FEB 2 1 2006

K060162

Section 3
ACL Elite and ACL Elite Pro
510(k) Summary

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421

Contact Person:

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Summary Prepared:

January 20, 2006

Device Name:

ACL Elite and ACL Elite Pro

Classification Name:

Regulation Section:	Multipurpose system for *in vitro* coagulation studies (864.5425)
Classification:	Class II
Product Code:	JPA
Panel:	Hematology

Legally Marketed Device:

K000053	ACL 9000 (ACL 8000 and ACL 10000)

Device Description:

The ACL Elite and ACL Elite Pro are fully automated, high-productivity analyzers designed specifically for *in vitro* diagnostic clinical use in the hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The systems provide results for both direct hemostasis measurements and calculated parameters.

The analytical modifications to the ACL 8000/9000/10000 introduced with the new family members (ACL Elite and ACL Elite Pro) include the following:

- Modification to the test parameter (revised use of the Secondary Algorithm) for several PT and APTT assays.
- Addition of dedicated calibration for HemosIL Factor VIII and HemosIL Factor IX Deficient Plasmas, when used in conjunction with HemosIL APTT-SP.
- Introduction of automated factor parallelism, which is a manual function on the ACL 8000/9000/10000.

Section 3 (Cont.)
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Statement of Technological Characteristics of the Device Compared to Predicate Device:

The indications for use/intended use, operating principle and performance claims of the ACL Elite and ACL Elite Pro are substantially equivalent to the legally marketed device, the ACL 8000/9000/10000 (K000053).

Summary of Performance Data:

Precision

Within run and total precision assessed over multiple runs on the ACL Elite/ACL Elite Pro using three levels of control plasma for factors deficient plasmas, APTT and PT, and two levels of control plasmas for fibrinogen gave the following results:

Test	FVIII (% Activity)				
HemosIL Factor VIII (K034007) w/ APTT-SP	**Material**	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	85.3	4.1	4.5
	Special Test Control Level 1	50	72.4	2.9	3.6
	Special Test Control Level 2	50	36.3	4.6	5.4
FIX (% Activity)					
HemosIL Factor IX (K031829) w/ APTT-SP	**Material**	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	115.6	2.7	5.2
	Special Test Control Level 1	50	76.2	2.3	4.5
	Special Test Control Level 2	50	41.0	3.3	5.1
APTT (Seconds)					
HemosIL APTT-SP (K973306)	**Material**	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	29.3	1.1	2.0
	Low Abnormal Control	50	46.1	1.9	4.1
	High Abnormal Control	50	56.9	2.2	4.7
APTT (Seconds)					
HemosIL SynthASil (K953981)	**Material**	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	29.0	0.8	1.8
	Low Abnormal Control	50	51.9	1.0	1.5
	High Abnormal Control	50	60.5	1.2	1.2

Summary of Performance Data (Cont.):

Precision (Cont.)

Test	Material	n	Mean	Within Run % CV	Total %CV
HemosIL PT-Fibrinogen (K862301)	**Prothrombin Time (Seconds)**				
	Normal Control	50	12.3	0.6	1.1
	Low Abnormal Control	50	20.7	0.9	1.1
	High Abnormal Control	50	25.5	0.8	1.4
	Fibrinogen (mg/dL)				
	Material	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	277.9	4.4	4.6
	Low Fibrinogen Control	50	132.9	3.6	5.5
HemosIL PT-Fibrinogen Recombinant (K981479)	**Prothrombin Time (Seconds)**				
	Material	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	10.7	1.0	1.1
	Low Abnormal Control	50	35.0	1.1	2.0
	High Abnormal Control	50	51.6	1.4	3.4
	Fibrinogen (mg/dL)				
	Material	**n**	**Mean**	**Within Run % CV**	**Total %CV**
	Normal Control	50	297.6	3.8	6.7
	Low Fibrinogen Control	50	113.1	5.3	6.4

Method Comparison

In comparison studies evaluating citrated plasma samples, the ACL Elite/ACL Elite Pro versus the ACL 9000 (predicate device) was shown to be statistically similar for the tests listed below:

Test	Parameter	n	Slope	r
HemosIL Factor VIII	FVIII w/ APTT-SP (% Act.)	47	0.909	0.9938
HemosIL Factor IX	FIX with APTT-SP (% Act.)	49	0.948	0.9914
HemosIL APTT-SP	APTT (Seconds)	54	1.032	0.9990
HemosIL SynthASil	APTT (Seconds)	52	1.009	0.9981
HemosIL PT-Fibrinogen	PT (sec)	49	0.989	0.9985
	Fibrinogen (mg/dL)	47	0.996	0.9848
HemosIL PT-Fibrinogen Recombinant	PT (sec)	49	0.972	0.9993
	Fibrinogen (mg/dL)	47	0.974	0.9992

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Carol Marble
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FEB 2 1 2006

Re: k060162
Trade/Device Name: ACL Elite and ACL Elite Pro
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: JPA
Dated: January 20, 2006
Received: January 23, 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): K060162

Device Name: ACL Elite and ACL Elite Pro

Indications for Use:

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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)

Joaquina Bautista

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K060162