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K050221

Section 3
HemosIL Silica Clotting Time - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

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Summary Prepared:

January 28, 2005

Name of the Device:

HemosIL Silica Clotting Time

Regulatory Information:

Regulation Section:	Partial Thromboplastin Time Tests (864.7925)
Classification:	Class II
Product Code:	GFO
Panel:	Hematology

Identification of Predicate Device(s):

K990302	HemosIL LAC Screen and HemosIL LAC Confirm

Description of the Device/Intended Use(s):

HemosIL Silica Clotting Time is intended for the detection of Lupus Anticoagulants in human citrated plasma on the IL Coagulation Systems by the use of screening (SCT Screen) and confirmatory (SCT Confirm) reagents sensitized to phospholipid dependent antibodies.

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

The HemosIL Silica Clotting Time is substantially equivalent to the commercially available predicate devices (HemosIL LAC Screen and HemosIL LAC Confirm) in performance and intended use.

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Summary of Performance Data:

Method Comparison

In an in-house study of 210 citrated plasma samples (120 normals/90 abnormals) on an ACL Advance, comparing HemosIL Silica Clotting Time to the predicate devices, the following correlation data were obtained:

Unit	slope	intercept	r	Reference method
Normalized LAC ratio	1.099	-0.086	0.874	LAC Screen/Confirm

In a clinical study of 206 citrated plasma samples (121 normals/85 abnormals), comparing HemosIL Silica Clotting Time (cut-off > 1.24) to the predicate devices (cut-off ≥ 1.20) on an ACL Futura, a relative Sensitivity of 92.4% (95% C.I. = 82.1-97.0) and a relative Specificity of 100% (95% C.I. = 97.6-100.0) were determined. All known Lupus Anticoagulant samples (n=48) tested as part of this study gave SCT normalized ratios > 1.24.

Within Run Precision

Within run and between run precision was assessed over multiple runs (n=80) using three levels of controls.

Instrument	Control	Mean Normalized Ratio	Within run %CV	Total %CV
ACL Advance	Normal Control	1.05	2.47	2.95
	Low LA Control	1.90	4.05	6.00
	High LA Control	2.77	5.24	5.60

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 3 0 2005

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

Re: k050221
Trade/Device Name: HemosIL Silica Clotting Time
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial thromboplastin time tests
Regulatory Class: Class II
Product Code: GFO
Dated: January 28, 2005
Received: January 31, 2005

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).

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): K050221

Device Name: HemosIL Silica Clotting Time

Indications for Use:

HemosIL Silica Clotting Time is intended for the detection of Lupus Anticoagulants in human citrated plasma on the IL Coagulation Systems by the use of screening (SCT Screen) and confirmatory (SCT Confirm) reagents sensitized to phospholipid dependent antibodies.

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)

Joaquim Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050221