CARDIOVASCULAR DIAGNOSTICS INC.

K971748 MAY 29 1997

510(k) Summary

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Date of Summary: May 5, 1997

Summary of Safety and Effectiveness Information **TAS PT-NC Controls**

Trade name: Thrombolytic Assessment System Prothrombin Time - Noncitrated Test Controls (TAS PT-NC test 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 PT-NC 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 PT-NC Controls are substantially equivalent to TAS PT controls (CVDI), in performance and in intended use, but are specifically to be used with the TAS Analyzer and TAS PT-NC test cards. The TAS PT controls are used with the TAS instrument and TAS PT and PT ONE test cards, which are to be used with citrated blood and plasma samples, to determine the integrity of the reagent/instrument system.

Description of the Device: The controls for TAS PT-NC test 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 an abnormally prolonged clotting time due to a deficiency of extrinsic coagulation factors. These controls are made with human plasma screened for antibodies to and antigens of hepatitis and Human Immunodeficiency viruses. To make the controls as easy to use as possible for point-of-care testing, we chose the patented packaging system of EDITek (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 PT-NC test card in an analyzer. The rest of the test procedure and the manner of signal production is identical to that for a patient sample.

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Summary of Safety and Effectiveness Information **TAS PT-NC Controls**

Intended Use: The new TAS PT-NC Controls are intended to be used with the TAS Analyzer and the TAS PT-NC test card to provide a method for quality control of the system. The controls produce clotting times which must be within accepted, standard ranges, to indicate that the analyzer and test cards are functioning properly and thereby help assure the accuracy of TAS PT-NC test results. The controls are substantially equivalent in intended use to other controls used in coagulation assays.

Comparison of the TAS PT-NC Controls to the Marketed Controls

Characteristic Controls	TAS PT-NC Controls	TAS PT
Intended use	assure performance of system by functional testing	same
For use with cards	TAS PT-NC test cards	TAS PT test
coagulation test system	noncitrated	citrated
Format	glass ampoule in plastic sleeve	same
Reagent	lyophilized plasma	same
Diluent	water plus calcium	water
Source	human	same
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 PT-NC Controls and the TAS PT controls used as the predicate device. The normal control produces a clotting time like that of a normal individual. Like other control manufacturers, we chose to make an abnormal control that responds like a patient with an extrinsic coagulation factor deficiency. The method of packaging the TAS controls for PT and PT-NC 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.

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Summary of Safety and Effectiveness Information **TAS PT-NC Controls**

TAS PT-NC Controls are stable for at least 13 weeks of storage at room temperature (20-25°C) indicating a probable refrigerator stability of at least one year. Controls must be used immediately upon reconstitution to minimize changes in clotting time.

Within day precision	PT-NC test cards			
	mean (sec)	SD	CV (%)	mean ranges
PT-NC Normal	10.1	1.4	4.1	9.3 - 11.0
PT-NC Abnormal	43.3	2.9	6.6	40.4 - 55.6

Lot to lot precision (n = 40 each

	PT-NC test cards			
PT-NC Normal		mean (sec)	SD	CV (%)
	1	10.1	1.4	4.2
	2	11.9	1.7	5.8
	3	12.2	0.7	6.1
PT-NC Abnormal				
	1	43.5	3.0	6.9
	2	41.4	3.4	8.3
	3	41.8	3.8	9.1

Specific Performance Characteristics

The wide range of CV for the abnormal control is due to coagulation changes in the control as time progress. Most of these studies were done with five to ten drops from the same vial. If "first drop" analysis of the clinical and performance data is done, the overall CV for this control (for all days and all experiments) was 7%, which should be more representative of the values expected for QA testing of the TAS Analyzer in the field.

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 PT-NC test 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.

Summary of Safety and Effectiveness Information **TAS PT-NC Controls**

Clinical Performance Data:

Studies were performed at one clinical study site and at CVDI to establish the performance of the TAS PT-NC Controls in the field. At each of the sites, the TAS PT-NC normal and abnormal controls were tested at least in duplicate each day for 20 days with TAS PT-NC test cards on TAS Analyzers to determine variation.

Field study of TAS PT-NC Controls on TAS PT-NC test cards

	Normal		Abnormal	
	Mean	CV	Mean	CV
Site A	10.7	9.9	45.2	13.6
Site B	10.5	6.3	49.7	8.0

Conclusions: TAS PT-NC Controls are substantially equivalent to the predicate device because they have the same intended use and similar technological characteristics. This application includes sufficient information to demonstrate that the TAS PT-NC Controls, to be used with the TAS Analyzer (K933092) and PT-NC test cards (K904325), are as safe and effective as a legally marketed device, and that they do not raise different questions of safety and efficacy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 29 1997

James M. Clinton
Director of QA, and Regulatory Affairs
Cardiovascular Diagnostics, Inc.
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Re: K971748
TAS PT-NCtest Controls
Regulatory Class: II
Product Code: GGN, GJS
Dated: May 7, 1997
Received: May 12, 1997

Dear Mr. Clinton:

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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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 Gutman

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: TAS PT-NC controls

Indications For Use:

The new TAS PT-NC Controls are intended to be used with the TAS Analyzer and PT-NC test cards to provide a method for quality control of the system. The controls produce clotting times which must be within accepted, standard ranges, to indicate that the analyzer and test cards are functioning properly and thereby help assure the accuracy of PT-NC test card results. These controls were designed to allow CVDI's point-of-care tests to maintain accepted laboratory standards and requirements. These controls also can be used to determine system (TAS Analyzer and PT-NC test cards) precision. The controls are substantially equivalent in intended use to other control materials used in coagulation tests.

(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 K041748

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)