AUG 26 1999

K992279

7.0 PREMARKET NOTIFICATION 510(k) SUMMARY

Applicant: Laura A. Worfolk, Ph.D.
Address: Pacific Hemostasis
11515 Vanstory Drive
Huntersville, NC 28078
Phone: (800) 528-0494 or (704) 875-0494
Fax: (704) 875-2092

Contact Person: Same as above.

Date: July 6, 1999

Trade Name: Heparin Control Plasma Level 2

Common Name: Heparin Control Plasma Level 2

Classification Name: Plasma, Coagulation Control

Equivalent Device: Dade Ci-Trol Heparin Control High, K771346

Description of Heparin Control Level 2

Pacific Hemostasis Heparin Control Level 2 is a lyophilized preparation of citrated plasma obtained from healthy donors, which contains sodium heparin, stabilizers and buffers. Each unit of source material used in the preparation of the reagent has been tested by an FDA approved method and found non-reactive for HBsAG and negative for antibodies to HIV and HCV.

Intended Use of Heparin Control Level 2

Pacific Hemostasis Heparin Control Level 2, an unassayed control plasma, is intended for use in heparin assay procedures. In addition, it can be used for quality control in monitoring heparin therapy with Activated Partial Thromboplastin Time (APTT) testing. It will yield APTT values in the moderately high abnormal range.

Summary of Performance Data for Substantial Equivalence Comparisons

Between-run and within-run precision studies yielded equivalent data for Pacific Hemostasis and Dade Brand Coagulation Heparin control plasmas. For both controls a CV of less than 3.0% was obtained for APTT between-run testing, and less than 2.0% for within-run testing.

Based on the data provided, the similar composition and intended use, it is our conclusion that these two products are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 26 1999

Laura A. Worfolk, Ph.D.
Research Scientist
Pacific Hemostasis
11515 Vanstory Drive
Suite 125
Huntersville, North Carolina 28078-8144

Re: K992279
Trade Name: Heparin Control Plasma Level 2
Regulatory Class: II
Product Code: GGN
Dated: August 9, 1999
Received: August 11, 1999

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 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.

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 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

STATEMENT OF INDICATIONS FOR USE

Pacific Hemostasis Heparin Control Plasma Level 2, an unassayed control plasma, is intended for use as a control in heparin assay procedures.

Peter E. Maybee

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992279

FDA/CDRH/ODE/DHC
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Prescription Use ✓