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

March 16, 2017

Maine Standards Company LLC
Mr. James Champlin
Director, QSHIE
221 US Route 1
Cumberland Foreside, Maine 04110

Re: K163498
Trade/Device Name: Validate® Heparin 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: February 14, 2017
Received: February 15, 2017

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), 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

Lea 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)*
K163498

Device Name
VALIDATE® Heparin Calibration Verification / Linearity Test Kit

Indications for Use *(Describe)*
VALIDATE® Heparin Calibration Verification / Linearity Test Kit solutions are assayed quality control materials intended for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for Heparin Anti-Xa activity on automated instruments in a clinical laboratory setting by laboratory personnel. The product is intended for use on the IL ACL TOP® analyzer.

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: K163498

A. Submitter:

Maine Standards Company LLC
221 US Route 1
Cumberland Foreside, ME 04110
Telephone: 207-892-1300
Fax: 207-892-2266

Contact Person:
James Champlin
Director, QSHIE
jchamplin@mainestandards.com
Telephone: 207-892-1300 Ext. 29

Date of Summary Preparation:
February 14, 2017

B. Device Classification:

Device classification name:	Plasma, Coagulation Control
Common name:	Calibration Verification / Linearity Test Kit
Proprietary Name:	VALIDATE® Heparin 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:
K090209, HemosIL® Liquid LMW/UF Heparin Controls, Instrumentation Laboratory

D. Candidate Device description: Each VALIDATE® Heparin Calibration Verification / Linearity Test Kit contains one analyte set of Heparin 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 Heparin Anti-X activity. 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® Heparin Calibration Verification / Linearity Test Kit solutions are assayed quality control materials intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for Heparin Anti-Xa activity on automated instruments in a clinical laboratory setting by laboratory personnel. The product is intended for use on the IL ACL TOP 500® analyzer.

F. Summary of Performance Data:
The performance of the new VALIDATE® Heparin Calibration Verification / Linearity Test Kit was compared to the predicate device k09209, HemosIL® Liquid LMW/UF Heparin Controls.

Table 1 summarizes the comparison of the new VALIDATE® Heparin Calibration Verification / Linearity Test Kit device to the predicate device.

Table 1 – Comparison to Predicate

	New Device VALIDATE® Heparin Calibration Verification / Linearity Test Kit	**Predicate (k09209)** HemosIL® Liquid LMW/UF Heparin Controls
Similarities		
Intended Use	For *in vitro* diagnostic use with HemosIL® reagents on the IL ACL TOP 500 instrument	Same
Test Kit	Assayed quality control	Same
Matrix	Human plasma base	Same
Number of Levels	5 levels	Same
FDA product Code	GGN	Same
Differences		
Analytes	Heparin Anti-Xa activity	LMW/UFH Heparin

Value Assignment
VALIDATE® Heparin 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 Heparin to a human plasma base matrix. Levels 1 through 5 must meet specified Heparin Anti-Xa 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 Heparin Anti-Xa. 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 2, 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 2- Typical Recovery Values

Set							
			Levels				
Instrument	Analyte	Units	1	2	3	4	5
IL ACL TOP 500®	Heparin Anti-Xa	IU/mL	0.11	0.52	0.94	1.36	1.77

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 calibration material.

Precision/Reproducibility

Precision was evaluated on the Instrumentation Laboratory (IL) IL ACL TOP 500® instrument system with the VALIDATE® Heparin product following the product package insert instructions. Three lots of VALIDATE® Heparin product were tested with one lot of IL HemosIL® Liquid Anti-Xa reagent and quality controls on one IL ACL TOP 500® 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® Heparin kit met the CV% acceptance criteria on the IL ACL TOP 500® instrument system.

Reproducibility was evaluated on the IL ACL TOP 500® instrument system with the VALIDATE® Heparin kit containing 5 levels following the product package insert instructions. One lot of VALIDATE® Heparin Calibration Verification / Linearity Test Kit was tested with one lot of IL Heparin HemosIL® 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® Heparin kit met the CV% acceptance criteria on the IL ACL TOP 500® instrument system.

Traceability

This product is traceable to a reference standard based on the automated instrument platform it is used on. The traceability of this product will be established per the respective end user automated instrument method calibrator traceability reference statement. The VALIDATE® Heparin kit is traceable through the IL HemosIL® calibrator to the 5th International WHO Standard 97/578 for UF heparin and the 2nd International WHO Standard 01/608 for LMW heparin.

Stability

Stability testing on four product lots was performed using the IL ACL TOP 500® 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/open vial stress stability assessment was also conducted in support of the product package insert two (2) freeze-thaw open vial events claim. All product levels tested within the acceptance criteria limits after 2 freeze-thaw vial events.

Shelf Life Claim: Stability of the VALIDATE® Heparin Calibration Verification / Linearity Test Kit was set at 5 months based on available real-time stability studies. 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® Heparin Calibration Verification / Linearity Test Kits on the Instrumentation Laboratory IL ACL TOP 500® coagulation instrument. Product linearity performance was demonstrated for this 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® Heparin Calibration Verification / Linearity Test Kit behaves substantially equivalent to the predicate device, K090209, HemosIL® Liquid LMW/UF Heparin Controls.