APR 13 2006

K060688

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 No.: 781-861-4467
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Prepared:

March 14, 2006

Device Name:

HemosIL SynthASil

Regulatory Information:

Regulation No.:	864.7925
Classification Name:	Partial Thromboplastin Time Tests
Product Code:	GFO
Panel:	Hematology

Predicate Device:

K953981	HemosIL SynthASil

Device Description:

HemosIL SynthASil is a high quality synthetic phospholipid reagent for the *in vitro* determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma on IL Coagulation and ELECTRA Systems.

The product is used for the evaluation of the intrinsic coagulation pathway, APTT substitution test and the monitoring of heparin therapy.

Reason for Submission:

The APTT parameter settings for HemosIL SynthASil 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 SynthASil with optimized APTT 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).

510(k) Summary (Cont.)
(Summary of Safety and Effectiveness)

Summary of Performance Data:

Within Run Precision

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

	Mean (Seconds)	CV% (Within run)	CV% (Total)
Normal	28.5	0.6	0.6
Low Abnormal	49.0	0.8	0.9
High Abnormal	62.5	0.7	0.8

Method Comparison

In a method comparison study evaluating citrated plasma samples, the slopes and correlations coefficient (r) are shown below for four different lots of the legally marketed HemosIL SynthASil tested on an ACL Advance with optimized APTT parameters versus on the ACL TOP:

SynthASil Lot	n	Slope	Intercept	r	Sample Range (Sec.)
Lot No. A	93	1.011	-0.664	0.9979	25.6 - 188.6
Lot No. B	93	0.984	0.293	0.9987	27.0 - 220.1
Lot No. C	93	0.994	0.159	0.9976	25.7 - 228.1
Lot No. D	92	0.973	1.260	0.9973	27.4 - 204.8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

APR 13 2006

Re: k060688
Trade/Device Name: HemosIL SynthASil
Regulation Number: 21 CFR § 864.7925
Regulation Name: Partial Thromboplastin Time Tests
Regulatory Class: II
Product Code: GFO
Dated: March 14, 2006
Received: March 15, 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): K060688

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

Indications for Use:

HemosIL SynthASil is a high quality synthetic phospholipid reagent for the *in vitro* determination of Activated Partial Thromboplastin Time (APTT) in human citrated plasma on IL Coagulation and ELECTRA Systems.

The product is used for the evaluation of the intrinsic coagulation pathway, APTT substitution test and the monitoring of heparin therapy.

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

K060688