
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: Laura A. Worfolk
Phone: 704-875-0494
Fax #: 704-875-2092

Date: June 21, 1999

Trade Name: Pacific Hemostasis ThromboScreen® 400C

Common Name: Manual Coagulation Instrument

Classification Name: Instrument, Coagulation (per 21 CFR section 864.5400)

Equivalent Devices: MLA-900C, #K884863 & the MLA-1000C, #K894052

Description of the ThromboScreen® 400C

The ThromboScreen® 400C (TS400C) is a photo-optical instrument used for the performance of in-vitro diagnostic clotting and chromogenic procedures in the clinical laboratory. The instrument utilizes photo-optical principles for both clotting and chromogenic assays. The ThromboScreen® 400C light source is provided by a halogen lamp. The incubator block is temperature regulated to 36.5 - 37.5°C and contains four measuring positions, five reagent and 24 cuvette prewarming positions. A detailed description of the device, including an explanation of how it functions, is described in the ThromboScreen® 400C Operator's Manual, section 1, Introduction.

Intended Use of the ThromboScreen® 400C

The Pacific Hemostasis ThromboScreen® 400C is a photo-optical instrument used for the performance of in-vitro diagnostic coagulation testing of citrated plasma samples 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. Chromogenic tests include assays such as Antithrombin III, Protein C and Heparin Xa.

Summary of Substantial Equivalence Comparisons

The ThromboScreen® 400C (TS400C) 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 utilize photo-optical measurement principles for both clot and chromogenic based assays.

The TS400C 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, and 405 nm for chromogenic assays. A halogen lamp is also utilized by the TS400C, however a 405 nm filter is used for both clotting and chromogenic assays. Although the TS400C utilizes a different wavelength for clotting assays compared to the MLA, it has been optimized for this specific light source/filter combination. The performance data generated support this statement (Tables 1-3).

Within-run and between-run precision studies were performed using Pacific Hemostasis (PH) brand reagents. Tables 1 and 2 summarize the data obtained from these studies. Comparison testing performed is shown in Table 3. 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. [Note: For derived Fibrinogen comparison testing, extrapolated data was included in the analysis. This was done so that a wide range of Fibrinogen results could be compared between the two instruments. In a normal clinical testing situation, patient values above the highest standard curve point are not reported. Rather, the user is advised to report the result as greater than the highest standard curve value, and use the Clauss methodology for Fibrinogen testing (page 48 of the Operator’s Manual).]

Table 1. Summary of Within-run Precision Studies, %CV

Test	TS400C			MLA		
	Low	Normal	High	Low	Normal	High
PT						
	Site 1	1.9	2.5	1.1	3.8	
Site 2		4.3	5.2	1.5	2.0	
APTT						
	Site 1	5.4	3.1	0.8	0.9	
Site 2		2.4	4.1	3.3	2.2	
Clauss Fib.*	7.2	6.7	6.4	2.8	1.2	3.8
Derived Fib.*	7.5	2.6	2.3	4.4	3.4	2.1
Factor V*	4.0	4.5		1.2	2.0	
Factor VIII*	9.9	9.7		5.3	4.7	
Chromogenic ATIII*	6.9	4.9		10.1	3.2	

*Testing at Site 1 only. (Shaded areas, no testing performed. Only clinically significant ranges tested.)
Note: MLA-1000C used at Site 1, MLA-900C used at Site 2.

Table 2. Summary of Between-run Precision Testing*

Test	TS400C			MLA-1000C		
	Low	Normal	High	Low	Normal	High
PT		3.4	6.0		1.4	4.5
APTT		2.5	1.8		1.4	1.2
Clauss Fib.	4.1	4.0	2.9	5.5	4.5	4.9
ATIII	9.4	4.5		9.9	5.1	

*Testing performed at Site 1 only.

Table 3. Summary of Method Comparison Studies Between the TS400C & the MLA-900C/1000C

Test (Reagent, Unit)	Site & Sample #	Correlation Coefficient, r	Regression Equation
Prothrombin Time (PT) (Thromboplastin DS, seconds)	Site #1 - 94	0.99	$y = 1.045x - 0.3358$
	Site #2 - 139	0.99	$y = 1.141x - 1.5248$
Prothrombin Time (Thromboplastin DS, INR)	Site #1 - 94	0.98	$y = 0.9395x + 0.1153$
	Site #2 - 139	0.99	$y = 0.9955x + 0.0617$
Derived Fibrinogen (Thromboplastin DS, mg/dL)	Site #1 - 47	0.98	$y = 1.0093x + 0.1442$
Activated Partial Thromboplastin Time (APTT-LS reagent, seconds)	Site #1 - 93	0.98	$y = 1.1449x + 1.3424$
	Site #2 - 117	0.96	$y = 0.9955x + 0.0617$
Clauss Fibrinogen (Thrombin reagent, mg/dL)	Site #1 - 50	0.98	$y = 0.9366x + 27.28$
	Site #2 - 20	0.98	$y = 0.9843x + 3.2104$
Factor VIII (APTT-LS, % activity)	Site #1 - 49	0.97	$y = 1.04x - 0.8112$
Factor V, (Thromboplastin DS, % activity)	Site #1 - 50	0.97	$y = 1.0511 - 5.6923$
Chromogenic ATIII (ATIII Chromogenic Kit, %)	Site #1 - 58	0.88	$y = 0.9417x + 7.6005$

Note: Site 1 used the MLA-1000C, Site 2 the MLA-900C.

In conclusion, the similar intended use, technological characteristics and the combined performance data support the claim that the ThromboScreen® 400C is substantially equivalent to the MLA-900C and the MLA-1000C.

11.0 ATTACHMENTS

1. ThromboScreen® 400C Operator's Manual.
2. The Introduction section of the MLA-1000C Operator's Manual. (With the exception of the Automatic Primary Tube Sampler, the MLA-900C is the same system as the MLA-1000C. Therefore the MLA-900C Operator's Manual was not included. Refer to page 1-1 of the MLA-1000C Operator's Manual.)
3. TS400C Power Supply approval certificates.
4. Manufacturer's Certificate of Software Traceability.
5. Manufacturer's Certificate of Y2K Compatibility.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 3 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K992130
Trade Name: Pacific Hemostasis ThromboScreen® 400C (TS400C)
Regulatory Class: II
Product Code: KQG
Dated: June 22, 1999
Received: June 23, 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.

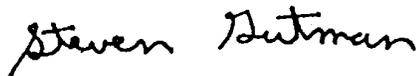
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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): K992130

Device Name: _____

Indications For Use:

STATEMENT OF INDICATIONS FOR USE

The Pacific Hemostasis ThromboScreen® 400C is a photo-optical instrument used for the performance of in-vitro diagnostic coagulation testing of citrated plasma samples in the clinical laboratory. The ThromboScreen® 400C has both clot and chromogenic testing capabilities. Assays performed on the instrument include routine clotting tests such as Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Clauss and Derived methods), and PT and APTT-based factor assays. Chromogenic tests include assays such as Antithrombin III, Protein C and Heparin Xa.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992130

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)