K082859

510(k) Summary

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
Alternate Contact:	Gabriella Erdosy, Regulatory Affairs Associate
Phone Number:	781-861-4467
Fax Number:	781-861-4207
Preparation Date:	November 7, 2008

DEC 19 2008

Device Trade Names (Products Sold Separately):

HemosIL Routine Control Level 1

HemosIL Routine Control Level 2

HemosIL Routine Control Level 3

Device Regulatory Information:

Common Name:	Plasma, Coagulation Control
Classification:	Class II
Product Code:	GGN
Regulation Number:	21 CFR 864.5425

Identification of Predicate Devices:

K021023	HemosIL Normal Control
K021022	HemosIL Low Abnormal Control
K021024	HemosIL High Abnormal Control

Device Descriptions:

- The HemosIL Routine Control Level 1 is a lyophilized product prepared using human citrated plasma from healthy donors. It contains buffer, stabilizers and preservatives.
- The HemosIL Routine Control Level 2 is a lyophilized product prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified, by means of a dedicated process, to stimulate an abnormal coagulation sample. It contains buffer and stabilizers. No preservatives are included.
- The HemosIL Routine Control Level 3 is a lyophilized product prepared using human citrated plasma from healthy donors (not heparinized plasma or plasma samples under oral anticoagulant therapy) and modified, by means of a dedicated process, to stimulate an abnormal coagulation sample. It contains buffer and stabilizers. No preservatives are included.

Device Indications for Uses:

- HemosIL Routine Control Level 1 is for the quality control of coagulation assays in the normal range. The product is intended in the assessment of precision and accuracy for PT, APTT and Fibrinogen tests performed on coagulation systems.
- HemosIL Routine Control Level 2 is for the quality control of coagulation assays in the low abnormal range. The product is intended in the assessment of precision and accuracy for PT and APTT tests performed on coagulation systems.
- HemosIL Routine Control Level 3 is for the quality control of coagulation assays in the high abnormal range. The product is intended in the assessment of precision and accuracy for PT and APTT tests performed on coagulation systems.

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

HemosIL Routine Control Levels 1, 2 and 3 are substantially equivalent to the predicate devices in performance, intended use and safety and effectiveness for the claimed analytes.

Substantial Equivalence Comparison Table:

Characteristic	**New Device: HemosIL Routine Control Level 1**	**Predicate Device: HemosIL Normal Control (K021023)**
Intended Use	For the quality control of coagulation assays in the normal range.	Same, except additional analytes are claimed for the indications for use.
Matrix	Human Plasma	Same
Form	Lyophilized	Same
Characteristic	**New Device: HemosIL Routine Control Level 2**	**Predicate Device: HemosIL Low Abnormal Control (K021022)**
Intended Use	For the quality control of coagulation assays in the low abnormal range.	Same, except additional analytes are claimed for the indications for use.
Matrix	Human Plasma	Same
Form	Lyophilized	Same
Characteristic	**New Device: HemosIL Routine Control Level 3**	**Predicate Device: HemosIL High Abnormal Control (K021024)**
Intended Use	For the quality control of coagulation assays in the high abnormal range.	Same, except additional analytes are claimed for the indications for use.
Matrix	Human Plasma	Same
Form	Lyophilized	Same

Summary Performance Data:

Precision

Within run precision was assessed over multiple runs using the three levels of HemosIL Routine Control with specific lots of reagents on representative coagulation systems:

HemosIL Routine Control Level 1				
Analyte	**Reagent**	**Instrument**	**Mean (n=80)**	**Within-Run %CV**
Prothrombin Time (PT) (Seconds)	HemosIL PT-Fibrinogen Recombinant (K981479)	ACL 9000	9.9	2.27
	HemosIL PT-Fibrinogen (K862301)	ACL Advance	11.5	1.48
	HemosIL PT-Fibrinogen HS Plus (K060931)	ACL 300	13.4	1.46
Fibrinogen (mg/dL)	HemosIL PT-Fibrinogen Recombinant (K981479)	ACL 6000	270.9	3.91
	HemosIL PT-Fibrinogen (K862301)	ACL Advance	319.0	3.13
	HemosIL PT-Fibrinogen HS Plus (K060931)	ACL 300	283.4	4.41
Activated Partial Thromboplastin (APTT) (Seconds)	HemosIL APTT-SP (K973306)	ACL 9000	28.7	0.98
	HemosIL SynthAFax (K955638)	ACL 6000	20.5	0.91
	HemosIL SynthASil (K060688)	ACL Advance	30.1	1.15

510(k) Summary (Cont.)

Summary Performance Data (Cont.):

Precision

HemosIL Routine Control Level 2				
Analyte	**Reagent**	**Instrument**	**Mean (n=80)**	**Within-Run %CV**
Prothrombin Time (PT) (Seconds)	HemosIL PT-Fibrinogen Recombinant (K981479)	ACL 9000	27.2	2.49
	HemosIL PT-Fibrinogen (K862301)	ACL Advance	22.6	1.24
	HemosIL PT-Fibrinogen HS Plus (K060931)	ACL 300	41.3	1.56
Activated Partial Thromboplastin (APTT) (Seconds)	HemosIL APTT-SP (K973306)	ACL 9000	47.9	1.69
	HemosIL SynthAFax (K955638)	ACL 6000	40.9	1.26
	HemosIL SynthASil (K060688)	ACL Advance	47.2	1.26

510(k) Summary (Cont.)

Summary Performance Data (Cont.):

Precision

HemosIL Routine Control Level 3				
Analyte	**Reagent**	**Instrument**	**Mean (n=80)**	**Within-Run %CV**
Prothrombin Time (PT) (Seconds)	HemosIL PT-Fibrinogen Recombinant (K981479)	ACL 9000	37.0	2.65
	HemosIL PT-Fibrinogen (K862301)	ACL Advance	31.4	2.61
	HemosIL PT-Fibrinogen HS Plus (K060931)	ACL 300	63.5	1.40
Activated Partial Thromboplastin (APTT) (Seconds)	HemosIL APTT-SP (K973306)	ACL 9000	60.7	0.62
	HemosIL SynthAFax (K955638)	ACL 6000	55.4	1.98
	HemosIL SynthASil (K060688)	ACL Advance	56.3	1.14

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Instrumentation Laboratory Co.
C/o Carol Marble
113 Hartwell Avenue
Lexington, Massachusetts 02421

DEC 19 2008

Re: k082859
Trade/Device Name: HemosIL Routine Control Level 1, 2, and 3
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GGN
Dated: September 26, 2008
Received: September 29, 2008

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Marian Chan, PhD
Acting Division 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): K082859

Device Name: HemosIL Routine Control Levels 1, 2 and 3

Indications for Use:

- HemosIL Routine Control Level 1 is for the quality control of coagulation assays in the normal range. The product is intended in the assessment of precision and accuracy for PT, APTT and Fibrinogen tests performed on coagulation systems.
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For *in vitro* diagnostic use.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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