maine standards COMPANY

JUN 25 2009

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: K091225

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Holly Cressman

Summary prepared on: April 17, 2009

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and un-assayed)*

Proprietary Name: VALIDATE® GC1 Calibration Verification / Linearity Test Set
VALIDATE® GC2 Calibration Verification / Linearity Test Set
VALIDATE® GC3 Calibration Verification / Linearity Test Set
VALIDATE® GC4 Calibration Verification / Linearity Test Set

Regulation Number: 21 CFR 862.1660
Product Code: JJY*

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

Regulatory Class: Class I

Predicate Devices:

VALIDATE® Chem 1 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 2 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 3 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 4 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 5 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 6 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.
VALIDATE® Chem 7 Calibration Verification / Linearity Test Set, Maine Standards Company, Windham, ME.

**Note: The VALIDATE® CHEM 4 K012120 that was filed contained the following analytes: ALT, AST, CK, LD, ALP, AMY, GGT, LIP, TBIL, and DBIL. Later, the TBIL and DBIL analytes were split off into a stand alone product called VALIDATE® CHEM 5.

Device description: VALIDATE® GC Calibration Verification / Linearity Test Sets are human and aqueous based calibration verification materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. There exists a linear relationship among each set of solutions.

Intended use: Validate® GC Calibration Verification / Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached 510k submission for the list of all analytes claimed.

Summary:
The VALIDATE® GC Calibration Verification / Linearity Test Sets behave in a manner suitable for the evaluation of calibration verification, verification of reportable range, and the linear response of the listed analytes over the ranges tested when compared to the predicate devices. VALIDATE® GC Calibration Verification / Linearity Test Sets are as safe, as effective, and perform as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2009

Maine Standards Company
c/o Ms. Holly A. Cressman
Manager QA/RA
765 Roosevelt Trail
Windham, ME 04062

Re: k091225
Trade/Device Name: VALIDATE GC1 Calibration Verification/Linearity Test Set, GC2 Calibration Verification/Linearity Test Set, GC3 Calibration Verification/Linearity Test Set and GC4 Calibration Verification/Linearity Test Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: April 17, 2009
Received: April 27, 2009

Dear Ms. Cressman:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K091225

Device Name:

VALIDATE® GC1 Calibration Verification / Linearity Test Set
VALIDATE® GC2 Calibration Verification / Linearity Test Set
VALIDATE® GC3 Calibration Verification / Linearity Test Set
VALIDATE® GC4 Calibration Verification / Linearity Test Set

Indication For Use:

Validate® GC Calibration Verification / Linearity Test Sets are intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range in automated, semi automated, and manual chemistry systems. See attached Package Insert labeling for all analytes claimed.

Prescription Use ___X___ And/Or Over the Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091225