510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

K060162

B. Purpose for Submission:

Special submission for a software modification to the PT and APTT test parameters of two new ACL 9000 family members- the ACL Elite and ACL Elite Pro.

C. Manufacturer and Instrument Name:

Instrumentation Laboratory ACL Elite and ACL Elite Pro

D. Type of Test or Tests Performed:

Coagulometric tests (PT-FIB, APTT, TT, Single Factors)

Absorbance Tests (Antithrombin, Heparin, Protein C, Plasmin Inhibitor, Plasminogen Fibrinogen C –Clauss method)

Immunological Tests (D-Dimer, free Protein S, von Willebrand Factor-Activity and Antigen)

Special Tests (Protein S, Factor V Leiden, LAC Screen and Confirm, ProClot C-clotting Protein C)

E. System Descriptions:

1. Device Description: The ACL is a family of fully automated computer-controlled, microcentrifugal analyzers. The ACL Elite/Elite Pro system incorporates a liquid crystal display (LCD) unit that shows the status of the instrument, permits the user to select desired procedures, and through the use of menus and options guides the operator through these procedures. Information and instructions are entered into the system either via a touch screen device or through a standard PC keyboard or mouse.

2. Principles of Operation:

When sample testing is initiated, the samples and reagents are sequentially pipetted into a 20-cuvette polystyrene rotor (loading process). A centrifugation process then mixes sample and reagents. The mixing is carried out by a combination or rapid acceleration and braking actions, which are effective in

thoroughly mixing the liquids. Reaction measurements (data acquisition) via the photometer are made while the rotor is spinning.

The ACL measures the parameters at 37°C ± 1° C, at ambient temperature from 15°C to 32°C. However, if the ACL is in a temperature –controlled environment where temperature is held constant, the measurements are made within a narrower temperature range: 37°C ± 0.25° C.

The results are displayed on the LCD and optionally printed by the external printer, and/or sent to a host computer. The ACL performs automatic calibration, offers a series of utility programs for the operator and manages a complete quality control program.

3. Modes of Operation:

   The user may program single or multiple tests on patient samples to be performed on a random access basis. Users also have the capability to pause the system during an analytical session for STAT samples.

4. Specimen Identification:

   On-board and external barcode reader, manual entry.

5. Specimen Sampling and Handling:

   Samples are collected, centrifuged, and loaded onto one of three different sample trays. The ACL contains an autosampler system that pipettes samples and reagents into the loading and analysis area.

6. Calibration:

   When required, the ACL Elite/Elite Pro prompts the user to perform a calibration. Calibration is performed with commercially available calibration material either prior to or simultaneously with sample analysis.

7. Quality Control:

   Commercial quality control material is available for daily monitoring of the instrument.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes___X_____ or No_____

F. Regulatory Information:

1. Regulation section:

   21 CRF 864.5425

2. Classification:

   II

3 Product code:

   JPA

4. Panel:

   81 Hematology

G. Intended Use:

1. Indication(s) for Use:

   The ACL Elite/ 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.

2. Special Conditions for Use Statement(s):

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   K000053 ACL 9000 (ACL 8000 and ACL 10000)

2. Comparison with Predicate Device:

Similarities		
Item	Device	Predicate
Intended use	*in vitro* diagnostic clinical use in the	same

Similarities		
Item	Device	Predicate
	hemostasis laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.	
Test parameters	PT-FIB, APTT, TT, Single Factors, Antithrombin, Heparin, Protein C, Plasmin Inhibitor, Plasminogen Fibrinogen C –Clauss method, D-Dimer, free Protein S, von Willebrand Factor-Activity and Antigen, Protein S, Factor V Leiden, LAC Screen and Confirm, ProClot C-clotting Protein C	same

Differences		
Item	Device	Predicate
Software modification for PT and APTT assays- Clot time from the Primary Algorithm is discrepant from the value determined with the Secondary algorithm	Reports results from secondary algorithm	Discrepancies between the primary and secondary algorithm flagged with a "Noisy baseline" warning

I. Special Control/Guidance Document Referenced (if applicable):

J. Performance Characteristics*:*

1. Analytical Performance:

   a. Accuracy:

