March 22, 2018

Instrumentation Laboratory Co.
Carol Marble
Regulatory Affairs Director
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K180486
Trade/Device Name: HemosIL Factor XII Deficient Plasma
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GJT
Dated: February 22, 2018
Received: February 23, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Leonthena R. Carrington -S

Lea Carrington
Director
Division of Immunology
and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180486

Device Name
HemosIL Factor XII Deficient Plasma

Indications for Use *(Describe)*
HemosIL Factor XII Deficient Plasma is human plasma immunodepleted of factor XII and intended for the in vitro diagnostic quantitative determination of factor XII activity in citrated plasma, based on the activated partial thromboplastin time (APTT) assay, 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.

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

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Instrumentation Laboratory
A Werfen Company

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CER 807.92 and the Safe Medical Device Act of 1990.

Submission Type	Special 510(k)

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA

Contact Person	Carol Marble, Regulatory Affairs Director Phone: 781-861-4467 Fax: 781-861-4207 Email: cmarble@ilww.com

Preparation Date	February 22, 2018

Device Trade Name	HemosIL Factor XII Deficient Plasma

Regulatory Information	**Regulation Number**	21 CFR 864.7290
	Regulation Description	Factor Deficiency Test
	Classification	Class II
	Product Code	GJT
	Classification Panel	Hematology (81)

Predicate Device	K043459	HemosIL Factor XII Deficient Plasma

Device Description	Factor XII activity in a patient's plasma is determined by performing a modified activated partial thromboplastin time test (APTT). Patient plasma is diluted and added to plasma deficient in factor XII. Correction of the clotting time of the deficient plasma is proportional to the concentration (% activity) of that factor in the patient plasma, interpolated from a calibration curve.

Intended Use	Human plasma immunodepleted of factor XII for the quantitative determination of factor XII (FXII) activity in citrated plasma, based on activated partial thromboplastin time (APTT) assay, on IL Coagulation Systems.

Indications for Use	HemosIL Factor XII Deficient Plasma is human plasma immunodepleted of factor XII and intended for the *in vitro* diagnostic quantitative determination of factor XII activity in citrated plasma, based on the activated partial thromboplastin time (APTT) assay, on IL Coagulation Systems.

Description of the Modification	The on-board instrument claim in the HemosIL Factor XII Deficient Plasma insert sheet is being updated as follows based on additional testing done to current CLSI EP25-A requirements.	
	Current Claim: 24 Hours	Modified Claim: 6 Hours

Reason Submission Qualifies as Special 510(k)	The submission meets the criteria for a Special 510(k) based on the following: • No change in indications for use or intended use • No change in operating principle • No change to performance claims, *except* for the on-board stability • No change to reagent preparation • No change to specimen collection and preparation • No change to formulation or materials • No change to data reduction software • No change to calibration • No change to quality controls

Design Control Activities	The verification testing to establish the modified on-board instrument stability claim for HemosIL Factor XII Deficient Plasma was conducted under design control and in accordance with CLSI EP25-A.

Comparison to Predicate		
Similarities		
Item	**Predicate (K043459)**	**Modified Device**
Intended Use	Human plasma immunodepleted of factor XII for the quantitative determination of factor XII (FXII) activity in citrated plasma, based on activated partial thromboplastin time (APTT) assay, on IL Coagulation Systems.	Same
Indications for Use	HemosIL Factor XII Deficient Plasma is human plasma immunodepleted of factor XII and intended for the *in vitro* diagnostic quantitative determination of factor XII activity in citrated plasma, based on the activated partial thromboplastin time (APTT) assay, on IL Coagulation Systems.	Same
Measurand	Factor XII Activity	Same
Type of Test	Functional Clotting Assay	Same
Methodology	Abnormalities of the intrinsic pathway factors are determined by performing a modified activated partial thromboplastin time (APTT) test. Patient plasma is diluted and added to plasma deficient in factor XII. Correction of the clotting time of the deficient plasma is proportional to the concentration (% activity) of factor XII in the patient plasma, interpolated from a calibration curve.	Same
Sample Type	Citrated Plasma	Same
On-Board Instrument Stability with Following Analyzers	ACL TOP Family: • ACL TOP 300 CTS • ACL TOP 500 CTS • ACL TOP 700 • ACL TOP 700 CTS • ACL TOP 700 LAS ACL TOP Family 50 Series: • ACL TOP 350 CTS • ACL TOP 550 CTS • ACL TOP 750 • ACL TOP 750 CTS • ACL TOP 750 LAS	Same
Expected Value Range	50-150% (0.50-1.50 IU/mL)	Same
Differences		
On-Board Claim	24 Hours	6 Hours

Conclusion	HemosIL Factor XII Deficient Plasma and the currently marketed deficient plasma share the same Intended Use/ Indications for Use, same test principle, same formulation and the same performance characteristics, except for the updated on-board instrument claim for the ACL TOP Family and ACL TOP Family 50 Series. Therefore, HemosIL Factor XII Deficient Plasma with an updated on-board instrument claim is substantially equivalent to the currently marketed predicate device that is FDA cleared under K043459.