August 19, 2020

Instrumentation Laboratory Co.
Nikita Malladi
Principal Regulatory Affairs Specialist
180 Hartwell Road
Bedford, Massachusetts 01730

Re: K200033
Trade/Device Name: HemosIL von Willebrand Factor Antigen
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GGP
Dated: July 17, 2020
Received: July 20, 2020

Dear Nikita 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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for Takeesha Taylor-Bell
Chief
Division of Immunology
and Hematology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200033

Device Name
HemosIL von Willebrand Factor Antigen

Indications for Use *(Describe)*
Automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (VWF:Ag) 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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Instrumentation Laboratory
A Werfen Company

510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 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	Nikita Malladi, Principal Regulatory Affairs Specialist Phone: 781-674-3245 Fax: 781-861-4207 Email: nmalladi@ilww.com

Preparation Date	August 4, 2020

Device Trade Name	HemosIL von Willebrand Factor Antigen

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

Predicate Device	K992704	HemosIL von Willebrand Factor Antigen

Device Description	The VWF:Ag kit is a latex particle enhanced immunoturbidimetric assay to quantify VWF:Ag in plasma. When a plasma containing VWF:Ag is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of VWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.

Intended Use/ Indications for Use	Automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (VWF:Ag) in human citrated plasma on IL Coagulation Systems.

Description of the Modification	The claim for Rheumatoid Factor in the "Limitations/Interfering substances" section of the HemosIL von Willebrand Factor Antigen insert sheet is being modified as follows:	
	Current Insert Claim	**Modified Insert Claim**
	The presence of Rheumatoid Factor may produce an overestimation of VWF:Ag results on ACL Family Systems. VWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 750 IU/mL.	VWF:Ag results on ACL Family Systems are not affected by Rheumatoid Factor up to 50 IU/mL. VWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 50 IU/mL.

Reason Submission Qualifies as Special 510(k)	This submission for the HemosIL von Willebrand Factor Antigen meets the criteria for a Special 510(k) outlined in the FDA guidance "*The Special 510(k) Program: Guidance for Industry and Food and Drug Administration Staff"* (September 13, 2019) based on the following: • The proposed change is submitted by the manufacturer legally authorized to market the existing device. • Performance data are unnecessary since the current Rheumatoid Factor claim in the HemosIL von Willebrand Factor Antigen insert is being replaced with a limitation and a supporting literature reference. In addition, the change described in this submission <u>does not</u> introduce: • Changes to indications for use or intended use • Changes to operating principle • Changes to assay formulation • Changes to analytical performance claims, ***except*** to Rheumatoid Factor interference claim • Changes to assay algorithms or data reduction software

Design Control Activities	The Rheumatoid Factor interference claim in the HemosIL von Willebrand Factor Antigen insert sheet is being modified to indicate that VWF:Ag results on ACL Family Systems, ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 50 IU/mL.

Comparison to Predicate		
Similarities		
Item	**Predicate (K992704)**	**Modified Device**
Intended Use	Automated latex enhanced immunoassay for the quantitative determination of von Willebrand Factor Antigen (VWF:Ag) in human citrated plasma on IL Coagulation Systems.	Same
Measurand	von Willebrand Factor Antigen	Same
Type of Test	Latex immunoassay	Same
Methodology	The VWF:Ag kit is a latex particle enhanced immunoturbidimetric assay to quantify VWF:Ag in plasma. When a plasma containing VWF:Ag is mixed with the Latex Reagent and the Reaction Buffer included in the kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of VWF:Ag in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates.	Same
Sample Type	Citrated Plasma	Same
Kit Composition	Latex Reagent: 2 vials x 3 mL of a suspension of polystyrene latex particles coated with a rabbit polyclonal antibody directed against VWF containing bovine serum albumin, buffer, stabilizer and preservative. Reaction Buffer: 2 vials x 4 mL of HEPES buffer containing bovine serum albumin, stabilizers and preservative.	Same

Differences		
	Current Insert Claim	**Modified Insert Claim**
Limitations/Interfering Substances	The presence of Rheumatoid Factor may produce an overestimation of VWF:Ag results on ACL Family Systems. VWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 750 IU/mL.	VWF:Ag results on ACL Family Systems are not affected by Rheumatoid Factor up to 50 IU/mL. VWF:Ag results on ACL TOP Family and ACL TOP Family 50 Series are not affected by Rheumatoid Factor up to 50 IU/mL.

Conclusion	HemosIL von Willebrand Factor Antigen and the currently marketed assay share the same Intended Use/Indications for Use, same operating principle, same formulation and comparable performance characteristics, except for the modified claim of no interference from Rheumatoid Factor up to 50 IU/mL. Therefore, HemosIL von Willebrand Factor Antigen with a modified Rheumatoid Factor interference claim is substantially equivalent to the currently marketed predicate device FDA cleared under K992704.