Site 1

Reagent	n	Slope	Intercept	r	Sample Range
HemosIL APTT-SP (seconds)	54	1.032	-1.30	0.9990	26.5-95.4
HemosIL SynthASil (seconds)	52	1.009	0.02	0.9981	9.7-80.4
HemosIL PT-Fib Recombinant PT (Seconds)	49	0.972	0.50	0.9993	10.8-44.7
HemosIL PT-Fib Recombinant Fibrinogen (mg/dl)	47	0.974	0.4	0.9992	133-808
HemosIL PT-Fibrinogen PT (seconds)	49	0.989	0.35	0.9985	11.3-21.2
HemosIL PT-Fibrinogen Fibrinogen (mg/dl)	47	0.996	-16.3	0.9848	141-869
HemosIL Factor VIII (% Activity)	47	0.909	1.549	0.9938	1.1-147
HemosIL Factor IX (% Activity)	49	0.948	1.47	0.9914	5.5-149

Site 2

Reagent	N	Slope	Intercept	R	Sample Range
HemosIL SynthASil (seconds)	72	0.988	-0.69	0.9756	24.7-60.3
HemosIL PT-Fibrinogen PT (seconds)	72	0.981	0.40	0.9944	11.4-47.1
HemosIL PT-Fibrinogen Fibrinogen (mg/dl)	58	1.013	18.1	0.9846	154-1204
HemosIL Liquid Antithrombin (% Activity)	55	1.074	1.04	0.9616	22.7-123.0
HemosIL Fibrinogen-C (mg/dl)	47	0.960	16.0	0.9585	119-698
HemosIL Thrombin Time (% Activity)	58	0.961	0.44	0.9836	9.0-35.2
HemosIL Factor VIII (% Activity)	49	1.198	-7.22	0.9909	2.8-149.0
HemosIL Factor IX (% Activity)	56	0.929	-6.12	0.9956	4.5-150.0
HemosIL Factor XII (% Activity)	51	1.054	-5.91	0,9943	7.5-135.0
HemosIL D-Dimer (% Activity)	63	1.263	-64.84	0.9887	86.9-3472

b. Precision/Reproducibility:

APTT (Seconds)

HemosIL APTT-SP (K973306)

	N	Mean	With-in 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

HemosIL SynthASil (APTT) (K953981)

	N	Mean	With-in 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

PT (Seconds)

HemosIL PT-Fibrinogen Recombinant (K981479)

	N	Mean	With-in 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

HemosIL PT-Fibrinogen (K862301)

	N	Mean	With-in Run %CV	Total %CV
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)

HemosIL PT-Fibrinogen Recombinant (K981479)

	N	Mean	With-in Run %CV	Total %CV
Normal Control	50	297.6	3.8	6.7
Low Abnormal Control	50	113.1	5.3	6.4

HemosIL PT-Fibrinogen (K862301)

	N	Mean	With-in Run %CV	Total %CV
Normal Control	50	277.9	4.4	4.6
Low Abnormal Control	50	132.9	3.6	5.5

Factor VIII (% Activity)

HemosIL Factor VIII (K034007) with APTT-SP

	N	Mean	With-in 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

HemosIL Factor IX (K031829) with APTT-SP

	N	Mean	With-in 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

c. *Linearity*:

d. *Carryover*:

e. *Interfering Substances*:

2. Other Supportive Instrument Performance Data Not Covered Above:

An additional study was conducted to support the use of the Secondary Algorithm

on the ACL Elite/Elite Pro to report unflagged results in the specific case where there is a discrepancy between the Primary and Secondary Algorithms. The data is summarized below:

	APTT-SP (Seconds)		SynthASIL (Seconds)		PT FIB		PT Recombinant	
	Primary	Secondary	Primary	Secondary	Primary	Secondary	Primary	Secondary
Mean	33.6	33.8	32.7	32.8	14.4	14.4	17.8	18.1

As required for a Special 510(k), the Sponsor has provided a risk analysis as well as a Declaration of Conformity with Design Controls indicating that development activities were conducted under appropriate design controls procedures, and the overall product specifications were met.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.