

MAR 28 2000

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Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850
November, 1999

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 K994194.

Submitted by: Cynthia Pritchard, Ph.D. (author)
Cardiovascular Diagnostics, Inc.

Address: 5301 Departure Drive
Raleigh, NC 27616

Phone: 1-800-247-4234

Fax: 1-919-954-9932

Contact: Peter Scott
VP of Quality Assurance and Regulatory Affairs

Date of Summary: November, 1999

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Summary of Safety and Effectiveness Information

LHMT Card

Trade name: (Rapidpoint Low range Heparin Management Test)

Common Name: LHMT

Classification Name: systems for in vitro coagulation studies, automated or semiautomated 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 Rapidpoint LHMT is substantially equivalent to the recently cleared to market Low Range Activated Clotting Time test (ACT-LR; International Technidyne Corporation), performed on the Hemochron Jr. and the Activated Clotting Time test (ACT; International Technidyne Corporation), performed on the Hemochron. These devices produce similar results with samples from patients on low to moderate doses of heparin (see package insert for predicate devices).

Description of the Device: The Rapidpoint LHMT provides a method to measure the response of a patient to heparin. A noncitratd whole blood sample can be used for this test. 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 initiate 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 flows 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 Rapidpoint Low range Heparin Management Test Card is to be used with the Rapidpoint Coag (formerly TAS) Analyzer to monitor the effects of low to moderate levels of unfractionated heparin on coagulation in noncitratd arterial whole blood samples from patients undergoing diagnostic and interventional procedures.

The test is for in vitro diagnostic use. It is especially suited for professional use in decentralized areas of the hospital near the patient's bedside, in the cardiac catheterization lab, and other areas where patients are treated with low to moderate levels of heparin.

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Comparison of Rapidpoint LHMT and the Predicate Device(s)

Hemochron ACT-LR or ACT (International Technidyne)

Characteristic	Predicate Device	Proposed Device
Intended Use	monitors effect of heparin at low to moderate doses	same
Format	dry reagent in cuvette or tube	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	Celite (ACT), celite, potato dextrin (ACT-LR)	celite, partial thromboplastin
Reaction	formation of a fibrin clot	same
Instrument	Hemochron Jr., Hemochron 401	Rapidpoint Analyzer
Endpoint monitored	coagulation time	same
Units reported	Seconds	same
Test interpretation	endpoint has direct correlation to heparin activity	same
Range	Up to 2.5 U/ml (ACT-LR) or 6 U/ml (ACT) of heparin	0 – 3 Units of heparin
Quality control	functional testing with two levels of quality control plasmas, electronic QC	Same and self tests performed by analyzer at power up and throughout operation

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LHMT Card

Stachrom Heparin (anti-Xa; Diagnostica Stago) (reference, tiebreaker method)

Characteristic	Reference Test	Proposed Device
Intended Use	determines heparin concentration	monitors effect of heparin at low to moderate doses
Format	chromogenic assay	lyophilized reagents in a flat shallow reaction chamber mounted on a thin plastic card
Reaction	two stage chemical	one stage coagulation
Sample type	plasma	noncitrate whole blood
Reagent base	antithrombin (AT), Xa, chromogenic substrate	celite, partial thromboplastin
Reaction	heparin in the sample combines with AT to inactivate Xa; remaining Xa catalyzes release of p-nitroaniline from the substrate; absorbance is inversely proportional to heparin level	formation of a fibrin clot
Instrument	MDA, Organon Teknika	Rapidpoint Coag analyzer, CVDI
Endpoint monitored	colorimetric reaction; absorbance at 405 nm	coagulation time
Test interpretation	heparin concentration	endpoint has direct correlation to heparin activity
Quality control	standards run with each set of assays	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

Nonclinical Performance Data: Preclinical testing was done at CDI using Rapidpoint LHMT cards and the Rapidpoint Coag analyzer to determine the performance characteristics of the system.

The Rapidpoint LHMT cards are stable at refrigerator temperatures or lower (<8°C) for a period of time up to or exceeding the expiration date recorded on the cards.

The LHMT is sensitive to the effects of heparin on coagulation, and responds in a linear manner from 0 to 3.0 U/ml of heparin. The LHMT card is relatively insensitive to deficiencies in the intrinsic and common coagulation pathways, as expected.

Lipid (to at least 15 mg/ml), nitroglycerin (to 1 ug/ml), and Dextran (to 6 mg/ml) had no effect on LHMT card results in the presence or absence of heparin. There was no effect of sample temperature (2 - 37°C) on LHMT card results.

LHMT Cards

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Clinical Performance Data: Noncitratd samples were obtained from 59 males and 61 females that were normal, healthy donors, ranging in age from 24 to 67 years. Normal ranges (mean +/- 2 SD) were 65 to 175 for noncitratd whole blood. Field testing and clinical testing were done at large hospitals to establish substantial equivalence of the Rapidpoint LHMT to the predicate devices (ACT or ACT-LR). The range with noncitratd patient "baseline" samples taken before the procedures were begun was 53 to 195 seconds. Samples also were taken from individuals expected to have abnormal LHMT results and were tested to compare results of the LHMT cards, the predicate device, and a chromogenic anti Xa assay for heparin activity. A total of 429 samples were drawn from 232 individuals undergoing a variety of treatments. These samples were tested on several different lots of LHMT cards on the Rapidpoint Coag Analyzer and with the predicate device. Noncitratd samples from all sites combined produced an overall correlation of 0.93 of the LHMT card to the ACT.



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 28 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Peter Scott
Vice President, Quality Assurance
and Regulatory Affairs
Cardiovascular Diagnostic, Inc.
5301 Departure Drive
Raleigh, North Carolina 27616

Re: K994194
Trade Name: Cardiovascular Diagnostics Rapidpoint Coag (TAS) Low range Heparin
Management Test (LHMT) Card
Regulatory Class: II
Product Code: JBP
Dated: March 14, 2000
Received: March 15, 2000

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.

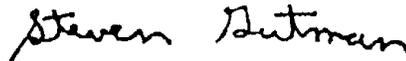
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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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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" (21CFR 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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): K994194

Device Name: Low range Heparin Management Test (LHMT) Card

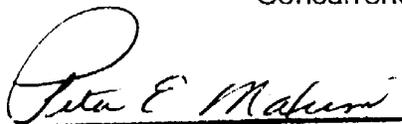
Indications For Use:

The Rapidpoint Coag Low range Heparin Management Test Card is to be used with the Rapidpoint Coag Analyzer to monitor the effects of low to moderate levels of unfractionated heparin on coagulation in noncitrated arterial whole blood samples from patients undergoing diagnostic and interventional procedures.

The test is for in vitro diagnostic use. It is especially suited for professional use in decentralized areas of the hospital near the patient's bedside, in the cardiac catheterization lab, and other areas where patients are treated with low to moderate levels of heparin.

(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 K994194
510(k) Number _____

Description 

(Optional Format 3-10-98)