December 29, 2023

Instrumentation Laboratory
Nikita Malladi
Regulatory Affairs Manager I
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K233790
Trade/Device Name: ACL TOP 970 CL
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose System For In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: JPA
Dated: November 28, 2023
Received: November 28, 2023

Dear Nikita 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 (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)*
K233790

Device Name
ACL TOP 970 CL

Indications for Use *(Describe)*

The ACL TOP 970 CL is a bench top, fully automated, random access analyzer designed specifically for in vitro diagnostic use by health care professionals in a clinical laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

The system provides results for both direct 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	Nikita Malladi Regulatory Affairs Manager I Phone: 781-353-1486 Fax: 781-861-4207 Email: nmalladi@werfen.com

Preparation Date	December 29, 2023

Device Trade Name	ACL TOP 970 CL

Predicate Device	ACL TOP Family 50 Series	K150877

Regulatory Information	Regulation Section No.	21 CFR 864.5425
	Regulation Description	Multipurpose system for *in vitro* coagulation studies
	Classification	Class II
	Product Code	JPA
	Panel	Hematology (81)

Device Description

The ACL TOP 970 CL is an additional member of the ACL TOP Family 70 Series previously FDA cleared under K231031. This family member consists of two side-by-side test modules:

- Main Module (ACL TOP 550 CTS, K150877) the subject of this submission
- Chemiluminescent (CL) Module previously FDA cleared under K221359

The Main Module to the ACL TOP 970 CL 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 970 CL is an additional member of the ACL TOP Family 70 Series (K231031) and utilizes the same consumables, reagents, calibrators, and controls, and provides the same analytical methodology for routine and specialty assay result reporting as the predicate (ACL TOP Family 50 Series).

The ACL TOP 970 CL 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 970 CL is a bench top, fully automated, random access analyzer designed specifically for in vitro diagnostic use by health care professionals in a clinical laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis.

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

Reason for Special 510(k) Submission

This Special 510(k) is submitted for the following reasons:

- To obtain FDA clearance for the Main Module (ACL TOP 550 CTS side) of the ACL TOP 970 CL instrument
- Following FDA clearance, to extend the current FDA cleared on-market hemostasis (non-chemiluminescent) assay menu for the ACL TOP Family 50 Series onto the ACL TOP 970 CL instrument through CLIA Categorization Requests

Summary Comparison of Technological Characteristics (Predicate)		
Item	**Predicate Device (K150877)**	**Subject Device**
Trade Name	ACL TOP Family 50 Series	ACL TOP 970 CL (Main Module: ACL TOP 550 CTS)
Similarities		
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.	The ACL TOP 970 CL is a bench top, fully automated, random access analyzer designed specifically for in vitro diagnostic use by health care professionals in a clinical laboratory for coagulation and/or fibrinolysis testing in the assessment of thrombosis and/or hemostasis. The system provides results for both direct measurements and calculated parameters.
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
Reagents, Controls and Calibrators	Packaging, formulation, performance claims in labeling	Same

*Note: Chemiluminescent measurement on the ACL TOP 970 CL previously FDA cleared under K221359.

Summary Comparison of Technological Characteristics (Predicate) (Cont.)		
Item	**Predicate Device (K150877)**	**Subject Device**
Trade Name	ACL TOP Family 50 Series	ACL TOP 970 CL (Main Module; ACL TOP 550 CTS)
Similarities (Cont.)		
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

Item	Predicate Device (K150877)	Subject Device
Differences		
Chemiluminescence Measurement	Not Applicable	Chemiluminescent (CL) Module previously FDA cleared under K221359

Performance Summary

Analytical studies (specifically internal precision and method comparison) were performed on one lot of selected representative assays to establish that the labeled performance data of the current menu of FDA-cleared (non-chemiluminescent) assays claimed for the ACL TOP Family 50 Series are applicable to the Main Module ACL TOP 970 CL. 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 an ACL TOP 970 CL instrument. 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 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	733	4.3	4.5
High Control	2664	2.5	2.8
Cut-off Plasma Pool	532	5.2	6.0
High Plasma Pool	2435	2.4	2.4

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

Material	Mean	Within Run %CV	Total %CV
Normal Control	93.3	3.7	4.6
Abnormal Control	26.5	3.7	6.5
Plasma Pool 1	41.5	6.3	7.3
Plasma Pool 2	5.8	4.4	5.4

