

K981178

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FDA/CDRH/ODE/DHC

APR 27 1998

510(k) Summary

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 _____.

Submitted by: Cynthia Pritchard, Ph.D.
Director of Test Development

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Contact: Cynthia Pritchard, Ph.D.
Director of Test Development

or

Peter Scott
VP of Quality Assurance and Regulatory Affairs

Date of Summary: March, 1998

PA
Class II

SK-36

Summary of Safety and Effectiveness Information

TAS LHMT Controls

Trade name: Thrombolytic Assessment System Low Range heparin Management Test Controls (TAS LHMT controls)

Common Name: *in vitro* coagulation controls

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: TAS LHMT Controls provided results that compared well with other legally marketed controls when used to test the operation of the TAS Analyzer and test cards. TAS LHMT Controls are substantially equivalent to TAS HMT controls (CVDI), in performance and in intended use, but are specifically to be used with the TAS Analyzer and TAS LHMT cards. The TAS HMT controls are used with the TAS instrument and TAS HMT cards, which are to be used with noncitratd blood and citratd blood and plasma samples, to determine the integrity of the reagent/instrument system.

Description of the Device: The controls for TAS LHMT cards consist of two separate vials. One was designed to mimic a sample from a normal individual, and the second to mimic a sample from a patient with a prolonged clotting time due to administration of heparin. These controls are made with pig plasma. To make the controls as easy to use as possible for point-of-care testing, we chose the patented packaging system of Medtox, (Burlington, NC). This consists of a closed, crushable glass ampoule containing lyophilized plasma which is inside a plastic sleeve. The sleeve contains water for diluent and has a capped dropper top with a filter in the tip (to remove glass shards from the sample). The entire assembly is shrink wrapped with a label and plastic seal. To use, the ampoule is crushed inside the plastic sleeve, which allows the diluent to mix with the lyophilized plasma. The mixture is reconstituted by shaking or vortexing the capped vial. The plastic seal and cap are removed and three drops of plasma suspension are discarded into a biohazard waste container (to eliminate the dilution effect of the diluent that is contained in the filter). A drop of the plasma suspension is added to a TAS LHMT card in an analyzer. The rest of the test procedure and the manner of signal production is identical to that for a patient sample.

Intended Use: The new TAS LHMT Controls are intended to be used with the TAS Analyzer and the TAS LHMT card to provide a method for quality control of the system. The controls produce clotting times which must be within accepted,

Summary of Safety and Effectiveness Information

TAS LHMT Controls

standard ranges, to indicate that the analyzer and test cards are functioning properly and thereby help assure the accuracy of TAS LHMT results. The controls are substantially equivalent in intended use to other controls used in coagulation assays.

Comparison of the TAS LHMT Controls to the Marketed Controls

<u>Characteristic</u>	<u>TAS LHMT Control</u>	<u>TAS HMT Control</u>
Intended use	assure performance of system by functional testing	same
For use with	TAS LHMT cards	TAS HMT cards
coagulation test system	citrate	citrate
Format	glass ampoule in plastic sleeve	same
Reagent	lyophilized plasma	same
Diluent	water plus antifoam	same
Source	pig	human
Reaction	formation of a fibrin clot	same
Results	clotting time (seconds)	same
Interpretation of results	system OK if clotting times are within set limits	same

There were no significant differences in the performance of the TAS LHMT Controls and the TAS HMT controls used as the predicate device. The normal control produces a clotting time like that of a normal individual; the heparin control mimics the response of a patient given a moderate level of heparin. The method of packaging the TAS controls for HMT and LHMT are the same, to make them more "user-friendly" for point-of-care testing. With this system, an operator does not have to search for a pipetting device and reagent-grade water for reconstitution, and does not have to wait for the reagent to reconstitute.

TAS LHMT Controls are stable for at least 6 weeks of storage at room temperature (20-25°C) indicating a probable refrigerator stability of at least six months. Reconstituted vials are stable for five minutes.

Summary of Safety and Effectiveness Information

TAS LHMT Controls

Within day precision	LHMT cards		
	mean (sec)	SD	CV (%)
Normal	151	1.7	1.1
Heparin	296	9.8	3.3

Lot to lot precision (n = 30 each)	LHMT cards			
		mean (sec)	SD	CV (%)
Normal	1	152	3.5	2.3
	2	153	1.9	1.3
	3	153	1.5	1.0
Heparin	1	293	10.8	3.7
	2	296	13.0	4.4
	3	293	16.7	5.7

Nonclinical Performance Data:

Freezing the intact vials has little effect on the performance of these controls; there was no significant difference in mean or CV produced by any of the controls stored at -80°C compared to vials stored in the refrigerator. Heating intact vials to 37°C for several days however, will cause an increase in the mean clotting time on LHMT cards. The angle at which drops from the control vials are dispensed has little effect on the mean clotting times or the CV of the results.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cynthia Pritchard, Ph.D.
Executive Director of Development
Cardiovascular Diagnostics Inc.
5301 Departure Drive
Raleigh, North Carolina 27616

Re: K981178
TAS LHMT Controls
Regulatory Class: II
Product Code: GGN
Dated: April 1, 1998
Received: April 1, 1998

Dear Dr. Pritchard:

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.

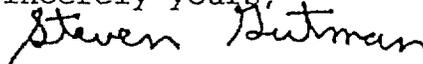
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known): _____

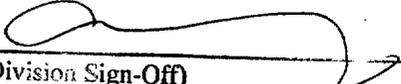
Device Name: LHMT controls

Indications For Use:

Intended for use with the TAE analyzer and TAE LHMT cards to provide a method for quality control of the system.

(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 K981178

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use