K043184

DEC 22 2004

Section 3
HemosIL RecombiPlasTin
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

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

Summary Prepared:

November 16, 2004

Device Name:

HemosIL RecombiPlasTin

Classification Name:

864.7750 81GJS	Prothrombin Time Test Test, Time, Prothrombin	Class II
864.7340 81GIS	Fibrinogen Determination System Test, Fibrinogen	Class II

Legally Marketed Device:

K012768 HemosIL RecombiPlasTin

Device Description:

HemosIL RecombiPlasTin is a high sensitivity thromboplastin reagent based on recombinant human tissue factor (RTF) for the quantitative *in vitro* diagnostic determination in human citrated plasma of:

- Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems
- Fibrinogen on IL Coagulation Systems only

The product is used for the evaluation of the extrinsic coagulation pathway and the monitoring of Oral Anticoagulant Therapy (OAT).

The PT and fibrinogen parameter settings for HemosIL RecombiPlasTin on the ACL Futura and ACL Advance are being optimized for improved correlation with the ACL TOP, impacting the instrument-specific performance claims in the product insert.

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

The performance of HemosIL RecombiPlasTin with optimized PT and fibrinogen parameter settings on the ACL Futura (K951891) and ACL Advance (K002400) is substantially equivalent to the performance of the current legally marketed device on the ACL TOP (K033414).

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Summary of Performance Data:

Within Run Precision

Within run and total precision assessed over multiple runs using three levels of control plasma for PT and two levels of control plasma for fibrinogen gave the following results:

Prothrombin Time (PT)	Mean (Seconds)	CV% (Within run)	CV% (Total)
Normal Control	11.6	0.9	1.3
Low Abnormal Control	30.3	1.4	2.3
High Abnormal Control	51.1	1.4	3.9

Fibrinogen	Mean (mg/dL)	CV% (Within run)	CV% (Total)
Normal Control	229.8	3.1	3.3
Low Fibrinogen Control	169.7	3.3	3.4

Method Comparison

In a method comparison study evaluating 98 citrated plasma samples, the slopes and correlation coefficients (r) are shown below for the legally marketed HemosIL RecombiPlasTin on an ACL Advance with optimized PT and fibrinogen parameters versus HemosIL RecombiPlasTin for PT and HemosIL Fibrinogen-C (K931721) for fibrinogen on the ACL TOP:

	Slope	r
PT (seconds)	1.039	0.9985
Fibrinogen (mg/dL)	0.938	0.9811

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 2004

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.
113 Hartwell Avenue
Lexington, MA 02421

Re: k043184
Trade/Device Name: HemosIL RecombiPlasTin- Optimized Parameter Settings on the ACL Futura/ ACL Advance
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin time set
Regulatory Class: Class II
Product Code: GJS
Dated: December 6, 2004
Received: December 8, 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 (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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
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): K043184

Device Name: HemosIL RecombiPlasTin – Optimized Parameter Settings on the ACL Futura/ACL Advance

Indications for Use:

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- Prothrombin Time (PT) on IL Coagulation and ELECTRA Systems
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Prescription Use ✓ **AND/OR** Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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