K023268

NOV 1 5 2002

510 (k) Summary

pHoenix ISE Standards for Roche AVL Systems

AVL was the original manufacturer of the AVL Systems. Recently Roche Diagnostics acquired AVL and these Chemistry Systems are now referred to as Roche AVL Systems.

pHoenix Diagnostics, Inc. is submitting a 510 (k) notification for Standard A, B, and C for the Roche AVL Systems for the quantitative determination of Na+, K+, Cl-, Ca+ and Li+ in human serum. These Standards are used for the calibration of the Roche AVL Systems.

pHoenix Diagnostics, Inc. is claiming substantial equivalence to predicate devices manufactured by Roche/AVL Diagnostics.

The products encompassed by this 510 (k) submission are Class II (75 JIX) In Vitro Diagnostic Solutions manufactured by pHoenix Diagnostics, Inc., 8 Tech Circle, Natick, MA 01760. These pHoenix ISE Standards are intended to serve as direct replacements to like named products manufactured by Roche Diagnostics.

Listed below are pHoenix products, their Roche Diagnostics equivalents and usages on the Roche AVL instruments:

pHoenix Cat.#	Roche Diagnostics Cat. #	Description and Utilities	Analytes and Concentrations						
			Na	K	Cl	Ca	Li	CO2	pH
4-001	BP0936	Standard A for AVL 982,983,985	150	5	115	0.9	0.3	/	/
4-009	BP0937	Standard B for AVL 985	100	1.8	72	1.5	0.3	/	/
4-010	BP0938	Standard C for AVL 985	150	5	115	0.9	1.4	/	/
4-005	BP0442	Standard B for AVL 982, 983	50	1.8	59.8	4	/	/	/
4-006	BP1232	Standard A for AVL 984, 987, 988	150	5	/	1.25	/	/	7.38
4-007	BP1218	Standard B for AVL 984, 987, 988	100	1.8	/	2.5	/	/	6.84
4-011	BP1203	Standard A for AVL 986	150	5	125.3	/	/	25	/
4-012	BP1201	Standard B for AVL 986	80	1.8	70.9	/	/	10	/

510 (k) Summary cont.

pHoenix Diagnostics uses a similar composition and design as that used by Roche Diagnostics in its products. pHoenix has shown performance equivalence of its products to Roche Diagnostics products in the following manner:

- Through a method comparison where results obtained on Roche AVL Systems calibrated with pHoenix products and compared with results obtained on the same analyzer calibrated with Roche Diagnostics products; and

- Through a precision study where pHoenix products were installed on Roche AVL systems and samples were measured over 20 runs.

A summary of the results of these studies is as follows:

Precision data was collected from the analysis of 2 levels of serum controls measured 2 runs per day, 2 times per run for 20 days on Roche AVL Systems for different electrolytes installed with pHoenix reagents. The NCCLS Guideline for precision evaluation, EP5-T, was followed. Typical Results are as follows:

AVL 983

Analyte	Level	N	Mean	STD	CV%	Min	Max
Na	1	80	124	1.52	1.2	121	127
Na	3	80	164	2.6	1.6	162	166
K	1	80	1.93	0.11	5.5	1.7	2.2
K	3	80	6.5	0.06	0.96	6.4	6.6
Cl	1	80	85.6	1.4	1.7	82	89
Cl	3	80	148	0.82	0.56	146	149

AVL 984

Analyte	Level	N	Mean	STD	CV%	Min	Max
Na	1	80	124	1.48	1.2	121	127
Na	3	80	165	1.75	1.06	162	170
K	1	80	1.91	0.105	5.5	1.7	2.2
K	3	80	6.7	0.101	1.52	6.4	6.8
Ca	1	80	2.36	0.112	4.76	2.2	2.6
Ca	3	80	0.84	0.014	1.69	0.81	0.87

510 (k) Summary cont.

AVL 985

Analyte	Level	N	Mean	STD	CV%	Min	Max
Na	1	80	123	1.33	1.1	121	126
Na	3	80	165	1.73	1.05	162	170
K	1	80	1.84	0.08	4.43	1.7	2
K	3	80	6.6	0.12	1.85	6.4	6.8
Li	1	80	1.75	0.087	5	1.6	1.9
Li	3	80	2.56	0.1	3.71	2.4	2.8

Correlation with Roche AVL Reagents

Correlation data was collected from 50 samples (patient serum samples, control samples and spiked samples) for Na^+, K^+, Cl^-, Ca^+ and Li^+ measured on Roche AVL Systems installed with pHoenix reagents as compared with Roche Diagnostics reagents separately. A Linear Regression Analysis was performed using Roche data as the independent X Variable and pHoenix Diagnostics Data as the Dependent Y Variable in the equation Y = a + bX. Typical results are as follows:

	AVL Model	N	Slope	Intercept	Correlation Coefficient	Range
Na+	983	50	1.03	-1.36	0.992	75 – 178
Na+	984	50	1.03	-0.71	0.996	74 – 177
Na+	985	50	1.03	0.98	0.994	75 – 177
K+	983	50	1.005	0.32	0.996	2.9 – 6.7
K+	984	50	1.001	0.29	0.998	2.8 – 6.7
K+	985	50	0.98	0.402	0.997	3.1 – 6.8
Cl-	983	50	0.98	6.18	0.997	52 – 151
Ca+	984	50	1.02	0.02	0.997	0.7 – 2.2
Li+	985	50	.989	0.03	0.998	0.3 – 2.4

I hope you find this information useful and informative.

Ram Nunna, President

8/20/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Ram Nunna
President
pHoenix Diagnostics, Inc.
8 Tech Circle
Natick, MA 01760

NOV 15 2002

Re: k023268
Trade/Device Name: pHoenix ISE Standards for Roche AVL 982, 983, 984, 985, 986, 987, 988, 9110/9140, 9120/9130, 9180/9181
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: August 20, 2002
Received: September 30, 2002

Dear Mr. Nunna:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 023268

Device Name: pHoenix ISE Standards for Roche AVL 982, 983, 984, 985, 986, 987 988, 9110/9140, 9120/9130, 9180/9181

Indications For Use:

Intended Use:

The pHoenix ISE Standard for Roche AVL Instruments are intended for use as ISE Reagents for the determination of Na^+, K^+, Cl^-, $Ca^+$and Li^+ in human serum samples on the Roche AVL Systems.

The standards are used for the calibration of the Roche AVL Instruments for the quantitative determination of Na^+, K^+ Cl^-, Ca^+ and Li^+ in serum samples.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use
(Optional Format 1-2-96)

Susan Cogan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023268