K033414

JAN 1 2 2004

Section 3
ACL TOP - 510(k) Summary
(Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

October 24, 2003

Name of the Device:

ACL TOP

Classification Name(s):

81GKP	Instrument, Coagulation, Automated	
864.5400	Coagulation Instrument	Class II
81JPA	System, Multipurpose for In Vitro Coagulation Studies	
864.5425	Multipurpose system for In Vitro Coagulation Studies	Class II

Identification of predicate device(s):

K002400 ACL Advance

Description of the device/intended use(s):

The ACL TOP is a bench top, fully automated, random access analyzer 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 system provides results for both direct hemostasis measurements and calculated parameters.

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

The ACL TOP is substantially equivalent in performance, intended use, safety and effectiveness to the ACL Advance (predicate device) for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

Section 3 (Cont.)
ACL TOP - 510(k) Summary
(Summary of Safety and Effectiveness)

Summary of Performance Data:

Precision

Within run and total precision assessed over multiple runs (n=80) using normal and abnormal levels of control plasma gave the following results:

Reagent Type	Control Level	Mean	Within Run %CV	Total %CV
Antithrombin (%)	Normal	108.5	5.7	5.8
	Low Abnormal	53.5	5.6	6.8
	High Abnormal	32.0	6.8	9.1
APTT (Seconds)	Normal	30.3	1.2	1.6
	Low Abnormal	49.3	0.9	2.1
	High Abnormal	59.0	0.9	1.4
D-Dimer (ng/mL)	Low Control	340	4.6	7.7
	High Control	729	2.5	4.5
Factor II (%)	Normal	110.7	4.2	5.2
	Low Abnormal	64.5	4.1	5.3
	High Abnormal	37.5	3.8	5.6
Factor V (%)	Normal	124.7	4.0	4.7
	Low Abnormal	79.9	3.0	4.7
	High Abnormal	43.4	3.6	4.8
Factor VII (%)	Normal	106.2	3.6	3.9
	Low Abnormal	61.3	2.1	3.7
	High Abnormal	33.0	2.9	4.4
Factor X (%)	Normal	114.6	1.8	2.8
	Low Abnormal	64.6	2.2	3.4
	High Abnormal	38.3	1.9	3.6
Fibrinogen-C (mg/dL)	Normal	364.7	7.9	8.8
	Low Fibrinogen	92.9	7.7	8.4
Protein C (%)	Normal	120.4	2.6	3.3
	Low Abnormal	30.9	3.0	4.3
	High Abnormal	18.4	3.7	4.7
Prothrombin Time (PT) (Seconds)	Normal	11.9	1.3	1.4
	Low Abnormal	25.7	1.5	2.7
	High Abnormal	37.3	1.8	3.0
PT-Based Fibrinogen (mg/dL)	Normal	302.6	3.7	4.1
	Low Fibrinogen	128.2	7.7	7.8

Section 3 (Cont.)
ACL TOP - 510(k) Summary
(Summary of Safety and Effectiveness)

Summary of in-house performance data (Cont.):

Method Comparison

In method comparison studies evaluating citrated plasma samples, the ACL TOP and the ACL Advance (predicate device) were shown to be statistically similar as shown below.

Reagent Type	n	Slope	Intercept	r	Sample Range
Antithrombin (%)	123	1.03	-1.418	0.9660	25.0 to 121.7
APTT (Seconds)	205	1.076	-0.380	0.9943	24.2 to 236.7
D-Dimer (ng/mL)	120	1.12	-16.0	0.993	84 to 19809
Factor II (%)	101	0.95	-0.551	0.9753	6.0 to 128.2
Factor V (%)	93	0.81	4.742	0.9822	2.1 to 149.3
Factor VII (%)	96	0.88	3.153	0.9922	6.3 to 147.4
Factor X (%)	110	0.97	2.995	0.9954	5.0 to 142.3
Fibrinogen-C (mg/dL)	98	1.00	-8.740	0.9759	121.6 to 695.0
Protein C (%)	123	1.15	-0.323	0.9902	9.4 to 129.7
Prothrombin Time (PT) (Seconds)	150	0.990	1.46	0.9987	9.8 to 107.4
PT-Based Fibrinogen (mg/dL)	93	1.084	-9.93	0.9587	121.6 to 695.0

Indications for Use Statement

510(k) Number (if known): K033414

Device Name: ACL TOP

Indications for Use:

The ACL TOP is a bench top, fully automated, random access analyzer 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 system provides results for both direct hemostasis measurements and calculated parameters.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 1 2 2004

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

Re: k033414
Trade/Device Name: ACL TOP
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation instrument
Regulatory Class: Class II
Product Code: GKP
Dated: October 24, 2003
Received: October 27, 2003

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
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): K033414

Device Name: ACL TOP

Indications for Use:

The ACL TOP is a bench top, fully automated, random access analyzer 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 system provides results for both direct hemostasis measurements and calculated parameters.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033414

Prescription Use ✓ **OR** Over-The-Counter Use _____

(Per 21 CFR 801.019)