10.0 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:	Larry Kopyta, Manager FDA Programs 704-875-0494 Fax # 704-875-2092
Date:	April 16, 1999
Trade Name:	Pacific Hemostasis ThromboScreen® 200
Common Name:	Manual Coagulation Instrument
Classification Name:	Instrument, Coagulation (per 21 CFR section 864.5400)
Equivalent Devices:	MLA-900C &1000C, #K884863, #K894052

Description of the ThromboScreen® 200

The ThromboScreen® 200 (TS200) is a photo-optical instrument used for the performance of in-vitro diagnostic clotting procedures in the clinical laboratory. The instrument utilizes photo-optical principles to measure and record the time required for patient plasma specimens to clot. The ThromboScreen® 200 light source is provided by a 470 nm LASER. The incubator block is temperature regulated to 36.5 - 37.5°C and contains two measuring positions, three reagent and 12 cuvette prewarming positions. A detailed description of the device, including an explanation of how it functions, is described in the ThromboScreen® 200 Operator's Manual, section 1, Introduction.

Intended Use of the ThromboScreen® 200

The Pacific Hemostasis ThromboScreen® 200 is a photo-optical instrument used for the performance of in-vitro diagnostic coagulation testing of citrated plasma specimens in the clinical laboratory. Coagulation testing capabilities of the device include routine clotting tests such as Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Clauss and Derived methods), as well as PT and APTT-based factor assays.

Summary of Substantial Equivalence Comparisons

The ThromboScreen® 200 (TS200) was compared to the MLA-900C and the MLA-1000C (K884863 & K894052, respectively). All three instruments have a similar intended use: for in-vitro diagnostic coagulation testing in the clinical laboratory. Further, the proposed device and the predicate devices have the same measurement system for clotting assays: photo-optical clot detection systems.

The TS200 is a "manual" coagulation instrument, in that the user must pipet both sample and test reagent. In contrast, the MLA-900C is semi-automated, and the MLA-1000C is a fully-automated instrument. The MLA-900C requires manual sample addition, but has an automatic pipet for reagent addition. The MLA-1000C has an automatic pipetting system, which adds *both* sample and test reagent. The light source for the MLA instruments is a Halogen lamp and the wavelength is set at 550 nm (for clotting assays). In contrast, the TS200 utilizes an LASER optic at 470 nm. Although differences in light source and wavelength exist, all instruments have been optimized for their light source/filter combinations. The performance data generated support this statement (Tables 1-3).

Comparison testing was performed in-house and at two external testing laboratories using Pacific Hemostasis (PH) brand reagents. Specimens were evaluated from apparently healthy individuals and from patients with different pathological conditions which are expected to affect the results for a particular assay. Table 1 summarizes the results of the comparison studies between the proposed and the predicate devices.

Table 1. Summary of Method Comparison Studies Between the TS200 & the MLA-900C/1000C

Test (Reagent, Unit)	Site & Sample #	Correlation Coefficient, r	Regression Equation
Prothrombin Time (PT) (Thromboplastin DS, seconds)	**Site #1 - 137** **Site #2 - 141**	**0.98** **0.99**	**y = 1.078x + 0.309** **y = 1.076x - 0.526**
Prothrombin Time (Thromboplastin DS, INR)	**Site #1 - 137** **Site #2 - 141**	**0.98** **0.99**	**y = 0.899x + 0.186** **y = 1.0754x - 0.1063**
Activated Partial Thromboplastin Time* (APTT-LS reagent, seconds)	**Site #1 - 104** **Site #2 - 121**	**0.98** **0.97**	**y = 1.328x - 0.305** **y = 1.072x + 4.351**
Clauss Fibrinogen (PH Thrombin reagent, mg/dL)	**Site #1 - 20** **Site #2 - 20** **PH - 49**	**0.99** **0.98** **0.98**	**y = 1.059x - 11.526** **y = 1.038x - 14.293** **y = 1.001x - 9.257**
Derived Fibrinogen (Thromboplastin DS, mg/dL)	**Site #1 - 19** **Site #2 - 47**	**0.99** **0.99**	**y = 0.775x + 96.12** **y = 0.896x + 23.02**
Factor VIII (APTT-LS, % activity)	**PH - 49**	**0.97**	**y = 0.844x + 14.07**
Factor V, (Thromboplastin DS, % activity)	**PH - 45**	**0.97**	**y = 1.071x +2.01**

The predicate device used at site #1 & PH was the MLA-1000C, at site # 2 , the MLA-900C. *=APTT

The following coefficients of variation were obtained for within-run and between-run precision studies:

Table 2. Summary of Within-run Precision Studies, %CV

Test	TS200 Low	TS200 Normal	TS200 High	MLA-900C/1000C Low	MLA-900C/1000C Normal	MLA-900C/1000C High
PT						
Site 1		1.9	2.3		1.1	2.8
Site 2		2.0	5.7		1.5	2.0
PH		2.8	3.2		1.0	2.8
APTT						
Site 1		5.1	1.6		1.4	2.9
Site 2		4.7	2.3		3.3	2.2
PH		3.3	2.5		0.9	1.2
Clauss Fib.*	6.7	6.8	5.0	2.0	2.1	2.8
Derived Fib.*	5.6	2.5	4.1	2.2	3.4	2.1
Factor V*	2.3	2.5		4.0	2.0	
Factor VIII*	9.6	10.2		5.3	4.7	

*Testing at PH only. (Shaded areas, no testing performed. Only clinically significant ranges tested.)

Table 3. Summary of PT & APTT Between-run Precision Testing

	Prothrombin Time Testing				Activated Partial Thromboplastin Time Testing			
	Normal Plasma		Abnormal Plasma		Normal Plasma		Abnormal Plasma	
	TS200	MLA	TS200	MLA	TS200	MLA	TS200	MLA
mean	12.9	12.8	45.1	40.0	35.4	29.7	69.5	59.0
SD	0.22	0.18	2.68	3.24	1.28	1.27	1.96	4.41
CV	1.7%	1.4%	5.9%	8.1%	3.6%	4.3%	2.8%	7.5%
n	39	40	38	40	39	40	40	40

Testing performed at PH only.

In conclusion, the similar intended use, technological characteristics and performance data support the claim that the ThromboScreen® 200 is substantially equivalent to the MLA-900C and the MLA-1000C.

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

Laura A. Worfolk, Ph.D.

April 16, 1999

K991331

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 21 1999

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

Re: K991321
Trade Name: Pacific Hemostasis ThromboScreen 200 (TS200)
Regulatory Class: II
Product Code: KQG
Dated: June 4, 1999
Received: June 7, 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

510(k) Number (if known): K991321

Device Name:_____

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Indications For Use:

The Pacific Hemostasis ThromboScreen® 200 is a photo-optical instrument used for the performance of in-vitro diagnostic coagulation testing in the clinical laboratory. Coagulation testing capabilities of the device include routine clotting tests such as Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Clauss and Derived methods), as well as PT and APTT-based factor assays.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maderi

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991321

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

(Optional Format 1-2-96)