Regulatory Class: II  
Product Code: JPA  
Dated: May 20, 1998  
Received: May 22, 1998

Dear Mr. Steineck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

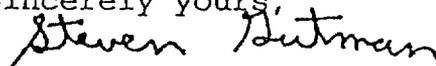
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### INTENDED USE STATEMENT

510(k) Number (if known): K 981815

Device Name: HEPtrac Electronic Quality Control

**Indications For Use:**

The HEPtrac Electronic Quality Control, manufactured by Medtronic Blood Management, is an interactive mechanical and software controlled verification cartridge for use with instruments that utilize the Hepcon Hemostasis Management cartridges. The purpose of the HEPtrac is to provide a means for performing quality control of the instruments in the clinical testing environment.

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(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*(Handwritten signature)*

(Division Sign-Off)  
Division of Clinical Laboratory Devices

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Prescriptive Use

OR

Over-the-Counter Use