11.0 PREMARKET NOTIFICATION 510(K) SUMMARY

DEC 0 9 2002

K023362

Applicant:

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Date: 10/4/02

Trade Name: Fisher Diagnostics ThromboScreen® 1000 Pacific Hemostasis® Fibrinogen Reagent *plus* Kaolin

Common Name: Automatic Coagulation Instrument
Fibrinogen Reagent

Classification Name: Coagulation Instrument
21 CFR 864.5400
Fibrinogen Test
21 CFR 864.7340

Equivalent Devices: MLA 900C (K884863)
MLA 1600C (K931206)
Fibrinogen Reagent (K781880)

Description of the Devices

The ThromboScreen® 1000 (TS1000) 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 subject plasma specimens to clot. The TS1000 light source is provided by a 660 nm LED. The incubator block is temperature regulated to 36.5 - 37.5°C and contains six measuring positions and six reagent positions. A detailed description of the device, including an explanation of how it functions, is described in the TS 1000 Operator's Manual, Section 1, Introduction.

The Pacific Hemostasis® Fibrinogen Reagent *plus* Kaolin is identical to the Pacific Hemostasis® Thrombin for Fibrinogen Kit, except that the thrombin is reconstituted with water containing kaolin rather than water. Kaolin is added to increase the visibility of the clot in the stirred reaction cell.

Intended Use of the Devices

The Fisher Diagnostics ThromboScreen® 1000 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), and Fibrinogen.

The Pacific Hemostasis® Fibrinogen Reagent *plus* Kaolin is intended to be used on the Fisher Diagnostics ThromboScreen® 1000 Coagulation Instrument for the quantitative determination of fibrinogen in plasma.

Summary of Substantial Equivalence Comparisons

The ThromboScreen® 1000 (TS1000) was compared to the MLA 900C and the MLA 1600C (K884863 & K931206, 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 TS1000 is an automated coagulation instrument. In contrast, the MLA 900C is semi-automated and the MLA 1600C is a fully-automated instrument. The MLA 900C requires manual save 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 TS1000 utilizes an LED optic at 660 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. As part of this submission, kaolin was added to the fibrinogen reagent used on the TS1000 to optimize detection. Specimens were evaluated from apparently healthy individuals and from subjects 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 ThromboScreen® 1000 and the MLA 900C/1600C

Test (Reagent, Unit)		Site & Sample #	Correlation Coefficient, r	Regression Equation
Prothrombin Time (PT) (Thromboplastin DS, seconds)	General Clinical Samples	Site 1 - 60 Site 2 – 60 Site 3 - 60	0.98 0.99 0.97	y = 1.475x – 6.66 y = 1.045x – 1.26 y = 1.126x – 2.51
Prothrombin Time (Thromboplastin DS, INR)		Site 1 Site 2 Site 3	0.99 0.98 0.98	y = 1.437x - 0.41 y = 1.037x - 0.11 y = 1.031x – 0.02
Prothrombin Time (PT) (Thromboplastin DS, seconds)	Coumadin Samples	Site 1 - 100 Site 2 – 100 Site 3 - 92	0.96 0.97 0.96	y = 1.142x – 1.16 y = 1.142x – 1.27 y = 0.924x + 6.04
Prothrombin Time (Thromboplastin DS, INR)		Site 1 Site 2 Site 3	0.96 0.97 0.96	y = 1.066x + 0.14 y = 0.984x + 0.13 y = 0.786x + 0.68
Activated Partial Thromboplastin Time* (APTT-LS reagent, seconds)	General Clinical Samples	Site 1 - 58 Site 2 – 60 Site 3 - 60	0.99 0.98 0.98	y = 1.189x – 2.99 y = 1.205x - 4.24 y = 1.161x – 2.93
	Heparin Samples	Site 1 - 60 Site 2 – 60 Site 3 - 60	0.94 0.97 0.94	y = 1.219x – 6.16 y = 0.896x + 6.87 y = 1.108x – 3.23
Fibrinogen Concentration (mg/dL)	General Clinical Samples	Site 1 - 28 Site 2 – 30 Site 3 - 30	0.97 0.95 0.96	y = 0.735x + 43.3 y = 0.696x + 56.09 y = 0.818x – 22.07

Precision studies were also performed to assess the performance of the TS1000. 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	TS1000			MLA 900C/1600C		
	Coag 1	Coag 2	Coag 3	Coag 1	Coag 2	Coag 3
PT						
Site 1	2.2%	3.2%	5.8%	2.9%	5.1%	3.1%
Site 2	1.9%	2.3%	4.8%			
Site 3	1.4%	2.2%	2.8%			
APTT						
Site 1	1.2%	2.0%	3.0%	0.9%	2.0%	0.7%
Site 2	1.6%	3.4%	3.1%			
Site 3	1.5%	1.8%	2.0%			
Fibrinogen Concentration						
Site 1	1.2%	2.0%	3.0%	0.9%	2.0%	0.7%
Site 2	1.6%	3.4%	3.1%			
Site 3	1.5%	1.8%	2.0%			

