DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 16, 2016

Instrumentation Laboratory Co.
Ms. Heather L. Harvey
Regulatory Affairs Specialist I
180 Hartwell Road
Bedford, MA 01730

Re: K160445
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: February 16, 2016
Received: February 18, 2016

Dear Ms. Harvey:

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 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
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)*
K160445

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.

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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"(March 20, 1998).

Submitter's Information	Instrumentation Laboratory (IL) Co. 180 Hartwell Road Bedford, MA 01730, USA
Contact Person	Heather L Harvey, Regulatory Affairs Specialist I Phone: 781-861-4549 Fax: 781-861-4207 Email: hharvey@ilww.com
Preparation Date	March 8, 2016
Device Trade Name	HemosIL Silica Clotting Time
Regulatory Information	Classification: Class II Regulation No.: 21 CFR 864.7925 Common Name: Activated Partial Thromboplastin Panel: Hematology (81) Product Code: GFO
Predicate Device	HemosIL Silica Clotting Time 510(k) No.: K050221
Device Indications for Use / Intended 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. For *in vitro* diagnostic use.
Device Description	The HemoIL SCT assay, consisting of SCT Screen and SCT Confirm, is intended to simplify and standardize the detection of Lupus Anticoagulants (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.

Comparison to Predicate:

The HemosIL Silica Clotting Time insert sheet is being updated to remove the current Heparin interference references in the Summary and Principle section and the Limitations/ Interfering Substances section based on current guidance *H60-A Laboratory Testing for the Lupus Anticoagulant; Approved Guideline (April 2014)*, with the associated references added to the Bibliography section. There is no change to the assay itself.

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 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 Silica Clotting Time (K050221) and HemosIL Silica Clotting Time with the insert sheet modifications:

Similarities		
Item	**Predicate (K050221)**	**Modified Device**
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
Analyzers	ACL TOP® Family ACL Futura/ACL Advance ACL ELITE®/ELITE PRO 8/9/10000	Same
Sample Type	Citrated Plasma Samples	Same

Comparison to Predicate (Cont.):

Differences		
Item	**Predicate (K050221)**	**Modified Device**
Insert Sheet Summary and Principle Section	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. Heparin interference up to 0.4 U/mL is neutralized by polybrene. Using a ratio of screen and confirm allows the SCT to be insensitive to warfarin treated samples.	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. Per CLSI Guideline H-60, patient samples containing heparin may exhibit falsely prolonged clotting times which could lead to incorrect results.
Insert Sheet Limitations/ Interfering Substances Section	SCT Screen/SCT Confirm results on the ACL Futura/ACL Advance and ACL ELITE/ELITE PRO 8/9/10000 are not affected by bilirubin up to 30 mg/dL, triglycerides up to 500 mg/dL and Heparin up to 0.4 U/mL. Do not use hemolyzed samples. SCT Screen/SCT Confirm results on the ACL TOP Family are not affected by bilirubin up to 30 mg/dL, triglycerides up to 850 mg/dL, UF Heparin up to 0.5 U/mL and LMW Heparin up to 1.0 U/mL. Do not use hemolyzed samples. LA assays based on different properties appear to be more or less sensitive to certain subgroups of LAs. Therefore at least two screening assays, based on different properties, should be performed before the possibility of LA is excluded.	SCT Screen/SCT Confirm results on the ACL Futura/ACL Advance and ACL ELITE/ELITE PRO 8/9/10000 are not affected by bilirubin up to 30 mg/dL, triglycerides up to 500 mg/dL. Do not use hemolyzed samples. SCT Screen/SCT Confirm results on the ACL TOP Family are not affected by bilirubin up to 30 mg/dL, and triglycerides up to 850 mg/dL. Do not use hemolyzed samples. Per CLSI Guideline H-60, patient samples containing heparin may exhibit falsely prolonged clotting times which could lead to incorrect results. LA assays based on different properties appear to be more or less sensitive to certain subgroups of LAs. Therefore at least two screening assays, based on different properties, should be performed before the possibility of LA is excluded.

Conclusion:

HemosIL Silica Clotting Time, with the modified Summary and Principle and Limitations/ Interfering Substances insert sections, is substantially equivalent to the legally marketed predicate device FDA cleared under K050221.