K994100

FEB 1 8 2000

8.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant:	Laura A. Worfolk, Ph.D. Pacific Hemostasis 11515 Vanstory Drive Huntersville, NC 28078 (704) 875-0494 or (704) 948-3276 Fax # (704) 875-2092
Contact:	Same as above.
Date:	December 2, 1999
Trade Name:	Pacific Hemostasis Thromboplastin D
Common Name:	Thromboplastin D
Classification Name:	Prothrombin Time Test, per 21 CFR section 864.7750
Comparison Device:	Dade Thromboplastin C Plus, K901325

Description of the Device and Intended Use

Pacific Hemostasis Thromboplastin D is a lyophilized extract of rabbit brain thromboplastin containing calcium, stabilizer and buffer. Thromboplastin D is an *in vitro* diagnostic reagent intended for use for the performance of Prothrombin Time (PT) testing and quantitative PT-based factor assays (for Factors II, V, VII and X).

Summary of Substantial Equivalence Comparisons

Pacific Hemostasis Thromboplastin D is substantially equivalent in intended use and performance to Dade Thromboplastin C Plus. Both the predicate device and the proposed product are formulated to detect deficiencies in factors II, V, VII and X (PT and PT-based factor assays). Further, both reagents can be used for monitoring oral anticoagulant (OAC) therapy. In correlation studies, PT testing of specimens from normal and abnormal patients, as well as samples from patients receiving OAC therapy were tested using both reagents. PT testing at two sites on multiple instruments yielded correlation coefficients ranging from 0.96-0.97 (R) and slopes ranging from 0.74-0.85. The bias was eliminated when the results were converted to INR, with correlation coefficients obtained ranging from 0.95-0.97 and slope values between 0.98-1.04. Within-run and between-run precision studies were also performed and CV's less than 3% were obtained for the proposed device, and less than 4% for the predicate device.

In summary, the identical intended use, similar technological characteristics and the performance data provided in this premarket notification demonstrate that Pacific Hemostasis Thromboplastin D is substantially equivalent to Dade Thromboplastin C Plus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2000

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

Re: K994100
Trade Name: Pacific Hemostasis Thromboplastin D
Regulatory Class: II
Product Code: GJS
Dated: February 3, 2000
Received: February 4, 2000

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.

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,

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): K994100

Device Name:_____

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Indications For Use:

Pacific Hemostasis Thromboplastin D is intended for use for performing the one-stage Prothrombin Time test (PT) and PT-based factor assays.

Peter E. Maggio

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994100

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)