FEB 0 1 2002

K020129

510 (k) Summary

pHoenix Electrolyte Calibration Set for the Roche® Cobas™ ISE Module

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. The Calibration Set consists of 2 levels and is intended for use in calibrating Na^+, K^+ and Cl^- on the Roche® Cobas™ ISE Module. Roche Diagnostics is the original equipment manufacturer (OEM) of the system.

The pHoenix products stated are currently cleared under docket K902675. Information herein will support pHoenix's position to extend the intended use of these products to the Roche® Cobas™ ISE Module. The Roche® Cobas™ ISE Module measures Na^+, K^+, and Cl^- by using Ion Selective Electrode Technology. The pHoenix Calibrator Reagents are intended to serve as direct replacements to like named products manufactured by Roche Diagnostics. pHoenix Product 17-200 and 17-201 are equivalent to Roche Product 44224.

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

- Through a method comparison where results obtained on Roche® Cobas™ ISE Module Chemistry Systems calibrated with pHoenix products and compared with results obtained on the same analyzer calibrated with Roche products; and

- Through a precision study where pHoenix products were installed on Roche® Cobas™ ISE Module and samples were measured over multiple runs.

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 a on Roche® Cobas™ ISE Module calibrated with pHoenix calibrator 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	120.0	1.50	1.20	117	122
	Run to Run	20	120.0	0.80	0.60	118	122
K^+	Total	80	2.0	0.110	5.0	1.85	2.15
	Run to Run	20	2.0	0.040	1.5	1.90	2.10
Cl^-	Total	80	100.0	0.60	0.60	97	102
	Run to Run	20	100.0	0.25	0.30	98	101

510 (k) Summary Cont.

Level 4

Analyte		N	Mean	STD	CV%	Min	Max
Na^+	Total	80	165	1.20	0.70	162	167
	Run to Run	20	165	0.70	0.40	163	167
K^+	Total	80	6.50	0.07	1.0	6.4	6.6
	Run to Run	20	6.50	0.04	0.6	6.4	6.5
Cl^-	Total	80	146	0.80	0.50	144	148
	Run to Run	20	146	0.60	0.40	125	148

Accuracy by Correlation with Roche Standard Reagents

Correlation data was collected from patient serum samples and control samples for Na^+, K^+ and Cl^- measured on a Roche® Cobas™ ISE Module calibrated with pHoenix reagents as compared with Roche reagents separately. A Linear Regression Analysis was performed using pHoenix data as the independent X Variable and Roche 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	1.01	1.1	0.990	120 – 180
K+	50	0.980	1.1	0.990	2.5 – 7.5
Cl-	50	0.990	1.1	0.980	78 – 120

I hope you find this information useful and informative.

Ram Nunna, President

1/11/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 01 2002

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

Re: k020129
Trade/Device Name: pHoenix Electrolyte Calibration Set for the Roche® Cobas™ ISE Module
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: November 2, 2001
Received: January 14, 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): K020129

Device Name: pHoenix Electrolyte Calibration Set for the Roche® Cobas™ ISE Module

Indications For Use:

Intended Use:

The products encompassed by this request are intended for invitro diagnostic use and are intended for use in calibrating Na^+, K^+, Cl^- electrodes in Roche Cobas ISE module. Roche is the original equipment manufacturer for the analyzer and predicate reagents. phoenix electrolyte calibration set is intended for use in place of like named products manufactured by Roche Diagnostics.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020129

(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)