K971428

JUN 17 1997

PREMARKET NOTIFICATION 510(K) SUMMARY

Submitter: Laura A. Worfolk, Ph.D.
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Contact Person: The same as above.

Date: 4/16/97

Trade Name: Coagulation Control Plasma (Abnormal) Level θ

Common Name: Not applicable

Classification Name: Plasma, Coagulation Control
(per 21 CFR section 864.5425)

Equivalent Device: Dade® Ci-Trol® Coagulation Control, Level I

Description of Coagulation Control Plasma (Abnormal) Level θ:

Control Level θ Plasma is a lyophilized preparation of fresh human citrated plasma with added stabilizers and buffers. The reconstitution volume is 1.0 mL (with deionized or distilled water). Control Level Theta contains markedly elevated levels of human fibrinogen and factor VIII, and produces an abnormally short Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) with a variety of end-point detection methods. Each unit of source material used in the preparation of this product has been tested by an FDA approved method and found non-reactive for HB_sAg (Hepatitis B Surface antigen) and negative for antibodies to HIV and HCV. However, since no known test method can offer complete assurance that product derived from human blood will not transmit

Hepatitis, AIDS, or other infectious diseases, this product should be handled as potentially infectious biological material.

Intended Use of Coagulation Control Plasma (Abnormal) Level θ:

Control Level θ Plasma is intended for use in a laboratory program of quality assurance for activated partial thromboplastin time (APTT) and prothrombin time (PT) results with short clotting times. PT and APTT clotting times at the low end, or below the locally determined normal reference range are often related to the presence of elevated levels of fibrinogen and factor VIII. Both of these proteins are elevated in response to an inflammatory stimulus, malignant disease process or trauma. Control Level θ Plasma provides a means for verifying the lower extent of the reportable range of the PT and APTT, particularly the imprecision of short clotting times often encountered with these screening tests.

Summary of Data Comparing Control Level θ Plasma to Dade® Ci-Trol® Level I:

Pacific Hemostasis Control Level Theta was compared to Dade® Ci-Trol® Level I, **a pre-amendment device.** Both Control Level Theta and Dade® Ci-Trol® Level I plasmas are lyophilized preparations of human citrated plasmas with added stabilizers and buffers. The intended use for both products is indistinguishable; as a control plasma for Prothrombin and Activated Partial Thromboplastin Time testing in a clinical laboratory program of quality assurance. Control Level Theta contains elevated levels of human fibrinogen and Factor VIII, which result in clotting times below the normal reference range. In contrast, Dade® Ci-Trol® Level I yields clotting times within the normal reference range.

Within-run precision studies performed on two different instruments (MLA®-1000C™ & MLA®-1600) using both Dade and Pacific Hemostasis brand PT and APTT reagents yielded comparable data. *The coefficient of variation (CV) for Control Level Theta and Dade® Ci-Trol® I was well below the*

performance specifications. (For Pacific Hemostasis Control Level Theta the CV for both PT and APTT must be ≤ 5%. The stated CV for Dade® Ci-Trol® I is ≤ 5% and ≤ 9% for PT and APTT, respectively.) Testing performed using Pacific Hemostasis brand PT and APTT reagents yielded a 1.23% (PT) and 0.74% (APTT) CV with Control Level Theta. The CV's for Dade® Ci-Trol® Level I using Pacific Hemostasis brand reagents was 0.82% (PT) and 0.79% (APTT). Testing was also performed using Dade brand PT and APTT reagents. For Control Level Theta, a 1.35% and 0.55% CV was obtained for PT and APTT testing respectively. Dade Ci-Trol Level I yielded a 0.74% and 0.48% CV for PT and APTT testing respectively. The following table summarizes this data:

Table 14. Summary of Within-Run Precision Studies

	PT		APTT	
	Theta Control	Dade® Ci-Trol®	Theta Control	Dade® Ci-Trol®
Dade Reagents	1.35	0.74	0.55	0.48
PH Reagents	1.23	0.82	0.74	0.79

Results are %CV.

Since the results for the between-run precision studies were indistinguishable between the two manufacturer's reagents, day-to-day precision studies were performed using Pacific Hemostasis brand reagents only. Testing was performed on the MLA®-1000C™. Control Level Theta had a 1.46% and 1.29% CV for PT and APTT testing respectively; Dade® Ci-Trol® Level I yielded a 1.87% and 1.41% CV for PT and APTT testing.

The reconstituted stability claim for Control Level Theta is for 6 hours at room temperature. (The manufacturing specification for Control Level Theta is for less than a 5% change in clot time over a 6 hour storage period.) Stability studies support this claim; there was a 1.39% change for PT and 2.43% change for APTT over a 6-hour time period. Dade® Ci-Trol® Level I was also tested at 6

hours and yielded comparable data; 1.37% and -0.19% for PT and APTT respectively. (These studies were also run on the MLA®-1000C™.)

Control Level Theta yields an abnormally short PT and APTT (when compared to normal plasma) with a wide variety of end-point detection methods. Control Level Theta and Pooled Normal Plasma were tested for the PT and APTT using nine PT reagents and seven APTT reagents. Testing for both the PT and APTT was performed on four different coagulation analyzers. The instruments used for this analysis were the manual LAbor Fibrintimer®, the semi-automated MLA®-700, and the fully automated ACL-3000^{plus} and the MLA®-1000C™. This combination of analyzers represents approximately 80% of the instruments currently in use (within the USA). All reagent-instrument testing combinations yielded shorter PT and APTT clot times for Control Level Theta when compared to Pooled Normal Plasma. This testing was not performed for Dade® Ci-Trol® Level I since it is intended primarily for use with Dade brand PT and APTT reagents.

In summary, within-run, between-run and reconstituted stability studies support the substantial equivalence claim for Pacific Hemostasis Coagulation Control Level Theta to Dade® Ci-Trol® Level I. The one new performance characteristic, shorter clotting times, is intended to extend the verifiable limits of PT and APTT testing with more precision than controls that have longer clot times. *Therefore based on the data provided, it is our conclusion that Control Level Theta is substantially equivalent to Dade® Ci-Trol® Level I.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 17 1997

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Re: K971428
Coagulation Control Plasma (Abnormal) Level θ
Regulatory Class: II
Product Code: GGN
Dated: April 16, 1997
Received: April 17, 1997

Dear Dr. Worfolk:

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): K971428

Device Name: Coagulation Control Plasma, Abnormal Level Theta

Indications For Use:

Pacific Hemostasis Control Plasma (Abnormal) Level Theta is intended for use in a laboratory program of quality assurance for APTT and PT results with short clotting times. PT and APTT clotting times at the low end, or below the locally determined normal reference range are often related to the presence of elevated levels of fibrinogen and factor VIII. Both of these proteins are elevated in response to an inflammatory stimulus, malignant disease process or trauma. Control Level Theta Plasma provides a means for verifying the lower extent of the reportable range of the PT and APTT, particularly the imprecision of short clotting times often encountered with these screening tests.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Veronica Celuia for Dr. Montgomery
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971428

scription Use ✓ OR Over-The-Counter Use ____
r 21 CFR 801.109)

(Optional Format 1-2-96)