JUN 0 4 2002

K020364

510 (k) Summary

pHoenix ISE Reagents for Beckman CX Systems

Beckman Instruments was the original manufacturer of the Beckman CX Systems. Recently Beckman Instruments acquired Coulter and these Chemistry Systems continued to be referred to as Beckman CX Systems. Beckman Coulter is the name of the new company.

pHoenix Diagnostics, Inc. is submitting a 510 (k) notification for the following: (1) Electrolyte Buffer, (2) Electrolyte Reference Reagent and (3) C02 Acid Reagent, (4) C02 Alkaline Buffer, (5) Wash Concentrate and (6) ISE Calibrator Level 1,2 and 3. These ISE Reagents are intended for use on the ISE Module of the Beckman CX Systems for the quantitative determination of Na+, K+, Cl- and C02 in human serum.

The Electrolyte Buffer is intended to provide constant ionic strength for measuring electrolytes in human serum samples. The Electrolyte Buffer is combined with the Wash Solution and introduced into the serum samples for the quantitative determination of Na+, K+, Cl- and C02. The Electrolyte Reference Reagent is to provide reference points for Na+, K+, Cl- and C02. The C02 Acid Reagent is to release C02 from serum samples. The C02 Alkaline Reagent is to provide a constant C02 concentration as reference for the C02 electrode. The Wash Concentrate is intended to be diluted with de-ionized water. The working Wash Solution is used to wash the systems sample probe and to dilute reagents on Beckman CX Systems. The Calibrators are used for the calibration of the CX ISE Modules.

pHoenix Diagnostics, Inc. is claiming substantial equivalence to predicate devices manufactured by Beckman Coulter, the original manufacturer of these reagents and Beckman CX Systems.

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

510 (k) Summary cont.

Listed below are pHoenix products and their Beckman Coulter equivalents.

pHoenix Cat.#	Beckman Cat. #	Description	Models	Class
47-2095	472095	Electrolyte Buffer	All CX Systems	1
45-0214	450214	Electrolyte Reference Reagent	All CX Systems	2
44-3320	443320	C02 Alkaline Buffer	All CX Systems	1
44-3330	443330	C02 Acid Reagent	All CX Systems	1
44-3335	443335	Wash Concentrate	All CX Systems	1
46-5908	465908	ISE Calibrator Level 1	All CX Systems	2
46-5909	465909	ISE Calibrator Level 2	All CX Systems	2
46-5910	465910	ISE Calibrator Level 3	All CX Systems	2

pHoenix uses a similar composition, description and packaging design as that used by Beckman Coulter in its products. pHoenix has shown performance equivalence of its products to Beckman instrument products in the following manner:

- Through a method comparison where results obtained on Beckman CX Clinical Chemistry Systems calibrated with pHoenix products and compared with results obtained on the same analyzer calibrated with Beckman CX Systems products; and

- Through a precision study where pHoenix products were installed on Beckman CX Systems Clinical Chemistry Systems and samples were measured one run per day for a 20 day period.

A summary of the results of these studies 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 Beckman CX Systems for Na^+, K^+, Cl^- and C02 installed with pHoenix reagents. The NCCLS Guideline for precision evaluation, EP5-T, was followed. Typical Results are as follows:
Level 2

Analyte		N	Mean	STD	CV%	Min	Max
Na^+	Total	80	121	1.47	1.2	120	124
	Run to Run	20	121	0.67	0.55	120	123
K^+	Total	80	1.93	0.104	5.42	1.8	2.1
	Run to Run	20	1.93	0.040	2.00	1.85	2.0
Cl^-	Total	80	70.6	1.42	2.01	68	73
	Run to Run	20	70.6	0.87	1.23	69	72
C02	Total	80	16.25	0.94	5.8	14.1	17.2
	Run to Run	20	16.25	0.57	3.57	14.7	17.2

510 (k) Summary cont.

Level 4

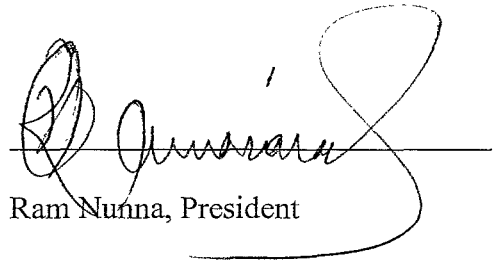
Analyte		N	Mean	STD	CV%	Min	Max
Na^+	Total	80	164.2	2.58	1.57	160	169
	Run to Run	20	164.2	1.07	0.65	162	166
K^+	Total	80	6.50	.062	0.96	6.4	6.6
	Run to Run	20	6.50	.028	0.44	6.4	6.5
Cl^-	Total	80	147.5	0.824	0.56	146	149
	Run to Run	20	147.5	.473	.32	147	148
C02	Total	80	34.1	1.87	5.48	30	39
	Run to Run	20	34.1	1.28	3.76	32	37

Correlation with Beckman Coulter Reagents

Correlation data was collected from 50 samples (patient serum samples, control samples and spiked samples) for Na^+, K^+, Cl^- and C02, measured on Beckman CX Systems installed with pHoenix reagents (Electrolyte Buffer, Electrolyte Reference Reagent, C02 Alkaline Buffer, C02 Acid Reagent, Wash Cincentrate, and Calibrators) as compared with Beckman Coulter reagents separately. A Linear Regression Analysis was performed using Beckman 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:

Analyte	N	Slope	Intercept	Correlation Coefficient	Range
Na+	50	1.027	0.60	0.999	100 – 200
K+	50	1.04	0.348	0.998	1 – 15
Cl-	50	0.977	7.17	0.996	50 – 200
C02	50	0.964	1,058	0.985	5 – 40

I hope you find this information useful and informative.



Ram Nunna, President

2/1/02

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 0 4 2002

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

Re: k020364
Trade/Device Name: pHoenix ISE Reagents for Beckman CX Systems 700/900 series
Regulation Number: 21 CFR 862.1665; 21 CFR 862.1600; 21 CFR 862.1170; 21 CFR 862.1120; 21 CFR 862.1150
Regulation Name: Sodium test system; Potassium test system; Chloride test system; Blood gases ($P_{CO}2$, P_O2) and blood pH test system; Calibrator
Regulatory Class: Class II
Product Code: JGS; CEM; CGZ, CHL, JIX
Dated: April 2, 2002
Received: April 8, 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): K020364

Device Name: pHoenix ISE Reagents for Beckman CX Systems 700/900 series

Indications For Use:

Intended Use:

The pHoenix ISE Reagents for Beckman CX Systems are intended for use as ISE Reagents for the determination of Na^+, K^+, Cl^- and C02 in human serum samples on the Beckman CX Systems.

The Electrolyte Buffer is diluted with the Wash Solution and introduced into the serum samples for the quantitative determination of Na+, K+, Cl- and C02.

The Electrolyte Reference Reagent is to provide reference points for Na+, K+, Cl- and C02.

The C02 Acid Reagent is to release C02 from serum samples.

The C02 Alkaline Buffer is to provide a constant C02 concentration as reference for the C02 electrode. The Wash Concentrate is intended to be diluted with de-ionized water. The working Wash Solution is used to wash the systems sample probe and to dilute reagents on Beckman CX Systems.

The Calibrators are used for the calibration of the CX ISE Modules for the quantitative determination of Na^+, K^+ Cl^- and C02 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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020364