MAY 1 9 2003

K031122

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

**Submitted by:**

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

**Contact Person:**

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

**Summary Prepared:**

April 7, 2003

**Name of the Device:**

HemosIL Factor X Deficient Plasma

**Classification Name(s):**

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

**Identification of Predicate Device(s):**

K893523 Hemoliance Factor X Deficient Plasma on ELECTRA Series Analyzers
K002400 IL Test Factor X 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 X Deficient Plasma is human plasma immunodepleted of Factor X and intended for the *in vitro* diagnostic quantitative determination of Factor X activity in citrated plasma, based on the prothrombin time (PT) assay, on IL Coagulation and ELECTRA Systems.

Abnormalities of the extrinsic pathway factors are determined by performing a modified prothrombin time (PT) test. Patient plasma is diluted and added to a plasma deficient in Factor X. Correction of the clotting time of the deficient plasma is proportional to the concentration (% activity) of the Factor X in the patient plasma, interpolated from a calibration curve.

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

HemosIL Factor X Deficient Plasma is substantially equivalent to Hemoliance Factor X Deficient Plasma (on ELECTRA Series Analyzers) and IL Test Factor X 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 (normal and abnormal), the slopes and correlation coefficients (r) for HemosIL Factor X Deficient Plasma versus the predicate devices are shown below:

**HemosIL Factor X Deficient Plasma vs.**
**Predicate Hemoliance Factor X Deficient Plasma on ELECTRA**

| IL System | n | Slope | r | PT Reagent Used |
|---|---|---|---|---|
| ELECTRA 1600C | 63 | 0.9461 | 0.9948 | RecombiPlasTin (K012768) |

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

| IL System | n | Slope | r | PT Reagent Used |
|---|---|---|---|---|
| ACL 3000 | 62 | 1.0328 | 0.9849 | PT-Fibrinogen Recombinant (K981479) |
| ACL Futura | 62 | 1.0680 | 0.9840 | PT-Fibrinogen Recombinant (K981479) |

## Within Run Precision

Within run and total precision assessed over multiple runs (n=80) using two levels of control gave the following results:

| Instrument | Control | Mean % Factor X | Within Run CV% | Between Run CV% |
|---|---|---|---|---|
| **ACL 300** | Normal Control | 113.2 | 3.5 | 4.6 |
| | Low Abnormal Control | 38.9 | 4.1 | 6.0 |
| **ACL 6000** | Normal Control | 114.0 | 3.3 | 4.3 |
| | Low Abnormal Control | 29.9 | 3.0 | 4.8 |
| **ACL 9000** | Normal Control | 117.7 | 1.4 | 2.1 |
| | Low Abnormal Control | 27.1 | 1.9 | 4.4 |
| **ACL Futura** | Normal Control | 96.3 | 4.2 | 4.5 |
| | Low Abnormal Control | 38.9 | 5.0 | 6.1 |
| **ELECTRA 1400C** | Normal Control | 96.6 | 0.9 | 2.9 |
| | Low Abnormal Control | 27.5 | 1.7 | 2.4 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 9 2003

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

Re: k031122
Trade/Device Name: HemosIL Factor X Deficient Plasma
Regulation Number: 21 CFR § 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: II
Product Code: GJT
Dated: April 7, 2003
Received: April 8, 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):** K031122

**Device Name:** HemosIL Factor X Deficient Plasma

## Indications for Use:

HemosIL Factor X Deficient Plasma is human plasma immunodepleted of Factor X and intended for the *in vitro* diagnostic quantitative determination of Factor X activity in citrated plasma, based on the prothrombin time (PT) assay, on IL Coagulation and ELECTRA Systems.

(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 K 031122
510(k) Number

Prescription Use ✓ **OR** Over-The-Counter Use _____