K091980

SEP 2 2 2009

510(k) Summary

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	113 Hartwell Avenue Lexington, MA 02421
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
Alternate Contact:	Gabriella Erdosy, Regulatory Affairs Associate
Phone Number:	781-861-4571
Preparation Date:	June 30, 2009

Device Trade Name:

ACL TOP 700 LAS

Regulatory Information:

Regulation Section:	Coagulation Instrument (864.5400)
Classification:	Class II
Product Code:	GKP
Panel:	Hematology

Predicate Device:

K073377	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.

Reason for Submission:

The ACL TOP 700 LAS is being introduced as a new family member to the ACL TOP (K073377), with the added feature of an extra arm and hardware to interface with laboratory automation systems (LAS). A Point-in-Space design solution is utilized where the patient sample remains under the control of the laboratory automation system (i.e., the automation track) and the ACL TOP 700 LAS analyzer aspirates an aliquot for sample analysis without removing the primary container from the automation track. The instrument's system software was also modified to interface with an IM (interface module) computer, which controls the communications to the LAS system.

NOTE: The ACL TOP 700 LAS shares with the other ACL TOP family members, the same intended use/indications for use, analytical technology/operating principle, analytical specifications, labeled performance characteristics, analytical data reduction, software, test parameters and uses the same consumables and racks.

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

Testing demonstrated that the performance of the ACL TOP 700 LAS is substantially equivalent to the performance of the current legally marketed ACL TOP family (K073377).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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Instrumentation Laboratory Co.
c/o Ms. Carol Marble
Regulatory Affairs Director
113 Hartwell Ave
Lexington, MA 02421

Re: k091980
Trade/Device Name: ACL TOP 700 LAS
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: Class II
Product Code: GKP
Dated: August 27, 2009
Received: August 28, 2009

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, PhD
Director
Division of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091980

Device Name: ACL TOP 700 LAS

Indications for Use:

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The system provides results for both direct hemostasis measurements and calculated parameters.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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