2/17/99

K990046

7.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Applicant:	Laura A. Worfolk, Ph.D. Pacific Hemostasis 11515 Vanstory Drive Huntersville, NC 28078 704-875-0494 Fax # 704-875-2092
Contact:	Mark Ellis, Regulatory Affairs Manager 704-948-3279 Fax # 704-875-2092
Date:	January 6, 1999
Trade Name:	Pacific Hemostasis Immunodepleted Factor VIII Deficient Plasma
Common Name:	Factor VIII Deficient Plasma
Classification Name:	Plasma, Coagulation Factor Deficient (per 21 CFR section 864.7290)
Comparison Device:	Biopool Factor VIII Deficient Plasma, K893525

Description of Immunodepleted Factor VIII Deficient Plasma

Pacific Hemostasis (PH) Immunodepleted Factor VIII Deficient Plasma is a lyophilized preparation of fresh human plasma with added stabilizer. The product is prepared from pooled normal citrated plasma, and then depleted of FVIII by immobilized highly specific antibodies. Factor VIII activity is less than 1%, all other coagulation Factors are within the normal range. Each unit of source material used in the preparation of this product has been tested and found negative for HBsAg (Hepatitus B Surface antigen) and negative for antibodies to HIV and HCV. The product is provided in 1.0mL vials, 10 vials per package.

Intended Use of Immunodepleted Factor VIII Deficient Plasma

This product is intended for use in a clinical laboratory for the quantitative measurement of Factor VIII activity. Factor VIII activity in patient or control plasma is assayed by the amount of Activated Partial Thromboplastin Time (APTT) correction produced by the test plasma when mixed with Factor VIII deficient plasma. Results are compared to the degree of APTT correction of a reference plasma with known Factor VIII activity.

Summary of Performance Data for Substantial Equivalence Comparisons

Pacific Hemostasis (PH) Immunodepleted Factor VIII Deficient Plasma was compared to Biopool (BP) Factor VIII Deficient Plasma. Both products are lyophilized preparations of normal human plasma, the PH product contains added stabilizer. The Factor VIII level in both is less than 1%; all other coagulation factors are within the normal range. The intended use for both products is identical; for the quantitative measurement of Factor VIII activity in patient plasma. Biopool FVIII deficient plasma may also be used as a negative control in von Willebrand Factor assays, however this claim is not made for the PH product.

Comparison studies performed for this application support the claim of substantial equivalence. Day-to-day precision studies were performed by preparing standard curves using both plasmas, and measuring FVIII activity contained in control plasmas over a 10 day period. The control plasmas tested contained FVIII activity levels ranging from normal to markedly abnormal low. The standard curves obtained using each plasma were indistinguishable over the 10 day testing period (R^2 = 0.98-0.99). Further, recovery of Factor VIII activity contained in six control plasmas was equivalent for both (Table 1). The correlation coefficient for recovered FVIII activity contained in the control plasmas was 0.98, with a regression line equation of y = 0.9911x + 0.8692.

Table 1. Recovery of FVIII Activity (%) Contained in Control Samples. Testing with PH or BP FVIII Deficient Substrate Plasmas**

	PNP*		Control 1		Control 2		Control 3		Control 4		Control 5	
	PH	BP	PH	BP	PH	BP	PH	BP	PH	BP	PH	BP
mean	114.7	117.0	130.9	127.1	95.5	96.6	65.6	65.7	33.6	34.1	18.0	18.1
1 SD	16.1	21.29	6.46	8.73	4.63	5.35	1.82	4.82	2.13	1.57	1.32	0.98
% CV	14.0%	18.2%	4.9%	6.9%	4.8%	5.5%	2.8%	7.3%	6.3%	4.6%	7.3%	5.4%
n (days of testing)	10	10	8	8	8	8	10	10	8	8	8	8

*PNP = pooled normal plasma, ** Testing on the MLA®-1000C™.

Several different instruments were used to assess the performance of the deficient plasmas, these included the Amelung KC 4 A™, MLA®-700, MLA®-1000C™ and the ACL-3000^{PLUS}. Standard curves were prepared, and the recovery of FVIII activity contained in control plasmas was determined using both products. The combined instrument data yielded a correlation coefficient of 0.99, with a regression line equation of y = 1.037x + 0.5603. Last, reconstituted stability studies were performed. Standard curves prepared with fresh or 8-hour aged deficient plasma were indistinguishable for both products. Further, there were no clinically significant differences observed in FVIII activity recovered in control plasmas between fresh and aged deficient plasmas, for PH and Biopool substrate plasmas.

In summary, the similar intended use, technological characteristics and combined performance data support the substantial equivalence claim for Pacific Hemostasis Immunodepleted Factor VIII Deficient Plasma to Biopool Factor VIII Deficient Plasma. *Therefore based on the data provided, it is our conclusion that Pacific Hemostasis Immunodepleted Factor VIII Deficient Plasma is substantially equivalent to Biopool Factor VIII Deficient Plasma.*

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(j)]

I certify that, in my capacity as a Research Scientist at Pacific Hemostasis, a Fisher Scientific Company, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Laura A. Worfolk 1/6/99

Laura A. Worfolk, Ph.D.

K990046

***(Premarket Notification [510(k)] Number)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 17 1999

Mr. Mark Ellis
Regulatory Affairs Manager
Pacific Hemostasis
11515 Vanstory Drive, Suite 125
Huntersville, North Carolina 28078-8144

Re: K990046
Trade Name: Pacific Hemostasis Immunodepleted Factor VIII Deficient Plasma
Regulatory Class: II
Product Code: GJT
Dated: January 6, 1999
Received: January 7, 1999

Dear Mr. Ellis:

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.

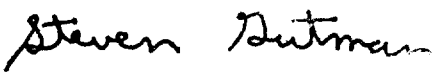
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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): K990046

Device Name: _____

_____

Indications For Use:

Statement of Indications for Use

Pacific Hemostasis Immunodepleted Factor VIII (FVIII) Deficient Plasma is intended for use as a substrate in the quantitative determination of Factor VIII activity in citrated plasma.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990046

(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)