July 24, 2025

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

Re: K251968
Trade/Device Name: HemosIL Fibrinogen-C; HemosIL Fibrinogen-C XL
Regulation Number: 21 CFR 864.7340
Regulation Name: Fibrinogen Determination System
Regulatory Class: Class II
Product Code: KQJ
Dated: June 26, 2025
Received: June 26, 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 -S

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)*
K251968

Device Name
HemosIL Fibrinogen-C
HemosIL Fibrinogen-C XL

Indications for Use *(Describe)*
For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Coagulation Systems.

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 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	June 26, 2025	
Device Trade Names	**Assay**	**Part No.**
	HemosIL Fibrinogen-C	0020301100
	HemosIL Fibrinogen-C XL	0020003900
Predicate Device and 510(k) Number	HemosIL Fibrinogen-C	K073367
Regulatory Information	**Assays**	
	Classification	Class II
	Classification Panel	Hematology (81)
	Regulation Section No.	21 CFR 864.7340
	Regulation Description	Fibrinogen determination system
	Product Code	KQJ

Device Description	**HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL**
	Several congenital abnormalities of fibrinogen result in impaired conversion of fibrinogen to fibrin during blood coagulation. Fibrinogen is also a useful marker in the evaluation of several disease states including disseminated intravascular coagulation, liver disease, inflammatory diseases and malignancy. High levels of fibrinogen are associated with an increased risk for cardiovascular disease. Increased levels are also found during pregnancy and oral contraceptive use, while reduced levels are found during thrombolytic therapy. The HemosIL Fibrinogen-C kit and HemosIL Fibrinogen-C XL kit use an excess of thrombin to convert fibrinogen to fibrin in diluted plasma. At high thrombin and low fibrinogen concentration, the rate of reaction is a function of fibrinogen concentration.
Intended Use / Indication for Use	**HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL**
	For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Coagulation Systems.

Reason Submission Qualifies as Special 510(k)

This Special 510(k) is being submitted to remove the reconstituted reagent frozen stability claim of 1 month at -20°C in the original vial for HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL.

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 reconstituted reagent frozen stability claim.

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 the reconstituted reagent frozen stability claim from the Instructions for Use and add "Do not freeze reconstituted reagent."
- Changes to assay algorithms or data reduction software

Comparison to Predicate		
Item	**Predicate Devices (K073367)**	**Subject Devices**
Trade Names	HemosIL Fibrinogen-C	HemosIL Fibrinogen-C HemosIL Fibrinogen-C XL
Manufacturer	Instrumentation Laboratory Co.	Same
Similarities		
Measurand	Fibrinogen	Same
Assay Type	Quantitative	Same
Product Code	KQJ	Same
Regulation Section	21 CFR 864.7340	Same
Classification	Class II	Same
Intended Use/ Indications for Use	For the quantitative determination of fibrinogen, based on the Clauss method, in human citrated plasma on IL Coagulation Systems.	Same
Methodology	Clauss method	Same
Composition	lyophilized bovine thrombin (35 UNIH/mL) with bovine albumin, calcium chloride, buffer and stabilizers.	Same
Calibrators (Sold Separately)	HemosIL Calibration Plasma	Same
Controls (Sold Separately)	HemosIL Normal Control Assayed HemosIL Low Abnormal Control Assayed HemosIL Low Fibrinogen Control	Same
Sample Type	Human citrated plasma	Same
Instrumentation	ACL Elite/ACL Elite Pro ACL TOP Family ACL TOP Family 50 Series ACL TOP Family 70 Series	Same
Differences		
Reconstituted Stability	**Current Insert Claim**	**Modified Insert Claim**
	1 month at -20°C in the original vial	Do not freeze reconstituted reagent

Conclusion
HemosIL Fibrinogen-C and HemosIL Fibrinogen-C XL remain substantially equivalent to their legally marketed predicate device, HemosIL Fibrinogen-C, last FDA cleared under K073367. This submission is limited in scope to the removal of the reconstituted reagent frozen stability claim and the addition of an instruction advising users not to freeze the reconstituted reagent.