Precision			
HemosIL RecombiPlasTin 2G (K070005) – Prothrombin Time Seconds			
Material	**Mean**	**Within Run %CV**	**Total %CV**
Normal Control	11.5	0.5	1.2
Abnormal Pool	26.3	0.8	2.3
Low Abn Control	22.9	1.6	2.1
High Abn Control	38.7	1.1	2.6
HemosIL RecombiPlasTin 2G (K070005) – Fibrinogen mg/dL			
Material	**Mean**	**Within Run %CV**	**Total %CV**
Normal Control	387	0.9	1.4
Low Fibrinogen Control	178	6.1	6.3
Normal Pool	392	1.3	2.0
Abnormal Pool	109	1.8	2.4
HemosIL Liquid Anti-Xa (K213464) – Heparin IU/mL			
Material	**Mean**	**Within Run %CV**	**Total %CV**
UF Low Control	0.35	1.82	2.81
UF High Control	0.65	1.43	2.36
UF Pool	0.55	1.69	2.27
LMW High Control	1.57	1.18	2.15
LMW Low Control	0.64	2.55	2.81
LMW Pool	0.71	1.49	2.05

Method Comparison					
Method comparison studies were performed using one lot of the following selected representative assays to compare the performance on the Main Module side of ACL TOP 970 CL (subject device) to the ACL TOP 550 CTS (predicate device). The studies included clinical samples spanning each assay's analytical measuring range (AMR) to demonstrate the equivalent performance between the predicate and subject devices. Summary results for are shown in the table below:					
HemosIL D-Dimer HS 500 (K172903) – D-dimer ng/mL FEU					
Subject System	**N**	**Slope**	**Intercept**	**r**	**Predicate System**
ACL TOP 970 CL	136	0.939	27.0	0.996	ACL TOP 550 CTS
HemosIL Factor VIII deficient plasma (K034007) – Factor VIII % Activity					
Subject System	**N**	**Slope**	**Intercept**	**r**	**Predicate System**
ACL TOP 970 CL	105	1.045	0.0	0.993	ACL TOP 550 CTS
HemosIL RecombiPlasTin 2G (K070005) – Prothrombin Time Seconds					
Subject System	**N**	**Slope**	**Intercept**	**r**	**Predicate System**
ACL TOP 970 CL	118	1.000	0.25	0.998	ACL TOP 550 CTS
HemosIL RecombiPlasTin 2G (K070005) – Fibrinogen mg/dL					
Subject System	**N**	**Slope**	**Intercept**	**r**	**Predicate System**
ACL TOP 970 CL	123	0.991	5.1	0.998	ACL TOP 550 CTS
HemosIL Liquid Anti-Xa (K213464) – Heparin IU/mL					
Subject System	**N**	**Slope**	**Intercept**	**r**	**Predicate System**
ACL TOP 970 CL	139	0.989	0.015	0.997	ACL TOP 550 CTS

Main System Verification for HemosIL CL On-Market Reagents	
A risk review of the Main System on the ACL TOP 970 CL, which has only minimal differences in hardware and software from the ACL TOP Family 50 Series to support the new Chemiluminescent (CL) System, was performed to identify the necessary verification testing. The following testing supports that there is no analytical impact on the existing HemosIL (non-chemiluminescent) test menu. Therefore, the current FDA-cleared assays can be extended onto the ACL TOP 970 CL without further testing.	
Thermal Verification	Verification testing was performed that confirmed the structural changes to the instrument (new skins, modified wall geometry) does not impact analytical results.
Optical Stray Light Verification	Verification testing was performed that a new back wall design does not impact analytical results.
Environmental Verification	Verification testing was performed that a change to the skin of the instrument and air intake modification does not impact analytical results.

Conclusion
Based on the substantial equivalence comparison and the results of the verification testing that was conducted, it was concluded that the indications for use and technological characteristics of the Main Module on the ACL TOP 970 CL are substantially equivalent to the cleared and currently marketed predicate device, ACL TOP Family 50 Series (K150877), with shared performance claims for the FDA cleared on-market hemostasis (non-chemiluminescent) assay menu. The differences between the subject and predicate devices do not impact safety and effectiveness.