March 20, 2026

Instrumentation Laboratory (IL) Co.
Kirivann Chhoeun
Regulatory Affairs Specialist III
180 Hartwell Rd.
Bedford, Massachusetts 01730

Re: K260551
Trade/Device Name: HemosIL Factor V Leiden (APC Resistance V)
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial Thromboplastin Time Tests
Regulatory Class: Class II
Product Code: GGW
Dated: February 18, 2026
Received: February 18, 2026

Dear Kirivann Chhoeun:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Takeesha Taylor-Bell

Takeesha Taylor-Bell
Deputy Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260551

Device Name
HemosIL Factor V Leiden (APC Resistance V)

Indications for Use *(Describe)*
For determination of resistance to activated Protein C, caused by the Factor V:Q506 (Factor V Leiden) mutation, in plasma from untreated individuals and from patients on oral anti-coagulant (OAT) or heparin therapy.

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.

werfen

510(k) Summary

This Special 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter	Instrumentation Laboratory Company 180 Hartwell Road Bedford, MA 01730-2443 (USA) Establishment Registration: 1217183	
Primary Contact	Kirivann Chhoeun Regulatory Affairs Specialist III Phone: 774-254-5359 Fax: 781-861-4207 Email: kchhoeun@werfen.com	
Preparation Date	February 18, 2026	
Device Trade Name	HemosIL Factor V Leiden (APC Resistance V)	
Predicate Device	HemosIL Factor V Leiden (APC Resistance V)	K963111
HemosIL Factor V Leiden (APC Resistance V)	**Regulatory Information**	
	Classification	Class II
	Classification Panel	Hematology (81)
	Regulation Section No.	21 CFR 864.7925
	Regulation Description	Partial thromboplastin time tests
	Product Code	GGW

Reason Submission Qualifies as Special 510(k)

This Special 510(k) is being submitted to modify the labeled on-board stability claims for HemosIL Factor V Leiden (APC Resistance V). The submission meets the criteria for a Special 510(k) based on the following:

- The proposed change is submitted by the manufacturer legally authorized to market the existing device.
- There is a well-established method to evaluate the change: CLSI EP25, 2nd Edition.
- The data can be reviewed in a summary or risk analysis format.

In addition, the change in this submission **does not** introduce:

- Changes to indications for use or intended use
- Changes to operating principle
- Changes to formulation
- Changes to labeled performance claims, ***except*** to reduce the ACL TOP on-board stability claim to 24 hours and to add the ACL Elite/ACL Elite Pro claim of 4 hours

Device Description

The APC resistance phenotype is, in more than 90% of cases, due to a mutation in the Factor V gene, resulting in a replacement of Arg^{506} (R) with Gln (Q) in the Factor V protein. The selectivity for the Factor V:Q^{506} or other mutations in the Factor V gene rendering the protein resistant to inactivation by APC is increased by normalizing the concentrations of other plasma proteins involved in formation and regulation of thrombin. By performing the APTT-based APC resistance assay in the presence of an excess of Factor V Reagent Plasma, the sensitivity and specificity for the Factor V:Q^{506} mutation is significantly increased. Further, this modification allows for the analysis of plasma from patients who are on OAT. Sample plasma is prediluted with Factor V Reagent Plasma and incubated with the APTT reagent for a standard period of time. Coagulation is triggered by the addition of $CaCl_2$ in the absence and presence of APC and the time of clot formation is recorded.

Intended Use /Indication for Use

HemosIL Factor V Leiden (APC Resistance V) is intended for determination of resistance to activated Protein C, caused by the Factor V:Q^{506} (Factor V Leiden) mutation, in plasma from untreated individuals and from patients on oral anti-coagulant (OAT) or heparin therapy.

HemosIL Factor V Leiden (APC Resistance V) Comparison to Predicate Device		
This table provides a comparative description of the similarities and differences between the subject device, HemosIL Factor V Leiden (APC Resistance V), and its predicate device, HemosIL Factor V Leiden (APC Resistance V), last cleared under K963111.		
Item	**Predicate Device (K963111)**	**Subject Device**
Trade Name	HemosIL Factor V Leiden (APC Resistance V)	Same
Manufacturer	Instrumentation Laboratory Co.	Same
Similarities		
Product Code	GGW	Same
Regulation Section	21 CFR 864.7925	Same
Classification	Class II	Same
Intended Use/ Indications for Use	HemosIL Factor V Leiden (APC Resistance V) is intended for determination of resistance to activated Protein C, caused by the Factor V:Q^{506} (Factor V Leiden) mutation, in plasma from untreated individuals and from patients on oral anti-coagulant (OAT) or heparin therapy.	Same
Methodology	APC resistance activity	Same
Composition	The HemosIL Factor V Leiden (APC Resistance V) kit consists of: • APTT reagent: 2 x 4 mL vials of purified phospholipids with colloidal silica as contact activator. • Factor V Reagent Plasma: 2 x 4 mL vials of lyophilized human plasma with a low level of Factor V activity and filler. • APC/Calcium chloride: 2 x 2 mL vials of human activated Protein C co-lyophilized with $CaCl_2$. • Calcium chloride: 2 x 2 mL vials of calcium chloride in Tris buffer containing bovine serum albumin. • APC Control Plasma Level 1: 2 x 1 mL vials of lyophilized human normal plasma. • APC Control Plasma Level 2: 2 x 1 mL vials of lyophilized human abnormal plasma.	Same

HemosIL Factor V Leiden (APC Resistance V) Comparison to Predicate Device (Cont.)		
Item	**Predicate Device (K963111)**	**Subject Device**
Trade Name	HemosIL Factor V Leiden (APC Resistance V)	Same
Manufacturer	Instrumentation Laboratory Co.	Same
Similarities (Cont.)		
Sample Type	Citrated Plasma Samples	Same
Claimed Instrumentation	ACL Elite/Elite Pro ACL TOP Family ACL TOP Family 50 Series ACL TOP Family 70 Series	Same
Differences		
Platform	**Current Labeled On-Board Stability Claim**	**New Labeled On-Board Stability Claim**
ACL Elite/Elite Pro	No claim in labeling	4 hours (added claim)
ACL TOP Family/ ACL TOP Family 50 Series/ ACL TOP Family 70 Series	3 days	24 hours (reduced claim)

Established Claims on the ACL TOP and ACL Elite Instruments			
The HemosIL Factor V Leiden (APC Resistance V) on-board stability study supports the following claims: • Reduced on-board stability claim from 3 days to 24 hours at 15°C on-board the ACL TOP Family, ACL TOP Family 50 Series, and ACL TOP Family 70 Series. • Added on-board stability claim of 4 hours at 15-25°C on the ACL Elite/Elite Pro.			
Lot	**Sample**	**ACL TOP Claim**	**ACL Elite Claim**
1	APC Control Level 1	24 hours	4 hours
	APC Control Level 2		
	Normal Plasma Sample		
	Heterozygous Plasma Sample		
	Homozygous Plasma Sample		
2	APC Control Level 1	24 hours	4 hours
	APC Control Level 2		
	Normal Plasma Sample		
	Heterozygous Plasma Sample		
	Homozygous Plasma Sample		
3	APC Control Level 1	24 hours	4 hours
	APC Control Level 2		
	Normal Plasma Sample		
	Heterozygous Plasma Sample		
	Homozygous Plasma Sample		

Conclusion
HemosIL Factor V Leiden (APC Resistance V), with modified on-board stability claims, remains substantially equivalent to its legally marketed predicate device, HemosIL Factor V Leiden (APC Resistance V), last FDA cleared under K963111.