August 16, 2024

Instrumentation Laboratory (IL) Co.
Sneh Pingle
Regulatory Affairs Manager I
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K242127
Trade/Device Name: ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS)
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: Class II
Product Code: GKP
Dated: July 18, 2024
Received: July 19, 2024

Dear Sneh Pingle:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding

When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Min Wu -S

Min Wu, Ph.D.
Branch Chief
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242127

Device Name
ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS)

Indications for Use *(Describe)*
The ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS) are bench top, fully automated, random access 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.

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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510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92.

Submitter's Information	Instrumentation Laboratory Company 180 Hartwell Road Bedford, MA 01730-2443 (USA)

Contact Person	Sneh Pingle Regulatory Affairs Manager I Phone: 781-674-3266 Fax: 781-861-4207 Email: spingle@werfen.com

Preparation Date	July 15, 2024

Device Trade Name	ACL TOP Family 50 Series Models: • ACL TOP 350 CTS • ACL TOP 550 CTS • ACL TOP 750 • ACL TOP 750 CTS • ACL TOP 750 LAS

Predicate Device	ACL TOP Family 50 Series	K150877

Regulatory Information	Regulation Section No.	21 CFR 864.5400
	Regulation Description	Coagulation instrument
	Classification	Class II
	Product Code	GKP
	Panel	Hematology (81)

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Device Description

The ACL TOP Family 50 Series 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 50 Series 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

The ACL TOP Family 50 Series also offers new pre-analytical features not available on the current ACL TOP Family as described below. These features are not intended to replace laboratory quality policies. The features simply alert the instrument operator to a potential HIL (Hemoglobin, Icteric and Lipemia) interference situation specific to the assays requested for a sample, underfilled sample tubes or a detected clog. The user will determine how to handle these situations (for example, by not reporting the results, or reporting the results with, or without, additional comments).

Intended Use / Indications for Use

The ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS) are bench top, fully automated, random access 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.

Special Conditions for Use Statement

• For prescription use only.

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Reason for Special 510(k) Submission
The new remote features introduced on the ACL TOP Family 50 Series are limited to adding permission-based remote-control function for desktop sharing and remotely delivering software, OS updates (patches) and test parameter releases, utilizing security and privacy controls by design and installed by default. These features do not impact the analytical performance of the instrument and are already available on the ACL TOP Family 70 Series, FDA cleared under K231031. The new remote features will be available to customers as an "optional add-on service" software tool called ProDx. This service software tool (ProDx) is being expanded beyond consistent monitoring, data gathering and capturing of quality control logs to now also include the following new remote features that are the subject of this Special 510(k): • Added permission-based remote-control function for desktop sharing. • Added functionality to remotely deliver software, OS updates (patches) and test parameter releases. The above features are managed through cloud architecture for seamless and secure deployment; the same cloud architecture as already used on the ACL TOP Family 70 Series. These new features will be available only for ACL TOP Family 50 Series instruments at Windows 10 (SW version 6.5.3). The features will not be available for ACL TOP Family 50 Series instruments at Windows 7.

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Summary Comparison of Technological Characteristics (Predicate)		
Item	**Predicate Device (K150877)**	**Subject Device**
Similarities		
Trade Name	ACL TOP Family 50 Series	ACL TOP Family 50 Series
Model Trade Names	• ACL TOP 350 CTS • ACL TOP 550 CTS • ACL TOP 750 CTS • ACL TOP 750 • ACL TOP 750 LAS	Same
Manufacturer	Instrumentation Laboratory Co.	Same
Indications for Use / Intended Use	The ACL TOP Family 50 Series (ACL TOP 750; ACL TOP 750 CTS; ACL TOP 750 LAS; ACL TOP 550 CTS; ACL TOP 350 CTS) are bench top, fully automated, random access 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.	Same
Test Methodology	• Coagulometric measurement • Chromogenic measurement • Immunological measurement	Same
Wavelengths	• 405 nm • 535 nm • 671 nm	Same
Test Menu	• Clotting Assays • Chromogenic Assays • Immunological Assays	Same
Test Parameters	Assay volumes, rinse and clean cycles, timing, optical parameters, data algorithms, material definition	Same

Summary Comparison of Technological Characteristics (Predicate) (Cont.)		
Item	**Predicate Device (K150877)**	**Subject Device**
Similarities (Cont.)		
Reagents, Controls and Calibrators	Packaging, formulation, performance claims in labeling	Same
Fluidic Handling	Aspiration, dispense, mixing, rinse, clean, temperature control, bulk fluids	Same
Sample Handling	Cap piercing, onboard storage	Same
Onboard Reagent Storage	Stirring, temperature control	Same
Reaction and Detection	Optics, temperature control	Same
System Software	Hardware control, user interface except as noted in the Differences section below	Same
Quality Control	Automated QC	Same
Pre-Analytical HIL Check	Standard for all models: Third measurement wavelength @535 nm and an additional emitter control channel	Same
Tube Fill Height Check	Standard for all models	Same
Clog Detection	Standard for all models	Same
External Skins and Chassis	External Skins and Chassis	Same
On-market instrument appearance	On-market instrument appearance	Same

Differences		
Item	**Predicate Device (K150877)**	**Subject Device**
Operating System	Windows 7 and Windows 10	Same.
Software/ Cybersecurity	On-market instrument software and cybersecurity	Added permission-based remote-control function for desktop sharing and remotely delivering software, OS updates (patches) and test parameter releases, utilizing security and privacy controls by design and installed by default. These new features will be available only for ACL TOP Family 50 Series instruments at Windows 10 (SW version 6.5.3). The features will not be available for ACL TOP Family 50 Series instruments at Windows 7.
		Added new risk mitigation controls (Example MS BitLocker, Digital Signature, MS AppLocker) for enhanced cybersecurity.

Conclusion
The technological and functional characteristics of the ACL TOP Family 50 Series (subject device) as described herein are substantially equivalent to that of the ACL TOP Family 50 Series (predicate device). The software verification and validation study results demonstrate that the ACL TOP Family 50 Series with updated non-analytical features is safe and effective for its intended purpose and equivalent in performance to the predicate device (K150877).