K060931

Section 3
HemosIL PT-Fibrinogen HS PLUS
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

MAY 2 2006

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone No.: 781-861-4467
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Summary Prepared:

April 4, 2006

Name of the Device:

HemosIL PT-Fibrinogen HS PLUS

Regulatory Information:

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

Identification of Predicate Device(s):

K933252 HemosIL PT-Fibrinogen HS PLUS

Device Description:

HemosIL PT-Fibrinogen HS PLUS is a very high sensitivity calcium thromboplastin for simultaneous determinations of Prothrombin Time (PT) and Fibrinogen (Fib), for evaluation of the extrinsic coagulation pathway and monitoring Oral Anticoagulant Therapy in human citrated plasma on the IL Coagulation Systems.

Reason for Submission:

The expected value ranges for PT and Fibrinogen on the ACL Futura/ACL Advance provided in the product insert for HemosIL PT-Fibrinogen HS PLUS are being updated based on data from a new normal range study.

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

The performance of HemosIL PT-Fibrinogen HS PLUS with the new expected value ranges for the ACL Futura and ACL Advance is not materially different from the FDA cleared device.

Summary of New Expected Values Data:

Assay	System	N	Range (units)
PT	ACL Futura/ACL Advance	119	11.1 – 14.5 (seconds)
Fibrinogen	ACL Futura/ACL Advance	119	262 - 433 (mg/dL)

These results were obtained using a specific lot of reagent. Due to the many variables which may affect clotting times, each laboratory should establish its own reference range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAY 2 2006

Re: k060931
Trade/Device Name: HemosIL PT-Fibrinogen HS PLUS
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin time test
Regulatory Class: II
Product Code: GJS, GIS
Dated: April 4, 2006
Received: April 5, 2006

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): K060931

Device Name: HemosIL PT-Fibrinogen HS PLUS

Indications for Use:

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For *in vitro* diagnostic use.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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)

Josephine Dantuta
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

(Optional Format 1-2-96) K060931