DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 27, 2016

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

Re: K160885
Trade/Device Name: HemosIL D-Dimer HS
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP
Dated: September 28, 2016
Received: September 29, 2016

Dear Ms. 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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Leonthena R. Carrington -S

Leonthena R. Carrington, MS, MBA, MT(ASCP)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160885

Device Name
HemosIL D-Dimer HS

Indications for Use *(Describe)*
HemosIL D-Dimer HS is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE).

For in vitro diagnostic use.

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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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	September 28, 2016

Device Trade Name	HemosIL D-Dimer HS

Regulatory Information	Classification:	Class II
	Regulation No.:	21 CFR 864.7320
	Common Name:	Fibrinogen and Fibrin split products, Antigen, Antiserum, Control
	Panel:	Hematology (81)
	Product Code:	DAP

Predicate Device	HemosIL D-Dimer HS	510(k) No.: K151534

Device Description	The D-Dimer HS Latex Reagent is a suspension of polystyrene latex particles of uniform size coated with the $F(ab')_2$ fragment of a monoclonal antibody highly specific for the D-Dimer domain included in fibrin soluble derivatives. The use of the $F(ab')_2$ fragment allows a more specific D-Dimer detection avoiding the interference of some endogenous factors like the Rheumatoid Factor. When a plasma containing D-Dimer is mixed with the Latex Reagent and the Reaction Buffer included in the D-Dimer HS kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

Device Indications for Use	HemosIL D-Dimer HS is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE). For *in vitro* diagnostic use.

Description of the Modification	The Limit of Detection (LoD) claim in the HemosIL D-Dimer HS insert sheet is being updated as follows based on additional testing done to current CLSI EP17-A2 requirements.	
	Current LoD Claim: 21 ng/mL	Updated LoD Claim: 137 ng/mL

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 labeled performance claims, *except* for the LoD claim based on an additional study • No change to stability claims or to storage instructions • 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 test parameters • No change to calibration

Design Control Activities	The verification testing to establish the updated Limit of Detection (LoD) claim for the HemosIL D-Dimer HS assay was conducted under design control and in accordance with CLSI EP17-A2. Per the Risk Management Report, the proposed change to the LoD claim does not introduce any additional risk and has no impact on the safety or effectiveness of the currently marketed device.

Comparison to Predicate:

Similarities		
Item	**Predicate (K151534)**	**Modified Device**
Intended Use	HemosIL D-Dimer HS is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on the ACL TOP Family and ACL TOP Family 50 Series for use, in conjunction with a clinical pretest probability (PTP) assessment model to exclude venous thromboembolism (VTE) in outpatients suspected of deep venous thrombosis (DVT) and pulmonary embolism (PE).	Same
Analyte	D-Dimer	Same
Methodology	Latex-enhanced immuoturbidimetric assay	Same
Claimed 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
Sample Type	Citrated Plasma	Same
Cut-off	230 ng/mL	Same
Linearity	150 – 69000 ng/mL	Same
Differences		
Detection Limit	21 ng/mL	137 ng/mL

Conclusion	HemosIL D-Dimer HS and the currently marketed assay share the same Intended Use/Indications for Use, same principles of operation, same formulation and comparable performance characteristics, except for the updated Limit of Detection (LoD) claim. Therefore, HemosIL D-Dimer HS with an updated LoD claim is substantially equivalent to the currently marketed predicate device FDA cleared under K151534.