K972004

510(k) Summary
for ALKO Reagents on the ISE Module of the Olympus AU 800™ /AU 5200™ Chemistry Systems

JUN 16 1997

The products encompassed by this 510(k) submission are Class II (75JIX) In Vitro Diagnostic Solutions manufactured by ALKO Diagnostic Corporation, 333 Fiske Street, Holliston, MA 01746. The ISE Reagents are intended for use on the ISE module of the Olympus Chemistry Systems. Olympus America Incorporated is the original equipment manufacturer (OEM) of the system and of predicate ISE Reagents which are necessary for the continued operation and use of the ISE module on these systems.

Information herein will support ALKO's position for the intended use of these products to the Olympus Chemistry System with the ISE module. The ISE module measures Na^+, K^+, Cl^- by using the system's Ion Selective Electrodes. The ALKO Reagents are intended to serve as direct replacements to like named products manufactured by Olympus America Incorporated. The Buffer dilutes all measured samples for the quantitative determinations of Na^+, K^+, and Cl^- concentrations in serum and urine by ISE. The Mid-Standard Solution is intended as a means of compensating for calibration drift in the quantitative determination of Na^+, K^+, and Cl^- in samples on the Olympus Chemistry Systems. The Reference Solution is intended to provide a stable reference potential for Na^+, K^+, and Cl^- electrodes on the Olympus Chemistry Systems. The ISE Serum/Urine and High/Low Standards are used to calibrate the electrodes of Na^+, K^+, and Cl^- on the system's ISE module. The ISE Na^+/K^+ Selectivity Check Solutions are intended for Na^+ and K^+ electrode verification.

ALKO product A101-100 (ISE Buffer) is equivalent to Olympus Chemistry System product AUH1011 (ISE Buffer). ALKO Product A101-200 (ISE Mid - Standard Solution) is equivalent to Olympus Chemistry System product AUH1012 (ISE Mid-Standard). ALKO product A101-300 (ISE Reference Solution) is equivalent to Olympus Chemistry System product AUH1013 (ISE Reference Solution). ALKO product A101-400 (ISE Low Serum Standard) is equivalent to Olympus Chemistry System product AUH1014 (ISE Low Serum Standard). ALKO product A101-500 (ISE High Serum Standard) is equivalent to Olympus Chemistry System product AUH1015 (ISE High Serum Standard). ALKO product A101-600 (ISE High/Low Urine Standard) is equivalent to Olympus Chemistry System product AUH1016 (ISE High/Low Urine Standard). ALKO product A101-800 (Na^+/ K^+ Selectivity Check Solution) is equivalent to Olympus Chemistry System product AUH1018 ((Na^+/ K^+ Selectivity Check Solution).

ALKO uses a similar composition, description and packaging design as that used by Olympus America in its products. ALKO has shown performance equivalence of its products to Olympus America products in the following manner:

- Through a method comparison where results obtained on an equivalent Olympus Chemistry System, calibrated with ALKO products and compared with results obtained on the same analyzer calibrated with Olympus products; and

- Through a precision study where ALKO products were installed on an equivalent Olympus Chemistry System and samples were measured over 20 runs.
  A summary of the results of these studies follows:

PERFORMANCE CHARACTERISTICS

Precision Data

Precision data was collected from the analysis of three levels of serum controls and two levels of urine controls, measured in duplicate per run, four runs per day for at least five days on the ISE Module of the Olympus AU800 analyzer for $Na^+/K^+/Cl^-$, calibrated with all ALKO reagents.

Serum Level 1

		N	Mean	STD	CV%
Na^+	Total	48	127	0.7535	0.5939
	W-Run	24	127	0.8165	0.6435
K^+	Total	48	3.2	0.0143	0.4466
	W-Run	24	3.2	0.0204	0.6383
Cl^-	Total	48	83	0.6641	0.7993
	W-Run	24	83	0.5774	0.6977

Serum Level 2

		N	Mean	STD	CV%
Na^+	Total	48	139	0.8777	0.6314
	W-Run	24	139	0.9789	0.7042
K^+	Total	48	4.5	0.0534	1.1749
	W-Run	24	4.5	0.0408	0.8989
Cl^-	Total	48	83	0.6641	0.7993
	W-Run	24	83	0.5774	0.6977

