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Food and Drug Administration  
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October, 1999

JAN 14 2000

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**510(k) Summary of Safety and Effectiveness Information**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

The assigned 510(k) number is K993519.

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and  
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Date of Summary: October, 1999

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**510(k) Summary of Safety and Effectiveness Information**

**Accent**

**Trade name:** Rapidpoint™ Accent

**Common Name:** Rapidpoint™ Accent

**Classification Name:** systems for in vitro coagulation studies, automated or semi-automated instruments and associated reagents and controls used to perform a series of coagulation studies and coagulation factor assays (Class II. 21 CFR864.5425)

**Predicate Device:** The proposed Accent, when used with the Rapidpoint™ Coag Analyzer, is substantially equivalent to the previously cleared Hepcon HMS produced by Medtronics Corporation. The 510(k) number for the Hepcon HMS submission is K911240.

**Description of the Device:** The Rapidpoint Accent is an accessory to the Rapidpoint Coag Analyzer. The Analyzer is a point of care instrument designed to determine hemostatic parameters of blood and plasma samples. The Accent works in conjunction with the Analyzer to provide dosing information for heparin and protamine during cardiopulmonary bypass procedures. The Accent determines this information by combining test results from the Analyzer with patient data entered into the Accent by the user. During the course of a CPB procedure, the user must perform a series of tests using the Analyzer. The test cards that must be used include the Heparin Management Test (HMT™), the Heparin Titration Test (HTT™), and the Protamine Response Test (PRT™). The results of these tests provide the Accent with information on how the patient's blood will respond to the addition of Heparin and Protamine. The Accent uses this information to calculate recommended dosages of Heparin or Protamine to be given to the patient to reach a target value entered into the Accent by the user. The target value may be either a heparin concentration or a clotting time.

The Accent includes an eight-inch diagonal touch screen for user interface and a built in printer for recording test results. The case is designed with a protective front cover that doubles as a holder for the Analyzer when the system is in use. The Accent is powered by an internal power supply that also provides power to the Analyzer. The Accent and the Analyzer communicate through a serial cable that must be plugged into the Analyzer and is permanently attached to the Accent.

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**Summary of Safety and Effectiveness Information**

**HTT Card**

**Trade name:** Heparin Titration Test (HTT)

**Common Name:** HTT

**Classification Name:** multipurpose system for in vitro coagulation studies (class II, 864.5425)

**Predicate Device:** The proposed HTT is substantially equivalent to the Heparin Dose Response Test (Medtronic, Inc), performed on the Hepcon HMS (Medtronic, Inc), used for determining individual responses to heparin.

**Description of the Device:** The HTT provides a method to determine the response of a patient to heparin. Before heparin administration, baseline Heparin Management Test (HMT) and HTT values are determined for the patient with the Rapidpoint™ Coag (formerly TAS) Analyzer. Using these values, the Rapidpoint ACCENT will calculate the dose of heparin necessary to produce a desired concentration or effect of this drug in the patient's blood. Both citrated or noncitrated whole blood samples can be used for these tests.

The test card has a magnetic stripe on the back, which encodes lot specific information such as number, expiration date, and mathematical factors specific to that lot. A room temperature test card is removed from the pouch and the card is passed through the card reader of the instrument to program the instrument to run a test. The instrument instructs the operator to insert a test card and then requests patient and sample information. The card is warmed and the operator is prompted to add a drop of blood to the card sample well. The sample is drawn into the card and rehydrates the reagent, which begins the reaction. As the reaction proceeds and clotting begins, the movement of the particles decreases, and the instrument signals the clotting time.

**Intended Use:** The HTT card is intended for use with the HMT card, the Rapidpoint™ Coag Analyzer (K933092; K990566) and the Accent to determine the potential response of a patient to heparin. The test helps identify patients who may be unusually sensitive or resistant to anticoagulation with unfractionated heparin. The test is based upon clotting time of citrated or noncitrated whole blood. The test is for in vitro diagnostic use, and is especially suited for professional use in the operating room, where higher levels of heparin are typically used.

