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

June 3, 2016

Maine Standards Company LLC
Mr. James W. Champlin
Manager, QA & RA
221 US Route 1
Cumberland Foreside, ME 04110

Re: K152961
Trade/Device Name: VALIDATE® D-Dimer Calibration Verification/Linearity Test Kit
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: May 4, 2016
Received: May 5, 2016

Dear Mr. Champlin:

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 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" (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
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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)*
K152961

Device Name
VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit

Indications for Use *(Describe)*
VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit solutions are an assayed quality control materials intended for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte: D-Dimer in a clinical laboratory setting by laboratory personnel. The product is intended for use with quantitative assays on the indicated analyzers specified in the labeling.

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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510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

The assigned 510(k) number is: K152961

A. Submitter:

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Contact Person:
James Champlin
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Telephone: 207-892-1300 Ext. 29

Date of Summary Preparation:
May 31, 2016

B. Device Classification:

Device classification name:	Plasma, Coagulation Control
Common name:	Calibration Verification / Linearity Test Kit
Proprietary Name:	VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit
Review Panel:	Hematology (81)
Regulation Number:	21 CFR 864.5425
Product Code:	GGN
Regulatory Class:	Class II

C. Predicate Device Identification:
Audit MicroCV D-Dimer Linearity Set,
AALTO Scientific Ltd, 1959 Kellog Ave., Carlsbad, CA 92008
K100716

D. Candidate Device description: Each VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit contains one analyte set of D-Dimer in a human plasma base matrix. The kit includes a set containing five liquid levels, 3.0 mL each. The set is provided to establish the relationship between theoretical and actual performance of the included analyte D-Dimer. Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA approved methods and was found to be non-reactive for HBsAG and to antibodies to HCV and HIV-1/2.

E. Intended use:
VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit solutions are an assayed quality control materials intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte: D-Dimer in a clinical laboratory setting by laboratory personnel. The product is intended for use with quantitative assays on the indicated analyzers specified in the labeling.

F. Summary of Performance Data:
The performance of the new VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit was compared to the predicate device k100716, Audit MicroCV D-Dimer Linearity Set.

Table 1 compares the technical characteristics of the new VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit with those of the predicate: Audit MicroCV D-Dimer Linearity Set.

Table 1 – Technical Comparison to Predicate

	New Device VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit	**Predicate (k100716)** Audit MicroCV D-Dimer Linearity Set
Similarities		
Test Kit	Calibration Verification/Linearity Test Kit	Same
Intended Use	For *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated instrument systems	Same
Analytes	D-Dimer	Same
Stability	Until expiration date	Same
Matrix	Human plasma base	Same
Number of Levels	5 levels	Same
Differences		
Preparation	Liquid, ready to use	Lyophilized
Storage	-10 to -25°C	2-8°C

Value Assignment
VALIDATE® D-Dimer Calibration Verification / Linearity Test Kits are manufactured such that an equal relationship exists among Levels 1 through 5; Level 1 being the lowest concentration and Level 5 being the highest. Levels 1 and 5 are prepared independently by the addition of D-Dimer to a human plasma base matrix. Levels 1 through 5 must meet specified D-Dimer target ranges at all stages of testing.

Specific recovery targets for Levels 1 through 5 are determined by the upper and lower detection limits for D-Dimer. Intermediate Levels 2, 3, and 4 are subsequently prepared from Levels 1 and 5 by equal part dilutions following EP6-A guidelines. Typical value ranges are provided in the package insert.

Typical recovery values, presented in Table 1, were established for Level 1 and Level 5 by testing 30 replicates, with values for Mid-Levels 2, 3, and 4 calculated based on an equal distance (delta) between levels.

The product is designed for laboratories to satisfy the requirements for calibration verification and verification of the systems reportable range as specified in the current CLIA regulations section 493.1255.

Table 1

Instrument	Analyte	Units	Levels				
			1	2	3	4	5
IL TOP®	D-Dimer	ng/mL DDU	191	966	1741	2515	3290

A linear relationship exists between each level in a kit. The quantitative determination of linearity, calibration verification, and verification of reportable range relies on the known relationship between each of the levels of the product, in this case equal deltas, as outlined in the CLSI EP6-A referenced standard.

This kit is not intended for use as a routine calibration material.

VALIDATE® D-Dimer calibration verification / linearity test kit is available in a product configuration formulated to validate and maximize reportable ranges of the test system, while minimizing the need for manual dilutions.

Precision/Reproducibility

Precision was evaluated on the Instrument Laboratory (IL) TOP® instrument system with the VALIDATE® D-Dimer product following the product package insert instructions. Three lots of VALIDATE® D-Dimer product, were tested with one lot of IL system HemosIL D-Dimer reagent and quality controls on the TOP® instrument system over 20 days, 2 runs per day, 2 replicates per run for Level 1 through Level 5 with a minimum of two operators to obtain a total of eighty (80) replicates per kit Level. All levels of the VALIDATE® D-Dimer kit met the acceptance criteria of $\leq$ 10% CV on the IL TOP® instrument system.

Reproducibility was evaluated on the Instrument Laboratory (IL) TOP® instrument system with the VALIDATE® D-Dimer kit containing 5 levels following the product package insert instructions. One lot of VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit was tested with one lot of IL HemosIL D-Dimer reagent and quality controls on three instruments, multi-site, over 5 days, with 1 run per day of Level 1-5, 5 replicates per run and a minimum of three operators to obtain seventy-five (75) replicates per kit level. All levels of the VALIDATE® D-Dimer kit met the acceptance criteria of $\leq$ 10% CV on the IL TOP® instrument system.

Traceability

This product is traceable to a reference standard based on the automated instrument platform it is used on. The traceability of our product will be established per the respective end user automated instrument calibrator traceability reference statement.

Stability

Stability testing was performed using the Instrumentation Laboratory TOP® instrument system. The study testing time points included date of manufacture (DOM), followed by testing at specific intervals post manufacture. Acceptance criteria are defined as 90 to 110% of DOM value.

A freeze-thaw vial stability assessment was also conducted with three lots in support of the product package insert four (4) freeze-thaw open vial events claim. All product levels tested within the 90 to 110% of control acceptance criteria limits after 6 freeze-thaw vial events.

Shelf Life Claim: Stability of the VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit was set at 9 months based on available real-time stability studies with three lots. Real time stability studies are ongoing to support an extended stability claim. The recommended storage temperature is -10 to -25ºC. All supporting data is retained on file at Maine Standards Company LLC.

Linearity:
Linearity testing was carried out with the new device VALIDATE® D-Dimer Calibration Verification / Linearity Test Kits Instrumentation Laboratory TOP® instrument system. Product linearity performance was demonstrated for the automated system. All supporting data is retained on file at Maine Standards Company LLC.

G. Conclusion:
Based upon the purpose of the device, the descriptions and labeling of the predicate device, the VALIDATE® D-Dimer Calibration Verification / Linearity Test Kit behaves substantially equivalent to the predicate for the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte: D-Dimer. The product is substantially equivalent to the predicate device, k100716, Audit MicroCV D-Dimer Linearity Set.