Serum Level 3

		N	Mean	STD	CV%
Na^+	Total	48	156	0.8268	0.5302
	W-Run	24	156	0.7360	0.4720
K^+	Total	48	5.9	0.0729	1.2266
	W-Run	24	5.9	0.0791	1.3310
Cl^-	Total	48	114	0.9270	0.8159
	W-Run	24	114	0.7638	0.6722

Urine Level 1

		N	Mean	STD	CV%
Na^+	Total	48	58	0.5770	0.9866
	W-Run	24	58	0.7906	1.3519
K^+	Total	48	23.4	0.1887	0.8065
	W-Run	24	23.4	0.1568	0.6700
Cl^-	Total	48	58	0.4560	0.7881
	W-Run	24	58	0.5401	0.9335

Urine Level 2

		N	Mean	STD	CV%
Na^+	Total	48	184	1.2741	0.6942
	W-Run	24	184	1.0801	0.5885
K^+	Total	48	130.6	0.9643	0.7383
	W-Run	24	130.6	0.7277	0.5572
Cl^-	Total	48	288	2.3629	0.8219
	W-Run	24	288	1.6583	0.5768

Note: W-Run = Within Run

Correlation with Olympus Reagents

Linear Regression Analyses were performed using the Olympus data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation $Y = a + bX$.

Serum Samples :
Correlation data were collected from 40 serum samples and 9 serum controls for $Na^+/K^+/Cl^-$; measured on the ISE Module of the Olympus AU800 analyzer, calibrated with ALKO as compared with Olympus reagents separately.

	Na	K	Cl
N	49	49	49
Slope	1.0242	0.9900	0.9892
Intercept	-3.4021	0.0242	-0.6464
R Sq.*	0.9995	0.9998	0.9997
Range	65 - 183	1.4 - 10.9	37 - 165

Urine Samples:

Correlation data were collected from 70 urine samples and 6 urine controls for Na^+/ Cl^-, and 66 urine samples and 6 urine controls for K+, measured on the ISE Module of the Olympus AU800 analyzer, calibrated with ALKO as compared with Olympus reagents separately.

	Na	K	Cl
N	76	72	76
Slope	1.0191	1.0325	1.0016
Intercept	-1.0199	-1.0404	0.4077
R Sq.*	0.9991	0.9997	0.9993
Range	13 - 361	5.7 - 306.0	13 - 452

*R Sq = Correlation Coefficient Squared

I hope that you find this information useful and informative.

Janet A McGrath 5/29/97

(date prepared)

Janet A.McGrath
Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 16 1997

Janet A. McGrath
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ALKO Diagnostics
333 Fiske Street
Holliston, Massachusetts 01746

Re: K972004
ISE Reagents for Olympus AU 800™/AU 5200™
Chemistry Systems
Regulatory Class: II
Product Code: CGZ, JGS, CEM
Dated: May 29, 1997
Received: May 30, 1997

Dear Ms. McGrath:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): K972004

Device Name: ISE Reagents on Equivalent Olympus Chemistry Systems

Indication For Use:

The products encompassed by this request are intended for in vitro diagnostic use and the quantitative determination of Na^+, K^+, and Cl^-, on the Olympus Chemistry Systems. Olympus America Incorporated is the original equipment manufacturer (OEM) of the chemistry systems and of the predicate Reagents. The Olympus Chemistry Systems performs a broad array of clinical chemistry tests. The Olympus Chemistry Systems with the ISE module measures sodium (Na^+), potassium (K^+), and chloride (Cl^-) by Ion Selective Electrodes. These Reagents are intended to be used with the equivalent Olympus Chemistry Systems. As such, ALKO products are intended to serve as direct replacements to like named products manufactured by Olympus .

The Buffer dilutes all measured samples for the quantitative determinations in Na^+, K^+, and Cl^- in serum and urine by ISE. The Mid-Standard Solution is intended as a means of compensating for calibration drift in the quantitative determination of Na^+, K^+, and Cl^- in samples on the Olympus Chemistry Systems. The Reference Solution is intended to provide a stable reference potential for Na^+, K^+, and Cl^- electrodes on the Olympus Chemistry System. The Serum High/Low Standard and Urine High/Low Standard are used to calibrate the Na^+, K^+, and Cl^- electrodes of the system's ISE module. The ISE Na^+/K^+ Selectivity Check Solutions are intended for Na^+, K^+, electrode verification. The products encompassed are to be handled using normal laboratory precautions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K972004

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

(Optional Format 1-2-96)