maine standards COMPANY LLC

NOV 2 0 2001

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: K013265."

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

Summary prepared on: September 27, 2001

Proprietary Name: VALIDATE Chem 7 Calibration Verification Test Set
Common Name: Calibration Verification
Classification Name: Calibrator, Multi-Analyte

Predicate Devices:

1. **DOCUMENT** Iron/Magnesium/Triglyceride CAL-VER, K893142, manufactured by CASCO NERL Diagnostics.
2. **DOCUMENT** Multi-Analyte CAL-VER, K870252, manufactured by CASCO-NERL Diagnostics.
3. **DOCUMENT** Ammonia/Ethanol CAL-VER, K962629, manufactured by CASCO-NERL Diagnostics.

Device description: VALIDATE Chem 7 Calibration Verification Test Set is an aqueous 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.

Intended use: VALIDATE Chem 7 Calibration Test Set is intended for *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the following analytes: iron, creatinine, ammonia, and ethanol.

Comparison of VALIDATE Chem 7 Calibration Verification Test Set to the predicate devices:

Table 1 compares characteristics of the VALIDATE Chem 7 Calibration Verification Test Set with those of the DOCUMENT Iron/Magnesium/Triglyceride CAL•VER, DOCUMENT Multi-Analyte CAL•VER, and DOCUMENT Ammonia/Ethanol CAL•VER.

TABLE 1. Comparison of Products

	VALIDATE CHEM 7 Calibration Verification Test Set	**DOCUMENT Iron, Magnesium, Triglyceride CAL•VER**	**DOCUMENT Multi-Analyte CAL•VER**	**DOCUMENT Ammonia / Ethanol CAL•VER**
Catalog #	10007	M-103	M-100	M-108
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 the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For *in vitro* diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.
Analytes	FE, CRE, NH_3, ETOH	FE, MG, TRIG	GLU, BUN, NA, K, CL, CRE, CA, PO_4	NH_3, ETOH
Matrix	aqueous	aqueous	aqueous	aqueous
Number of Levels	6 including Zero	5	5	5
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	5.0 mL each level	10.0 mL each level	15 mL each level	3.0 mL each level
Stability	Until Expiration	Until Expiration	Until Expiration	Until Expiration
Storage	2-8°C	2-8°C	18-25°C	2-8°C

The performance of VALIDATE Chem 7 Calibration Verification Test Set solutions on the Beckman CX instrument system as compared to DOCUMENT Iron/Magnesium/Triglyceride CAL•VER, DOCUMENT Multi-Analyte CAL•VER, and DOCUMENT Ammonia/Ethanol CAL•VER has been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 7 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 7 Calibration Verification Test Set and the predicate device are presented in Table 2.

TABLE 2. Linear Regression Statistical Comparison of VALIDATE Chem 7 Calibration Verification Test Set to the predicate devices.

	VALIDATE Chem 7 Calibration Verification Test Set		DOCUMENT Iron, Magnesium, Triglyceride CAL•VER	
Analyte	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**
FE	0.99997	.327 + 1.001X	0.99979	-5.539 + 1.007X

	VALIDATE Chem 7 Calibration Verification Test Set		DOCUMENT Multi-Analyte CAL•VER	
Analyte	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**
CRE	0.99952	.091 + .983X	0.99987	-.099 + 1.007X

	VALIDATE Chem 7 Calibration Verification Test Set		DOCUMENT Ammonia/Ethanol CAL•VER	
Analyte	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**	**Correlation Coefficient (r)**	**Regression Equation Y = intercept + slope(X)**
NH3	0.99994	-.363 + 1.019X	0.99809	-11.616 + 1.074X
ETOH	0.99998	-.159 + 1.009X	0.99872	-1.261 + 1.04X

Summary:

Linear regression analysis was carried out on recovered values for iron, creatinine, ammonia, and ethanol. The analytes were tested in triplicate. The VALIDATE Chem 7 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Iron/Magnesium/Triglyceride CAL•VER, DOCUMENT Multi-Analyte CAL•VER, and DOCUMENT Ammonia/Ethanol CAL•VER.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

NOV 2 0 2001

Re: k013265
Trade/Device Name: VALIDATE Chem 7 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: September 27, 2001
Received: October 1, 2001

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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number: K013265

Device Name: VALIDATE Chem 7 Calibration Verification Test Set

Indications for Use:

The VALIDATE Chem 7 Calibration Verification Test Set is used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the following analytes: iron, creatinine, ammonia, and ethanol.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013265

Concurrence of CDRH, Office of Device Evaluation (ODE)

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