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**Summary of Safety and Effectiveness Information**

**HTT Card**

**Comparison of HTT and the Predicate Device**

**Heparin Dose Response (HDR) (Hepcon HMS; Medtronic, Inc)**

<b>Characteristic</b>	<b>Predicate Device</b>	<b>Proposed Device</b>
Intended Use	Determines potential response of an individual to heparin	same
Format	Dry reagent in cuvette	lyophilized reagents in a flat shallow reaction chamber mounted on a thin plastic card
Reaction	one stage	one stage
Sample type	Noncitratd whole blood	citratd or noncitratd whole blood
Reagent base	Kaolin	Celite
Reaction	Formation of a fibrin clot	Same
Instrument	Hepcon HMS	Rapidpoint™ Coag Analyzer, Rapidpoint™ ACCENT
Endpoint monitored	coagulation time	same
Test interpretation	endpoint has direct correlation to heparin activity	same
Quality control	None available; manufacture recommends using normal donor	self tests performed by analyzer at power up and throughout operation, plus functional testing of each test card with two levels of quality control plasmas, electronic QC

**Summary of Safety and Effectiveness Information**

**HTT Card**

**Nonclinical Performance Data:** Preclinical testing was done at CVDI with HTT cards and the Rapidpoint™ Analyzer to determine the performance characteristics of the system.

The HTT cards are stable at refrigerator temperatures or lower (<8°C) for at least six months. They are stable at room temperature (20 - 25°C) for about two weeks.

The HTT card is sensitive to inhibitors of heparin. The performance characteristics of the HTT cards with respect to factor sensitivity have not been established.

Lipid (to at least 15 mg/ml), nitroglycerin (to 1 ug/ml), and Dextran (to 6 mg/ml) had no effect on HTT card results in the presence of absence of polybrene (added to simulate resistance to heparin). There was no effect of sample temperature from 2°C to 37°C on HTT card results. Samples should not be drawn into acid citrate tubes.

**Clinical Performance Data:** "Normal ranges" (mean +/- 2 SD) were 477 to 693 seconds for both citrated and noncitrated whole blood samples. Field and clinical testing was done at three large hospitals to establish substantial equivalence of the HTT to the predicate device, Hepcon Heparin Dose Response (Medtronic). Samples from 139 individuals were drawn and split to provide citrated and noncitrated blood samples. These samples were tested on several different lots of HTT cards on the Rapidpoint™ (formerly TAS) Coag Analyzer/ Rapidpoint™ ACCENT and with the predicate device. The heparin dosages calculated from the HTT by the Accent for each patient were compared to the heparin dosages calculated by the Hepcon HDR at each test site. No significant differences ( $p = \geq 0.05$ ) in dosage were observed between the two systems by ANOVA testing.

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**Summary of Safety and Effectiveness Information**

**PRT Card**

**Trade name:** Protamine Response Test Card (PRT)

**Common Name:** PRT

**Classification Name:** multipurpose system for *in vitro* coagulation studies (class II, 864.5425)

**Predicate Device:** The proposed PRT is substantially equivalent to the Heparin Assay Cartridges (Medtronic, Inc), performed on the Hepcon HMS (Medtronic, Inc), used for determining heparin levels in individual patients by protamine sulfate titration.

**Description of the Device:** The PRT card is made for use with citrated or noncitrated blood samples containing heparin. The PRT is a modification of the HMT card and consists of a single test card that contains calcium chloride to initiate coagulation in citrated blood samples, celite as activator, stabilizers, and protamine sulfate. The test results will depend on heparin activity in the blood, which in turn depend on the levels of heparin, of coagulation factors, and of heparin inhibitors in the sample. The higher the level of heparin activity, the greater the protamine sulfate dosage required to inhibit it. The results of the PRT card are used with values produced on HMT cards with samples taken just before protamine administration, to determine the response of the individual to the agent. The values are stored by the ACCENT, which performs the calculations to determine the protamine dose recommended to neutralize the heparin present in the patient.

The test card has a magnetic stripe on the back, which encodes lot specific information such as number, expiration date, and mathematical factors specific to that lot. A room temperature test card is removed from the pouch and the card is passed through the card reader of the instrument to program the instrument to run a test. The instrument instructs the operator to insert a test card and then requests patient and sample information. The card is warmed and the operator is prompted to add a drop of blood to the card sample well. The sample is drawn into the card and rehydrates the reagent, which begins the reaction. As the reaction proceeds and clotting begins, the movement of the particles decreases, and the instrument signals the clotting time.

**Intended Use:** The PRT card is intended for use with the HMT card, the Rapidpoint™ Coag Analyzer (K933092; K990566) and the Rapidpoint™ Accent to recommend the dose of protamine sulfate required to neutralize the heparin in a patient. The test is based upon protamine titration of heparin. Citrated or noncitrated whole blood samples can be used for this test. The test is for *in vitro* diagnostic use, and is especially suited for professional use in the operating room, where higher levels of heparin are typically used.

