June 21, 2023

Instrumentation Laboratory Company
Carol Marble
Senior Director of Regulatory Affairs
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K231031
Trade/Device Name: ACL TOP Family 70 Series
Regulation Number: 21 CFR 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: Class II
Product Code: GKP
Dated: April 10, 2023
Received: April 11, 2023

Dear Carol 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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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)*
K231031

Device Name
ACL TOP Family 70 Series

Indications for Use *(Describe)*

The ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570 and ACL TOP 770 / 770s / 770 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use by health care professionals 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	Carol Marble Senior Director of Regulatory Affairs Phone: 781-861-4467 Fax: 781-861-4207 Email: cmarble@werfen.com

Preparation Date	June 15, 2023

Device Trade Names	ACL TOP Family 70 Series models: • ACL TOP 370 • ACL TOP 570 • ACL TOP 770 • ACL TOP 770s • ACL TOP 770 LAS

Predicate Device	ACL TOP Family 50 Series	K150877

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

Device Description

The ACL TOP Family 70 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 50 Series.

The ACL TOP Family 70 Series instrument performs the following types of tests, using the same optical measuring wavelengths and test parameters as the predicate ACL TOP Family 50 Series:

- Coagulometric (Turbidimetric) Measurements
- Chromogenic (Absorbance) Measurements
- Immunological Measurements

The ACL TOP Family 70 Series also offers the same pre-analytical features available on the ACL TOP Family 50 Series. These features 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.

Intended Use / Indications for Use

The ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570 and ACL TOP 770 / 770s / 770 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use by health care professionals 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.

Summary Comparison of Technological Characteristics (Predicate)		
Item	**Predicate Device (K150877)**	**Subject Device**
Similarities		
Trade Names	ACL TOP Family 50 Series	ACL TOP Family 70 Series
Model Trade Names	ACL TOP 350 CTS ACL TOP 550 CTS ACL TOP 750 CTS ACL TOP 750 ACL TOP 750 LAS	ACL TOP 370 ACL TOP 570 ACL TOP 770 ACL TOP 770s ACL TOP 770 LAS
Manufacturer	Instrumentation Laboratory Co.	Same
Classification	Class II	Same
Review Panel	Hematology (81)	Same
Regulation Description	Instrument, Coagulation, Automated	Same
Product Code	GKP	Same
Regulation Section	21 CFR 864.5400	Same
Indications for Use / Intended Use	The ACL TOP Family 50 Series (ACL TOP 350 CTS, ACL TOP 550 CTS, ACL TOP 750, ACL TOP 750 CTS, ACL TOP 750 LAS) 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 provides results for both direct hemostasis measurements and calculated parameters.	The ACL TOP Family 70 Series (ACL TOP 370, ACL TOP 570 and ACL TOP 770 / 770s / 770 LAS) are bench top, fully automated, random access analyzers designed specifically for in vitro diagnostic clinical use by health care professionals 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.
Test Methodology	• Coagulometric measurement • Chromogenic measurement • Immunological measurement	Same
Wavelengths	• 405 nm • 535 nm • 671 nm	Same

Summary Comparison of Technological Characteristics (Predicate) (Cont.)		
Item	**Predicate Device (K150877)**	**Subject Device**
Similarities (Cont.)		
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
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

Summary Comparison of Technological Characteristics (Predicate) (Cont.)		
Item	**Predicate Device (K150877)**	**Subject Device**
Differences		
External Skins and Chassis	On-market instrument appearance	Updated instrument appearance
Control Module Monitor	17-inch color touchscreen monitor	22-inch color touchscreen monitor
Software / Cybersecurity	On-market instrument software and cybersecurity	Updated Graphical User Interface (GUI) for aesthetics (e.g., higher resolution icons)
		Added the Study Mode internal function to support laboratories in more efficiently meeting their Quality System requirements. The Study Mode provides the interface for laboratories to organize and execute their internal performance studies, including collection of data for lot comparison, instrument comparison, or reference intervals.
		Added permission-based remote-control function for desktop sharing and remote software delivery and upgrades, utilizing security and privacy controls by design and installed by default.

Performance Summary

Analytical studies (specifically internal precision and method comparison) were performed on one lot of selected representative assays to establish that the updates introduced with the ACL TOP Family 70 Series do not impact the labeled performance data of the current menu of FDA-cleared assays claimed for the ACL TOP Family 50 Series. These studies followed recognized guidelines:

- CLSI EP05-A3
- CLSI EP09c, 3rd Ed

All analytical studies were performed in accordance to established plans and protocols and design control procedures. Testing verified that all acceptance criteria were met and results equivalent to the predicate device.

