JAN 3 1 2003

510(k) Summary
for Thermo ALKO Calibration Packs for use on Equivalent AVL 9100 Series Electrolyte Analyzers

1. Submitter's Name and Address:

Thermo Orion, Inc.
Thermo ALKO
500 Cummings Center
Beverly, MA 01915

Contact Person:

Patrick K. Chiu
Quality Assurance Manager
Thermo ALKO products
(978) 232-6054

Date of Preparation: November 12, 2002

2. Device Identification:

Proprietary name/Trade name:	Calibration Pack
Common or usual name:	Calibration Standards for Electrolyte (ISE) Analyzers
Classification name:	Calibrator, Multi-Analyte Mixture
Device Classification:	II
Regulation Number:	21 CFR 862.1150
Panel:	Clinical Chemistry (75)
Product Code:	JIX

3. Substantial Equivalence:

Thermo ALKO Calibration Packs, Product No. A9100-101S and A9100-103S, are claimed to be substantially equivalent to AVL ISE SnapPak™, Product Number BP5016 and BP5186, respectively, (encompassed in the 510(k) under the device name "AVL 9180 Electrolyte Analyzer", 510(k) number K961458 previously cleared by the FDA on 06/12/1996), manufactured and distributed by Roche Diagnostics (AVL Scientific).

4. Device Description:

Thermo ALKO Calibration Packs are intended for use on equivalent Roche/AVL 9100 Series Analyzers. Calibration Pack, Product No. A9100-101S, contains Standard A, Standard B, Reference Solution and a waste container. It is intended for calibration of equivalent Roche/AVL 9120 and 9130 Analyzers. Calibration Pack, Product No. A9100-103S, contains Standard A, Standard B, Standard C, Reference Solution and a waste container. It is intended for calibration of equivalent Roche/AVL 9180 and 9181 Analyzers.

AVL Scientific, a trade name owned by Roche Diagnostics, is the original equipment manufacturer (OEM) of the analyzers and of predicate device (ISE SnapPak™) which is necessary for the continued operation and use of the analyzers. The Roche/AVL 9100 Series Analyzers perform electrolyte tests wherein samples are analyzed for the quantitative determinations of electrolytes by Ion Selective Electrode (ISE) method. Both Roche/AVL 9120 and 9130 Analyzers can measure Na^+ and K^+ with the exception that the Roche/AVL 9130 also measures Cl^- in addition to Na^+ and K^+. Both Roche/AVL 9180 and 9181 Analyzers can measure Na^+, K^+, Cl^-, Ca^{++}, and Li^+ with the exception that the Roche/AVL 9181 has an added autosampler.

Thermo ALKO Calibration Packs are intended to be used with equivalent Roche/AVL Analyzers. As such, Thermo Orion (Thermo ALKO) products are intended to serve as direct replacements to like named products manufactured and distributed by Roche Diagnostics (AVL Scientific).

Thermo Orion (Thermo ALKO) uses a similar composition, description and packaging design as that used by Roche Diagnostics (AVL Scientific) in its products. Thermo Orion (Thermo ALKO) has shown performance equivalence of its products to the Roche Diagnostics (AVL Scientific) products in the following manner:

- Through a method comparison where results are obtained on equivalent Roche/AVL Analyzers, calibrated with Thermo Orion (Thermo ALKO) products and are compared with results obtained on the same Analyzers calibrated with Roche Diagnostics (AVL Scientific) products; and
- Through a precision study where Thermo Orion (Thermo ALKO) products were installed on equivalent Roche/AVL Analyzers and samples were measured in multiple runs over a defined period.

A summary of the results of these studies follows:

5. Performance Characteristics:

Thermo ALKO Calibration Pack, Product Number A9100-101S:

Precision Data

Precision data were collected from the analysis of two levels of human serum based materials in duplicate per run on an AVL 9130 analyzer over a period of 23 days calibrated with Thermo ALKO Calibration Pack.

