K133550

FEB - 5 2014

## 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: K133550.

**A. Submitter:**

Maine Standards Company LLC
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Cumberland Foreside, ME 04110
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Contact Person:
James Champlin
Manager, Quality Assurance & Regulatory Affairs
Telephone: 207-892-1300 Ext. 29

Date of Summary Preparation:
December 6, 2013

**B. Device Classification:**

| | |
|---|---|
| Device classification name: | Quality control material (assayed and un-assayed)* |
| Common name: | Calibration Verification / Linearity Test Kit |
| Proprietary Name: | VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit |
| Review Panel: | Clinical Chemistry |
| Regulation Number: | 21 CFR 862.1660 |
| Product Code: | JJX* |

*Note: *There is no FDA product code for calibration verification / linearity materials. Therefore, as with previous submissions by Maine Standards Company and other calibration verification / linearity manufacturers, JJX was selected as the "best fit" FDA code for this product.*

Regulatory Class: Class I

**C. Predicate Device Identification:**
VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit
Maine Standards Company LLC, Cumberland Foreside, ME 04110.
510(k) Number: K013119

**D. Candidate Device description:** Each VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit contains purified chemicals in a human serum base. Five liquid levels, 3.0mL each, ranging from 0.5 to 2000 ng/mL typical values, are provided to establish the relationship between theoretical and actual performance of the included analyte ferritin. 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® FERRITIN Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte, ferritin, on automated instrument systems. 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® FERRITIN Calibration Verification / Linearity Test Kit was compared to the predicate device K013119,VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit. Table 1 compares the technical characteristics of the new VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit with those of the predicate VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit.

**Table 1 – Technical Comparison to Predicate**

| | **New Device** VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit | **Predicate (K013119)** VALIDATE® Chem 6 Calibration Verification / Linearity Test Kit |
|---|---|---|
| **Similarities** | | |
| Test Kit | Calibration Verification Test Kit | Same |
| Number of analytes | One analyte | One analyte |
| Preparation | Liquid, ready to use | Liquid, ready to use |
| Stability | Until expiration date | Until expiration date |
| **Differences** | | |
| Intended Use | For *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated instrument systems | For *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems |
| Matrix | Human serum base | Aqueous |
| Number of Levels | 5 levels | 5 levels plus a level zero |
| Analytes | Ferritin | Uric Acid |
| Packaging | 3.0 mL each level | 5.0 mL each level |
| Storage | -10 to -25°C | 2 to 8°C |

Value Assignment
VALIDATE® FERRITIN Calibration Verification / Linearity Test Kits are manufactured such that a 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 ferritin to a human serum base. Specific recovery targets for Levels 1 and 5 are determined by the upper and lower detection limits for the intended analyzers. 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 value ranges for the each level of the linearity set on representative Roche Cobas 6000 and Beckman Access instruments are summarized in the table below.

| **Instrument Typical Recovery Values ng/mL** | | | | | |
|---|---|---|---|---|---|
| **Instrument** | **Level 1** | **Level 2** | **Level 3** | **Level 4** | **Level 5** |
| **Cobas 6000** | 2.5 | 438 | 887 | 1334 | 1864 |
| **Beckman Access** | 1.5 | 342 | 720 | 1026 | 1472 |

The VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit is tested on an analyzer to confirm adequate recovery across all levels. Levels 1 through 5 must meet specified ferritin target ranges at all stages of testing.

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 EP6A referenced standard) not on an expected value. As such, the product use is not limited to a particular instrument system. Expected target values may change depending on instrumentation, methodology, and assay temperature.

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 Beckman Coulter® Access II and Roche COBAS 6000 instrument systems. The study testing time points included date of manufacture (DOM), followed by testing at specific intervals post manufacture. The last testing event is one month post-expiration. Acceptance criteria are defined as 90 to 110% of DOM value for product levels 2-5.

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

Shelf Life Claim: Stability of the VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit was set at 12 months based on real-time open vial studies as a worst case scenario. The recommended storage temperature is -10 to -25°C. All supporting data is retained on file at Maine Standards Company LLC.

Linearity:
Linearity testing was carried out on DOM through Day 431 with the candidate device VALIDATE® FERRITIN Calibration Verification / Linearity Test Kits using a Roche® Cobas 6000 Chemistry Analyzer and Beckman-Coulter® Access II Immunochemistry Analyzer (instrument of manufacture). Product linearity performance was demonstrated for 431 days (14 months) for both automated systems. 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® FERRITIN Calibration Verification / Linearity Test Kit behaves substantially equivalent to the predicate for the evaluation of calibration verification, verification of reportable range. The product is substantially equivalent to the predicate device k013119.

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

February 5, 2014

MAINE STANDARDS COMPANY, LLC
JAMES CHAMPLIN
MANAGER, QA AND RA
221 US ROUTE 1
CUMBERLAND FORESIDE ME 04110

Re: K133550
Trade/Device Name: VALIDATE FERRITIN Calibration Verification/ Linearity Test Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJX
Dated: December 19, 2013
Received: January 7, 2014

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 regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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 on last page.*

510(k) Number *(if known)*
k133550

Device Name
VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit

Indications for Use *(Describe)*

VALIDATE® FERRITIN Calibration Verification / Linearity Test Kit solutions are intended for in vitro diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range for the following analyte, ferritin, on automated instrument systems. 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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