OCT 15 2004

maine standards COMPANY

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: **K041975**."

Submitter: Maine Standards Company
Address: 765 Roosevelt Trail
Windham, ME 04062
Telephone: 207-892-1300
Fax: 207-892-2266
Contact: Christine Beach, Dir. RA/QA

Summary prepared on: July 14, 2004

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

Predicate Device:

1. Chem 4 Calibration Verification Test Set (K012120), manufactured by Maine Standards Company, Windham, ME.

Device description: VALIDATE Lipoprotein Calibration Verification Test Set is a human protein serum based calibration verification test set containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. Each set contains one bottle each of six (6) levels, including zero. Each bottle contains 5 milliliters. There exists a linear relationship among each set of solutions.

Intended use: VALIDATE Lipoprotein Calibration Test Set is intended for *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity on clinical chemistry for the following analytes: cholesterol, HDL-cholesterol, LDL-cholesterol, Apolipoprotein A (Apo-A), and Apolipoprotein B (Apo-B).

Comparison of VALIDATE Lipoprotein Calibration Verification Test Set to the VALIDATE Chem 4 Calibration Verification Test Set:

The VALIDATE Lipoprotein Calibration Verification Test Set is substantially equivalent to the VALIDATE Chem 4 Calibration Verification Test Set (K012120) also manufactured by Maine Standards Company and previously cleared by the FDA, for its stated use.

	VALIDATE Lipoprotein Calibration Verification Test Set	**VALIDATE Chem 4 Calibration Verification Test Set**
Intended Use	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.
Analytes	CHOL, HDL, LDL, Apo-A, Apo-B	ALP, ALT, AMY, AST, CK, GGT, LD, LIP, TBIL, DBIL
Matrix	human serum	protein
Number of Levels	6 including zero	6 including zero
Preparation	Liquid, ready to use	Liquid, ready to use
Packaging	5.0 mL each level	5.0 mL each level
Stability	Until Expiration	Until Expiration
Storage	-10 to -20°C	-10 to -20°C

Summary:

The information provided in this pre-market notification demonstrates that the performance of VALIDATE Lipoprotein Calibration Verification Test Set is substantially equivalent in form and function to VALIDATE Chem 4 Calibration Verification Test Set (K012120) for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 15 2004

Ms. Christine Beach
Director QA/RA
Maine Standards Co.
765 Roosevelt Trail
Windham, ME 04062

Re: k041975
Trade/Device Name: VALIDATE® Lipoprotein Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: July 22, 2004
Received: July 22, 2004

Dear Ms. Beach:

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K041975

Device Name: VALIDATE® Lipoprotein Calibration Verification Test Set

Indications for Use:

The VALIDATE Lipoprotein Calibration Verification Test Set is used by trained laboratory professionals for the quantitative determination of linearity, calibration verification and verification of reportable range in manual, semi-automated and automated clinical chemistry systems for the following analytes: cholesterol, HDL cholesterol, LDL cholesterol, Apolipoprotein A, and Apolipoprotein B.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-The-Counter Use

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Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041975