

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

**A. 510(k) Number:** K073377

**B. Purpose for Submission:** Software modification

The ACL TOP has two modules: (1) The Control Module handles the instrument's user interface, and (2) The Analytical Module is responsible for the patient sampling processing and data generation. System software V3.0.0 is being introduced on the ACL TOP family (with and without the feature of closed tube sampling) to support the conversion from the Windows 2000 Operating System to the Windows XP Operating System, which affects the Control Module. This software also includes additional features and ease-of-use enhancements (non-analytical improvements).

**C. Manufacturer and Instrument Name:** Instrumentation Laboratory Co., ACL TOP

**D. Type of Test or Tests Performed:** Coagulation and/or fibrinolysis

**E. System Descriptions:**

1. Device Description: K063679
2. Principles of Operation: K063679
3. Modes of Operation: K063679
4. Specimen Identification: K063679
5. Specimen Sampling and Handling: K063679
6. Calibration: K063679
7. Quality Control: K063679
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: Coagulation Instrument

2. Classification: Class II
3. Product code: GKP
4. Panel: Hematology

**G. Intended Use:**

1. Indication(s) 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 measurement and calculated parameter.

2. Special Conditions for Use Statement(s): N/A

**H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers: ACL TOP, K063679 and K033414
2. Comparison with Predicate Device:

Similarities		
Item	Device Software V3.0.0	Predicate Software V2.8.7
Intended Use	Same	The ACL TOP is a bench top, fully automated, random access analyzer designed specifically for <i>in vitro</i> 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 measurement and calculated parameter.

Differences		
Item	Device Software V3.0.0	Predicate Software V2.8.7
Software	Windows XP Operating System	Windows 2000 Operating System

**I. Special Control/Guidance Document referenced (if applicable):** N/A

**J. Performance Characteristics:** see K063679

1. Analytical Performance:

*a. Accuracy:*

*b. Precision/Reproducibility:*

*c. Linearity:*

*d. Carryover:*

*e. Interfering Substances:*

2. Other Supportive Instrument Performance Data Not Covered Above:

**K. Proposed Labeling:**

There are no changes in the ACL TOP test parameters, which are separate from the system software. Therefore, there are no changes to the labeled indications for use/intended use or performance claims of either the instruments or its reagents.

**L. Conclusion:**

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