January 9, 2026

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

Re: K253957
Trade/Device Name: HemosIL Silica Clotting Time
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial thromboplastin time tests
Regulatory Class: Class II
Product Code: GFO
Dated: December 10, 2025
Received: December 10, 2025

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 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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253957

Device Name

HemosIL Silica Clotting Time

Indications for Use *(Describe)*

HemosIL Silica Clotting Time is intended for the detection of Lupus Anticoagulants in human citrated plasma on the IL Coagulation Systems by the use of screening (SCT Screen) and confirmatory (SCT Confirm) reagents sensitized to phospholipid dependent antibodies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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 (IL) 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	December 10, 2025	
Device Trade Name	HemosIL Silica Clotting Time	
Predicate Device	HemosIL Silica Clotting Time	K160445
Regulatory Information	**Assays**	
	Classification	Class II
	Classification Panel	Hematology (81)
	Regulation Section No.	21 CFR 864.7925
	Regulation Description	Partial thromboplastin time tests
	Product Code	GFO

Device Description

SCT Screen and SCT Confirm are reagents intended to simplify and standardize the detection of LA in clinical evaluations. SCT Screen is poor in phospholipid making it sensitive to LA. The additional amount of phospholipid in SCT Confirm neutralizes LA to give shorter clotting times.

Silica Clotting Time in the presence of calcium, directly activates the intrinsic pathway of coagulation. SCT Screen and SCT Confirm are therefore unaffected by factor VII deficiencies or inhibitors. Using a ratio of screen and confirm allows the SCT to be insensitive to warfarin treated samples. As a result, SCT Screen and SCT Confirm are more specific tests for the evaluation of LA than APTT or dilute PT. Per CLSI Guideline H-60, patient samples containing heparin may exhibit falsely prolonged clotting times which could lead to incorrect results.

Intended Use /Indication for Use

HemosIL Silica Clotting Time is intended for the detection of Lupus Anticoagulants in human citrated plasma on the IL Coagulation Systems by the use of screening (SCT Screen) and confirmatory (SCT Confirm) reagents sensitized to phospholipid dependent antibodies.

Reason Submission Qualifies as Special 510(k)

This Special 510(k) is being submitted to remove claims for the ACL Elite/Elite Pro from the HemosIL Silica Clotting Time labeling.

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 devices.
- No new performance data are needed to remove the assay claims on the ACL Elite/ACL Elite Pro.

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 remove all performance claims for the ACL Elite/Elite Pro

Comparison to Predicate		
Item	**Predicate Devices (K160445)**	**Subject Device**
Trade Names	HemosIL Silica Clotting Time	HemosIL Silica Clotting Time
Manufacturer	Instrumentation Laboratory Co.	Same
Similarities		
Product Code	GFO	Same
Regulation Section	21 CFR 864.7925	Same
Classification	Class II	Same
Intended Use/ Indications for Use	HemosIL Silica Clotting Time is intended for the detection of Lupus Anticoagulants in human citrated plasma on the IL Coagulation Systems by the use of screening (SCT Screen) and confirmatory (SCT Confirm) reagents sensitized to phospholipid dependent antibodies.	Same
Methodology	Clotting Time in the presence of reagents	Same
Composition	The HemosIL Silica Clotting Time kit consists of: • **SCT Screen**: 3 x 5 mL vials of a liquid preparation containing colloidal silica, buffer and preservative. • **SCT Confirm**: 3 x 5 mL vials of a liquid preparation containing colloidal silica, synthetic phospholipids, buffer and preservative. • **SCT $CaCl_2$**: 3 x 10 mL vials of Calcium Chloride (0.025 Mol/L) with polybrene and preservative.	Same
Controls (Sold Separately)	HemosIL Normal Control Assayed HemosIL LA Positive Control HemosIL LA Negative Control	Same
Sample Type	Citrated Plasma Samples	Same
Differences		
Claimed Instrumentation	ACL Elite/Elite Pro ACL TOP Family ACL TOP Family 50 Series ACL TOP Family 70 Series	ACL TOP Family ACL TOP Family 50 Series ACL TOP Family 70 Series **Claims for ACL Elite/Elite Pro Removed**

Conclusion
HemosIL Silica Clotting Time, with the removal of claims for the ACL Elite/Elite Pro, remains substantially equivalent to its legally marketed predicate device, HemosIL Silica Clotting Time, last FDA cleared under K160445.