FEB - 9 2005

K043459

Section 3
HemosIL Factor XII Deficient Plasma - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

December 14, 2004

Name of the Device:

HemosIL Factor XII Deficient Plasma

Regulatory Information:

Regulation Section:	Factor Deficiency Test (864.7290)
Classification:	Class II
Product Code:	GJT
Panel:	Hematology

Identification of Predicate Device(s):

K893534	Hemoliance Factor XII Deficient Plasma on ELECTRA Series Analyzers
K002400	HemosIL Factor XII Deficient Plasma* on ACL Family of Analyzers
	*NOTE: FDA cleared as part of the each ACL instrument 510(k): for example, the ACL Advance (K002400)

Description of the Device/Intended Use(s):

HemosIL Factor XII Deficient Plasma is human plasma immunodepleted of factor XII and intended for the *in vitro* diagnostic quantitative determination of factor XII activity in citrated plasma, based on the activated partial thromboplastin time (APTT) assay, on IL Coagulation and ELECTRA Systems.

Abnormalities of the intrinsic pathway factors are determined by performing a modified activated partial thromboplastin time (APTT) test. Patient plasma is diluted and added to a plasma deficient in factor XII. Correction of the clotting time of the deficient plasma is proportional to the concentration (% activity) of the factor XII in the patient plasma, interpolated from a calibration curve.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The new HemosIL Factor XII Deficient Plasma is substantially equivalent to Hemoliance Factor XII Deficient Plasma (on ELECTRA Series Analyzers) and HemosIL Factor XII Deficient Plasma (on ACL Family of Analyzers) in performance, intended use and safety and effectiveness.

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Summary of Performance Data:

Method Comparison

In an in-house method comparison study evaluating approximately 70 citrated plasma samples, the slopes and correlation coefficients (r) for HemosIL Factor XII Deficient Plasma versus the predicate devices are shown below:

NOTE: HemosIL APTT-SP and SynthASil were used as the APTT reagents in testing.

New HemosIL Factor XII Deficient Plasma vs.
Predicate HemosIL Factor XII Deficient Plasma on ACL Family

IL System	n	Slope	r
ACL 3000	71	0.9284	0.9882
ACL 10000	71	0.9116	0.9704
ACL Advance	70	1.0065	0.9687
ACL TOP	72	1.0739	0.9551

New HemosIL Factor XII Deficient Plasma vs.
Predicate Hemoliance Factor XII Deficient Plasma on ELECTRA

IL System	n	Slope	r
E1600C	73	0.9918	0.9863

Within Run Precision

Within run and between run precision was assessed over multiple runs (n=80) on different instruments using a specific lot of APTT reagent (APTT-SP and SynthASil) and both normal and abnormal controls.

Instrument	Control	Mean % Factor XII	Within run %CV	Between Run %CV
ACL 9000	Normal Control	100.0	1.9	3.4
	Special Test Control Level 2	30.4	2.6	3.3
ACL Futura	Normal Control	95.1	3.0	2.9
	Special Test Control Level 2	31.4	2.3	3.8
ACL TOP	Normal Control	103.0	4.7	3.1
	Special Test Control Level 2	33.9	6.1	3.2
ELECTRA 1600C	Normal Control	102.4	3.4	7.8
	Special Test Control Level 2	36.0	3.5	4.3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 9 2005

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, Massachusetts 02421

Re: k043459
Trade/Device Name: HemosIL Factor XII Deficient Plasma
Regulation Number: 21 CFR § 864.7290
Regulation Name: Plasma, coagulation deficient
Regulatory Class: II
Product Code: GJT
Dated: December 14, 2004
Received: December 15, 2004

Dear Ms. Marble:

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 (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
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): K043459

Device Name: HemosIL Factor XII Deficient Plasma

Indications for Use:

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Prescription Use ✓
(Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K043459