DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Instrumentation Laboratory (IL) Co.
Nikita Malladi
Regulatory Affairs Specialist II
180 Hartwell Road
Bedford, MA 01730

March 3, 2016

Re: K160276
Trade/Device Name: ACL TOP (ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS, ACL TOP 300 CTS)
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: Class II
Product Code: GKP
Dated: February 1, 2016
Received: February 2, 2016

Dear Ms. Malladi:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kelly Oliner -S

For Leonthena R. Carrington, MS, MBA, MT(ASCP)
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ACL TOP (ACL TOP 700; ACL TOP 700 CTS; ACL TOP 700 LAS; ACL TOP 500 CTS; ACL TOP 300 CTS)

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Instrumentation Laboratory
A Werfen Company

510(k) Summary

The submission meets the criteria for a Special 510(k) under the FDA guidance "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA
Contact Person	Nikita Malladi, Regulatory Affairs Specialist II Phone: 781-674-3245 Fax: 781-861-4207 Email: nmalladi@ilww.com
Preparation Date	February 24, 2016
Device Trade Name	ACL TOP: • ACL TOP 700 • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS • ACL TOP 300 CTS
Regulatory Information	Classification: Class II Regulation No.: 21 CFR 864.5400 Common Name: Coagulation Instrument Panel: Hematology (81) Product Code: GKP
Predicate Device	ACL TOP: K073377; K091980 (LAS model)
Device Indications for Use / Intended 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.
Device Description	The ACL TOP Family are fully automated coagulation analyzers that utilize the same intuitive software, the same consumables, reagents, calibrators and controls, and provide the same analytical methodology for routine and specialty assay result reporting as the predicate ACL TOP Family. The ACL TOP Family instrument performs the following types of tests, using the same optical measuring wavelengths and test parameters as the predicate ACL TOP Family: • Coagulometric (Turbidimetric) Measurements • Chromogenic (Absorbance) Measurements • Immunological Measurements

Comparison to Predicate:

This Special 510(k) is being submitted to switch the operating system from Windows XP to Windows 7 for ACL TOP Family Instruments.

The submission meets the criteria for a Special 510(k) based on the following:

- No change in indications for use or intended use
- No change in operating principle
- No change to labeled performance claims, for the instrument family of the associated reagents
- No change to hardware
- No change to data reduction software
- No change to test parameters
- No change to calibration
- No change to quality controls
- No change to consumables
- No change to reagents

Following is a description of the similarities and differences between the currently marketed ACL TOP Family (K073377, K091980 (LAS model)) and ACL TOP Family with the Software 5. 3 update:

Item	Predicate	Updated Device (with SW 5.3)
Trade Names	**ACL TOP** • ACL TOP 700 • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS • ACL TOP 300 CTS	**ACL TOP** • ACL TOP 700 • ACL TOP 700 CTS • ACL TOP 700 LAS • ACL TOP 500 CTS • ACL TOP 300 CTS
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.	Same
Matrix	3.2% Citrated Plasma	Same
Methodology	The ACL TOP Family performs the following types of tests: • Coagulometric (Turbidimetric) Measurements (405 nm or 671 nm) • Chromogenic (Absorbance) Measurements (405 nm) • Immunological Measurements (405 nm or 671 nm)	Same
Test Menu	Clotting, chromogenic and immunological assays	Same
Quality Control	Automated QC	Same
Software (Operating System)	Windows XP	Windows 7

Conclusion:

Based on the shared indications for use, operating principle, consumables, reagents, controls and calibrators, the ACL TOP Family with software v5.3 running on the Windows 7 operating system can be concluded to be substantially equivalent to the cleared and currently marketed predicate device, ACL TOP Family.