DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 6, 2015

INSTRUMENTATION LABORATORY CO.
NIKITA MALLADI
REGULATORY AFFAIRS SPECIALIST
180 HARTWELL ROAD
BEDFORD, MA 01730

Re: K151534
Trade/Device Name: HemosIL D-Dimer HS
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: II
Product Code: DAP
Dated: June 5, 2015
Received: June 8, 2015

Dear Ms. Malladi:

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 regulations (21 CFR Parts 801 and 809), 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" (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.

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 yours,

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
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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)*

K151534

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

The submission meets the criteria for a Special 510(k) under the FDA guidance "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications".

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA
Contact Person	Nikita Malladi, Regulatory Affairs Specialist II Phone: 781-674-3245 Fax: 781-861-4207 Email: nmalladi@ilww.com
Preparation Date	June 5, 2015
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.: K070927
Device Indications for Use / 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 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.
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).

Comparison to Predicate:

This Special 510(k) is being submitted to add general information from peer-reviewed published literature to the Summary and Principle section of the HemosIL D-Dimer HS insert sheet regarding the association of patient age with D-Dimer levels.

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, including no change to the assay cut-off
- 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
- No change to quality controls

Following is a description of the similarities and differences between the currently marketed HemosIL D-Dimer HS (K070927) and HemosIL D-Dimer HS with the insert sheet modifications:

Similarities		
Item	**Predicate (K070927)**	**Modified 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 Family 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
Analyzers	ACL TOP Family	Same
Sample Type	Citrated Plasma	Same
Cut-off	230 ng/mL	Same
Linearity	150 – 69000 ng/mL	Same
Detection Limit	21 ng/mL	Same
Performance Claims	No change to labeled performance claims	

Comparison to Predicate (Cont.):

Differences		
Item	**Predicate (K070927)**	**Modified Device**
Insert Sheet Summary and Principle Section	Current insert language: Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC). D-Dimer levels also rise during the normal pregnancy, but very high levels are associated with complications.	Insert revisions in *italic*: Elevated levels of D-Dimer are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC). D-Dimer levels also rise *with age, and* during the normal pregnancy, but very high levels are associated with complications. *Further, age-adjusted cut-off values for DVT and PE suspicion have been shown to increase the specificity of D-Dimer and reduce the number of unnecessary imaging studies in patient populations greater than 50 years.* NOTE: Bibliography in insert updated with applicable supporting references.

Conclusion:

HemosIL D-Dimer HS, with the modified Summary and Principle insert section, is substantially equivalent to the legally marketed predicate device FDA cleared under K070927.