Precision

Precision studies were performed using one lot of the following selected representative assays tested on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770). These studies used samples and controls with each material run for 20 days at two runs per day, 2 replicates per run (n=80).

Summary results for a representative ACL TOP Family 70 Series model are shown in the table below:

HemosIL D-Dimer HS 500 (K172903) – D-dimer ng/mL FEU

Material	Mean	Within Run %CV	Total %CV
Low Control	676.9	4.5	4.8
High Control	2488.9	1.7	2.1
Cut-off Pool	569.9	6.4	6.5
High Pool	2486.6	2.0	2.0

HemosIL Factor VIII deficient plasma (K034007) – Factor VIII % Activity

Material	Mean	Within Run %CV	Total %CV
Normal Control	94.22	2.6	3.4
Abnormal Control	29.58	2.0	4.8
Plasma Pool 1	33.30	2.7	3.8
Plasma Pool 2	9.01	2.4	2.7

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Precision			
HemosIL RecombiPlasTin 2G (K070005) – Prothrombin Time Seconds			
Material	**Mean**	**Within Run %CV**	**Total %CV**
Normal Control	11.94	0.6	1.8
Normal Control	23.24	0.7	3.7
Low Abn Control	36.93	0.8	5.0
High Abn Control	38.10	0.9	4.0
HemosIL RecombiPlasTin 2G (K070005) – Fibrinogen mg/dL			
Material	**Mean**	**Within Run %CV**	**Total %CV**
Normal Control	339.1	0.9	3.9
Low Fibrinogen Control	140.7	6.4	8.1
Normal Pool	284.5	2.1	3.8
Abnormal Pool	136.9	4.3	5.0
HemosIL Liquid Anti-Xa (K213464) – Heparin IU/mL			
Material	**Mean**	**Within Run %CV**	**Total %CV**
UF Low Control	0.36	1.4	1.8
UF High Control	0.66	1.5	1.8
UF Pool	0.56	1.2	2.2
LMW High Control	1.50	1.9	2.2
LMW Low Control	0.58	2.2	2.6
LMW Pool	0.66	2.0	2.4

Method Comparison

Method comparison studies were performed using one lot of the following selected representative assays to compare the performance on representative ACL TOP Family 70 Series models (ACL TOP 370, ACL TOP 570, and ACL TOP 770 or ACL TOP 770 LAS) to a representative ACL TOP Family 50 Series model (ACL TOP 750 CTS). The studies included clinical samples spanning each assay's analytical measuring range (AMR) to demonstrate the equivalent performance between the subject and predicate devices.

Summary results for a representative ACL TOP Family 70 Series model are shown in the table below:

HemosIL D-Dimer HS 500 (K172903) – ng/mL FEU

Subject System	N	Slope	Intercept	r	Predicate System
ACL TOP Family 70 Series	116	1.022	0.5575	0.998	ACL TOP Family 50 Series

HemosIL Factor VIII deficient plasma (K034007) – % Activity

Subject System	N	Slope	Intercept	r	Predicate System
ACL TOP Family 70 Series	104	1.006	-0.0587	0.998	ACL TOP Family 50 Series

HemosIL RecombiPlasTin 2G (K070005) – Prothrombin Time (Seconds)

Subject System	N	Slope	Intercept	r	Predicate System
ACL TOP Family 70 Series	116	1.012	-0.0940	1.000	ACL TOP Family 50 Series

HemosIL RecombiPlasTin 2G (K070005) – Fibrinogen (mg/dL)

Subject System	N	Slope	Intercept	r	Predicate System
ACL TOP Family 70 Series	114	0.9756	-1.1220	0.999	ACL TOP Family 50 Series

HemosIL Liquid Anti-Xa (K213464) – Heparin (IU/mL)

Subject System	N	Slope	Intercept	r	Predicate System
ACL TOP Family 70 Series	207	0.9804	-0.0145	0.999	ACL TOP Family 50 Series

Conclusion
The technological and functional characteristics of the ACL TOP Family 70 Series (subject device) as described herein are substantially equivalent to that of the ACL TOP Family 50 Series (predicate device). The analytical study results demonstrate that the ACL TOP Family 70 Series with updated non-analytical features is safe and effective for its intended purpose and equivalent in performance to the predicate device (K150877).