JUL 3 1 2003

K031829

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

Submitted by:

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Summary Prepared:

June 12, 2003

Name of the Device:

HemosIL Factor IX Deficient Plasma

Classification Name(s):

864.7290	Factor Deficiency Tests	Class II
81GJT	Plasma, Coagulation Factor Deficient	

Identification of Predicate Device(s):

K893524 Hemoliance Factor IX Deficient Plasma on ELECTRA Series Analyzers
K002400 IL Test Factor IX Deficient Plasma* on ACL Family of Analyzers
*NOTE: Reagent was 510(k) cleared as part of multiple analyzer systems, most recently the ACL Advance.

Description of the Device/Intended use(s):

HemosIL Factor IX Deficient Plasma is human plasma immunodepleted of Factor IX and intended for the *in vitro* diagnostic quantitative determination of Factor IX 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 IX. Correction of the clotting time of the deficient plasma is proportional to the concentration (% activity) of the factor IX in the patient plasma, interpolated from a calibration curve.

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

HemosIL Factor IX Deficient Plasma is substantially equivalent to Hemoliance Factor IX Deficient Plasma (on ELECTRA Series Analyzers) and IL Test Factor IX 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 field site studies evaluating citrated plasma samples, the slopes and correlation coefficients (r) for HemosIL Factor IX Deficient Plasma versus the predicate devices are shown below:

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

HemosIL Factor IX Deficient Plasma vs.
Predicate Hemoliance Factor IX Deficient Plasma on ELECTRA

IL System	n	Slope	r
E1600C	65	1.0049	0.9584

HemosIL Factor IX Deficient Plasma vs.
Predicate IL Test Factor IX Deficient Plasma on ACL Family

IL System	n	Slope	r
ACL 3000	76	1.1076	0.9793

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 or SynthASil) and both normal and abnormal samples.

Instrument	Control	Mean % Factor IX	Within run CV%	Between Run CV%
ACL 6000	Normal Control	102.3	5.8	2.6
	Low Abnormal Control	24.2	8.5	4.1
ACL 9000	Normal Control	121.2	3.0	3.8
	Low Abnormal Control	32.8	2.3	5.9
ACL Futura	Normal Control	118.2	4.4	2.9
	Low Abnormal Control	38.2	6.0	2.7
ELECTRA 1400C	Normal Control	111.5	8.4	8.3
	Low Abnormal Control	28.9	8.0	7.6
ELECTRA 1800C	Normal Control	119.2	8.8	5.7
	Low Abnormal Control	30.2	8.8	6.4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
Regulatory Affairs Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, Massachusetts 02421-3125

JUL 31 2003

Re: k031829
Trade/Device Name: HemosIL Factor IX Deficient Plasma
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GJT, GGP
Dated: June 12, 2003
Received: June 13, 2003

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 (301) 594-3084. 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/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): K 031829

Device Name: HemosIL Factor IX Deficient Plasma

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k)

(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 _____