Level	Analyte	Ttl Runs	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na^+	25	116.4	0.63	0.54	0.34	0.29
	K^+	25	2.71	0.055	2.03	0.017	0.62
	Cl^-	25	103.6	1.24	1.20	0.32	0.31
Level 2	Na^+	25	149.8	1.09	0.73	0.36	0.24
	K^+	25	6.09	0.072	1.18	0.029	0.47
	Cl^-	25	139.9	2.39	1.71	0.32	0.23

WR SD = within-run standard deviation
Ttl SD = total standard deviation

Correlation Data

Correlation data were obtained from 47 human serum samples and control materials for Na^+, K^+ and Cl^- measured on an AVL 9130 Analyzer, calibrated with Thermo ALKO Calibration Pack and AVL ISE SnapPak™, separately. Linear Regression Analysis was performed using Thermo ALKO Data as the Dependent Y Variable and AVL Data as the Independent X Variable in the equation $Y = a + bX$. Values of R Squared are 0.9993 for Na^+, 0.9988 for K^+ and 0.9989 for Cl^-. Values of slopes are 0.9796 for Na^+, 0.9786 for K^+ and 0.9818 for Cl^-.

Analyte	(N)	Slope	Intercept	R Sq	Range (mM)
Na^+	56	0.9796	2.2385	0.9993	65.1 to 187.6
K^+	56	0.9786	0.0633	0.9988	1.80 to 11.5
Cl^-	52	0.9818	2.0605	0.9989	50.1 to 163.5

R Sq = Correlation coefficient Squared

Thermo ALKO Calibration Pack, Product Number A9100-103S:

Precision Data

Precision data were collected from the analysis of two levels of human serum based materials in duplicate per run on an AVL 9180 analyzer over a period of 24 days calibrated with Thermo ALKO Calibration Pack.

Level	Analyte	Ttl Runs	Mean	Ttl SD	Ttl CV%	WR SD	WR CV%
Level 1	Na^+	22	115.8	0.51	0.44	0.41	0.35
	K^+	22	2.71	0.029	1.08	0.017	0.62
	Cl^-	22	101.5	0.91	0.90	0.27	0.27
	Ca^{++}	22	0.90	0.019	2.07	0.016	1.80
	Li^+	22	1.025	0.022	2.11	0.013	1.31
Level 2	Na^+	22	149.5	0.91	0.61	0.36	0.24
	K^+	22	6.21	0.047	0.76	0.036	0.57
	Cl^-	22	141.2	0.88	0.62	0.40	0.29
	Ca^{++}	22	1.71	0.037	2.15	0.031	1.80
	Li^+	22	2.906	0.046	1.58	0.011	0.39

WR SD = within-run standard deviation
Ttl SD = total standard deviation

Correlation Data:

Correlation data were obtained from 48 human serum samples and control materials for Na^+, K^+, Cl^-, Ca^{++} and Li^+ measured on an AVL 9180 Analyzer, calibrated with Thermo ALKO Calibration Pack and AVL ISE SnapPak™, separately. Linear Regression Analysis was performed using Thermo ALKO Data as the Dependent Y Variable and AVL Data as the Independent X Variable in the equation $Y = a + bX$. Values of R Squared are 0.9998 for Na^+, 0.9993 for K^+, 0.9999 for Cl^-, 0.9994 for Ca^{++} and 0.9994 for Li^+. Values of slopes are 0.9991 for Na^+, 1.0069 for K^+, 1.0032 for Cl^-, 1.0073 for Ca^{++} and 0.9930 for Li^+.

Analyte	(N)	Slope	Intercept	R Sq	Range (mM)
Na^+	57	0.9991	-0.3118	0.9998	65.0 to 198.4
K^+	57	1.0069	-0.0513	0.9993	1.75 to 12.03
Cl^-	50	1.0032	-0.4125	0.9999	55.3 to 174.9
Ca^{++}	55	1.0073	-0.0166	0.9994	0.24 to 4.91
Li^+	46	0.9930	-0.0089	0.9994	0.21 to 5.63

R Sq = Correlation Coefficient Squared

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 31 2003

Mr. Patrick K. Chiu
Quality Assurance Manager
Thermo Orion, Inc.
500 Cummings Center
Beverly, MA 01915

Re: k023792
Trade/Device Name: Calibration Packs for use on equivalent Roche/AVL 9100 Electrolyte Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: November 12, 2002
Received: November 13, 2002

Dear Mr. Chiu:

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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K023792

Device Name: Calibration Packs for use on equivalent Roche/AVL 9100 Series Electrolyte Analyzers

Indications For Use:

The products encompassed by this request are intended for in vitro diagnostic use only and are intended for use in the calibration of equivalent Roche/AVL 9100 Series Electrolyte Analyzers .

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023792

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)