Table 3a
Summary of Between-Run Precision Testing - PT

		Coag 1	Coag 2	Coag 3
TS1000				
	Site 1			
	Within-run	2.3%	3.0%	4.9%
	Run-to-run	2.8%	4.3%	8.0%
	Day-to-day	3.6%	4.5%	9.4%
	Total	**2.5%**	**3.7%**	**6.6%**
	Site 2			
	Within-run	1.1%	1.7%	2.3%
	Run-to-run	2.1%	2.6%	6.9%
	Day-to-day	1.8%	2.6%	7.4%
	Total	**1.8%**	**2.2%**	**5.1%**
	Site 3			
	Within-run	1.8%	1.8%	2.9%
	Run-to-run	2.7%	3.2%	4.4%
	Day-to-day	3.4%	3.5%	4.2%
	Total	**2.3%**	**2.6%**	**3.7%**
MLA				
	Site 1			
	Within-run	1.8%	2.0%	2.4%
	Run-to-run	2.5%	8.8%	8.8%
	Day-to-day	3.0%	6.4%	8.5%
	Total	**2.2%**	**6.4%**	**6.4%**
	Site 2			
	Within-run	2.1%	2.7%	2.6%
	Run-to-run	2.9%	9.3%	9.4%
	Day-to-day	3.2%	10.3%	11.1%
	Total	**2.5%**	**6.8%**	**6.8%**
	Site 3			
	Within-run	1.5%	2.2%	2.3%
	Run-to-run	3.9%	6.9%	8.2%
	Day-to-day	4.3%	6.9%	9.6%
	Total	**3.0%**	**5.1%**	**6.0%**

Table 3b
Summary of Between-Run Precision Testing - APTT

		Coag 1	Coag 2	Coag 3
TS1000				
	Site 1			
	Within-run	1.7%	2.1%	2.7%
	Run-to-run	2.9%	5.3%	2.9%
	Day-to-day	2.2%	7.2%	3.3%
	Total	**2.4%**	**4.0%**	**2.9%**
	Site 2			
	Within-run	1.4%	1.7%	1.9%
	Run-to-run	4.9%	4.9%	4.8%
	Day-to-day	4.5%	4.5%	5.9%
	Total	**3.8%**	**3.8%**	**4.4%**
	Site 3s			
	Within-run	2.2%	1.7%	2.3%
	Run-to-run	6.0%	7.1%	10.4%
	Day-to-day	7.3%	7.2%	13.2%
	Total	**4.5%**	**5.1%**	**7.5%**
MLA				
	Site 1			
	Within-run	1.5%	0.4%	0.7%
	Run-to-run	2.6%	3.6%	3.8%
	Day-to-day	2.9%	4.4%	3.6%
	Total	**2.2%**	**2.5%**	**2.7%**
	Site 2			
	Within-run	1.1%	0.8%	0.9%
	Run-to-run	3.1%	3.3%	3.4%
	Day-to-day	3.2%	3.3%	3.8%
	Total	**2.3%**	**3.7%**	**2.5%**
	Site 3			
	Within-run	0.9%	0.9%	0.8%
	Run-to-run	6.1%	8.0%	7.6%
	Day-to-day	5.8%	10.7%	8.9%
	Total	**4.2%**	**5.6%**	**5.3%**

Table 3b
Summary of Between-Run Precision Testing - Fibrinogen

		Low Fib		Coag 1		High Fib	
TS1000		time	conc	time	conc	time	conc
	Site 1						
	Within-run	3.2%		4.1%		5.2%	
	Within-day		5.4%		5.3%		6.4%
	Run-to-run	6.7%		5.3%		8.2%	
	Day-to-day	8.0%	8.2%	4.2%	3.5%	9.1%	7.7%
	Total	**5.1%**	**6.8%**	**4.7%**	**4.5%**	**6.8%**	**7.1%**
	Site 2						
	Within-run	3.5%		2.4%		4.1%	
	Within-day		3.6%		3.8%		6.5%
	Run-to-run	4.4%		4.1%		8.7%	
	Day-to-day	5.2%	5.4%	3.7%	3.4%	8.9%	7.6%
	Total	**4.1%**	**4.6%**	**3.3%**	**3.5%**	**6.1%**	**7.1%**
	Site 3						
	Within-run	4.9%		2.3%		3.6%	
	Within-day		8.7%		5.5%		7.5%
	Run-to-run	7.8%		6.9%		9.4%	
	Day-to-day	7.3%	8.1%	7.6%	6.5%	10.6%	9.0%
	Total	**6.5%**	**8.5%**	**5.1%**	**6.0%**	**7.4%**	**8.2%**

In conclusion, the similar intended use, technological characteristics and performance data support the claim that the ThromboScreen® 1000 is substantially equivalent to the MLA 900C and the MLA 1600C.

Furthermore, the TS1000 specific fibrinogen assay reagent, Fibrinogen Reagent *plus* Kaolin, is substantially equivalent the Pacific Hemostasis® Fibrinogen Reagent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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DEC 0 9 2002

Food and Drug Administration
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Re: k023362
Trade/Device Name: Fisher Diagnostics ThromboScreen 1000; Pacific Hemostasis Fibrinogen Reagent plus Kaolin
Regulation Number: 21 CFR § 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: II
Product Code: GKP, GIS
Dated: October 4, 2002
Received: October 7, 2002

Dear Dr. Steiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023362

Device Name: Pacific Hemostasis® Fibrinogen Reagent *plus* Kaolin

Sponsor Name: Fisher Diagnostics

Indications for Use:

The Pacific Hemostasis® Fibrinogen Reagent *plus* Kaolin is intended to be used on the Fisher Diagnostics ThromboScreen® 1000 Coagulation Instrument for the quantitative determination of fibrinogen in plasma.

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023362

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The Fisher Diagnostics ThromboScreen® 1000 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), and Fibrinogen.

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