**Summary of Safety and Effectiveness Information**

**PRT Card**

**Comparison of PRT and the Predicate Device**

**Heparin Assay Cartridges (Hepcon HMS; Medtronic, Inc)**

<b>Characteristic</b>	<b>Predicate Device</b>	<b>Proposed Device</b>
Intended Use	Determines the amount of heparin in a blood sample by protamine titration	same
Format	Dry reagent in cuvette	lyophilized reagents in a flat shallow reaction chamber mounted on a thin plastic card
Reaction	one stage	one stage
Sample type	noncitrate whole blood	citrate or noncitrate whole blood
Reagent base	Thromboplastin; protamine sulfate	Celite; protamine sulfate
Reaction	Formation of a fibrin clot	Same
Instrument	Hepcon HMS	Rapidpoint™ Coag Analyzer, Rapidpoint™ ACCENT
Endpoint monitored	Clot formation	Same
Test interpretation	endpoint has direct correlation to heparin activity	Same
Quality control	Heparinized Hepcon HMS controls	self tests performed by analyzer at power up and throughout operation, plus functional testing of each test card with two levels of quality control plasmas, electronic QC

**Summary of Safety and Effectiveness Information**

**PRT Card**

**Nonclinical Performance Data:** Preclinical testing was done at CVDI with PRT cards and the Rapidpoint™ Coag Analyzer to determine the performance characteristics of the system.

The PRT cards are stable for at refrigerator temperatures or lower (<8°C) for at least 11 months. They are stable at room temperature (20 - 25°C) for at least 2 weeks.

The PRT card is sensitive to levels of heparin activity from 0.4 to at least 8 U/ml. The performance characteristics of the PRT cards with respect to factor sensitivity have not been established.

Lipid (to at least 15 mg/ml), nitroglycerin (to 1 ug/ml), and Dextran (to 6 mg/ml) had no effect on PRT card results in the presence of heparin. There was no effect of sample temperature from 2°C to 37°C on PRT card results. Samples should not be drawn into acid citrate tubes.

**Clinical Performance Data:** Citrated and noncitrated samples from normal individuals produce results of less than 40 seconds on PRT cards, indicating the absence of heparin. Field and clinical testing was done at three large hospitals to establish substantial equivalence of the PRT to the predicate device (Hepcon Heparin Assay cartridges). Samples from 139 individuals were drawn and split to provide citrated and noncitrated blood samples. These samples were tested on several different lots of PRT cards on the Rapidpoint™ (formerly TAS) Coag Analyzer/Rapidpoint™ ACCENT and with the predicate device. The protamine sulfate dosages calculated from the PRT by the Accent for each patient were compared to the protamine sulfate dosages calculated by the Hepcon Heparin Assay Cartridges at each test site. No significant differences ( $p = \geq 0.05$ ) in dosage were observed between the two systems by ANOVA testing.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**JAN 14 2000**

Food and Drug Administration  
2098 Gaither Road  
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Mr. Peter Scott  
Vice President of Quality Assurance  
and Regulatory Affairs  
Cardiovascular Diagnostics, Inc.  
5301 Departure Drive  
Raleigh, North Carolina 27616

Re: K993519  
Trade Name: Rapidpoint™ Accent  
Regulatory Class: II  
Product Code: JOX  
Dated: October 18, 1999  
Received: October 18, 1999

Dear Mr. Scott:

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 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). 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 (Premarket 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 premarket 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.

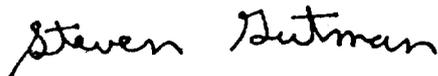
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsma/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

510(k) Number (if known): 4993519

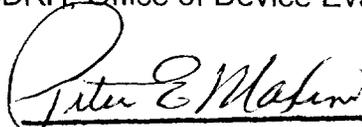
Device Name: Rapidpoint Accent. Heparin Titration Test Card, Protamine Response Test Card

Indications For Use:

The Rapidpoint Accent is an accessory to the Rapidpoint Coag Analyzer. When used in conjunction with the Rapidpoint Coag and the Heparin Management Panel Cards (Heparin Management Test, Heparin Titration Test, and Protamine Response Test) Cards, its intended use is to generate information on heparin management.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number 4993519

Prescription ✓