maine standards COMPANY LLC

MAR 2 3 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: K083891"

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
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Contact: Holly A. Cressman, Mgr. QA/RA

Summary prepared on: December 19, 2008

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and un-assayed)
Proprietary Name: VALIDATE® THY Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Product Code: JJY
Regulatory Class: Class I

Predicate Device:
VALIDATE® THY Calibration Verification Test Set (K062501), Maine Standards Company Windham, Maine

Device description: VALIDATE® THY Calibration Verification Test Sets are human serum based calibration verification / linearity materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. Each test set consists of one bottle each of Levels 1 through 5. One bottle of Base Matrix is also included. There exists a linear relationship among Levels 1 through 5.

Intended use: Each VALIDATE® THY Calibration Verification / Linearity Test Set consists of two sets of bottles, a THY Set and a FT4 Set. The THY set consists of five (5) levels of the following four analytes: triiodothyronine (T3), thyroxine (T4), human thyroid stimulating hormone (TSH), and cortisol, and the FT4 set consists of five (5) levels containing Free T4.

VALIDATE® THY Calibration Verification / Linearity Test Set solutions 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.

Summary:
The information provided in this pre-market notification demonstrates that the performance of VALIDATE® THY Calibration Verification Test Sets is substantially equivalent in form and function to the predicate device for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 3 2009

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

Re: k083891
Trade/Device Name: VALIDATE® THY Calibration Verification 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: February 17, 2009
Received: February 17, 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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

Indications for Use

510(k) Number: K083891

Device Name: VALIDATE® THY Calibration Verification Test Set

Indications For Use:

Each VALIDATE® THY Calibration Verification / Linearity Test Set consists of two sets of bottles, a THY Set and a FT4 Set. The THY set consists of five (5) levels of the following four analytes: triiodothyronine (T3), thyroxine (T4), human thyroid stimulating hormone (TSH), and cortisol, and the FT4 set consists of five (5) levels containing Free T4.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K083891