K984384

DEC 23 1998

510(k) Summary
for ALKO Reagents on CHIRON
(Ciba-Corning) 248 pH/ Blood Gas Analyzer

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 Reagents are intended for use on equivalent Chiron (Ciba-Corning) pH/ Blood Gas Analyzers. Chiron Diagnostics (formally Ciba-Corning) is the original equipment manufacturer (OEM) of the analyzers and of predicate reagents which are necessary for the continued operation and use of the analyzers.

Information herein will support ALKO's position for the intended use of these products to the equivalent Chiron (Ciba-Corning) pH/ Blood Gas Analyzers. The Chiron (Ciba-Corning) 248 pH/Blood Gas Analyzer performs a broad array of blood gas tests. ALKO manufactures the buffer reagents for the analyzer's analyte pH (concentration of hydrogen ions) which is measured by the glass membrane electrode. ALKO also manufactures the Wash Solution. The ALKO Reagents are intended to serve as direct replacements to like named products manufactured by Chiron Diagnostics. The Buffer Pack which consists of one bottle each of 6.8 and 7.3 Buffer, are Buffered Solutions for calibration of the pH electrode. The Wash Solution is used to rinse the analyzers sample flow path.

- ALKO product A473-496 (6.8 / 7.3 Buffer Pack) is equivalent to Chiron Diagnostics product 473496 (6.8 / 7.3 Buffer Pack).
- ALKO Product A473-497 (Wash Solution), is equivalent to Chiron Diagnostics product 473497 (Wash Solution).

ALKO uses a similar composition, description and packaging design as that used by Chiron Diagnostics in its products. Equivalence is explained in the packaging section of this submission. ALKO has shown performance equivalence of its products to Chiron Diagnsotics products in the following manner:

- Through a method comparison where results obtained on an equivalent Chiron (Ciba-Corning) pH Blood Gas Analyzer, calibrated with ALKO products and compared with results obtained on the same analyzer calibrated with Chiron Diagnostics products; and
- Through a precision study where ALKO products were installed on an equivalent Chiron (Ciba-Corning) pH Blood Gas Analyzer and samples were measured four runs per day for five days. A summary of the results of these studies follows:

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PERFORMANCE CHARACTERISTICS

Precision Data

Precision data were collected from the analysis of three levels of control materials, measured in duplicate per run, four runs per day for five days on a Chiron 248 pH/blood gas analyzer calibrated with all ALKO reagents.

Level 1

		N	Mean	STD	CV%
pH	Total	40	7.166	0.0025	0.0351
	W-Run	20	7.166	0.0017	0.0231
pCO_2	Total	40	79.3	1.2343	1.5574
	W-Run	20	79.3	1.1177	1.4103
pO_2	Total	40	57.6	1.5465	2.6843
	W-Run	20	57.6	1.3294	2.3064

Level 2

		N	Mean	STD	CV%
pH	Total	40	7.431	0.0019	0.0262
	W-Run	20	7.431	0.0013	0.0170
pCO_2	Total	40	43.7	0.4989	1.1409
	W-Run	20	43.7	0.4461	1.0202
pO_2	Total	40	96.2	1.1632	1.2089
	W-Run	20	96.2	0.7857	0.8165

Level 3

		N	Mean	STD	CV%
pH	Total	40	7.653	0.0030	0.0394
	W-Run	20	7.653	0.0012	0.0159
pCO_2	Total	40	18.9	0.1856	0.9811
	W-Run	20	18.9	0.1294	0.6841
pO_2	Total	40	149.3	2.8649	1.9183
	W-Run	20	149.3	1.5502	1.0380

Note: W-Run = Within Run

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orrelation with Chiron reagents

Correlation data were obtained from 120 human blood samples for pH, pCO_2 and pO_2, measured on two Chiron 248 analyzers; one calibrated with all ALKO reagents as compared with the other one calibrated with all Chiron reagents. Linear regression analysis was performed using Chiron data as the Independent X variable and ALKO data as the Dependent Y variable in the equation Y=a+ bX.

	N	Slope	Intercept	R.Sq.	Range
pH	120	0.9949	0.0382	0.9939	6.946 - 7.962
pCO_2	120	0.9968	0.1342	0.9931	9.3 - 101.8
pO_2	120	0.9977	0.0608	0.9983	2.4 - 293.1

Note: R Sq. = Correlation Coefficient squared

I hope you find this information useful and informative.

12/3/98
(date prepared)

Janet A, McGrath
Regulatory Affairs

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1998

Janet A. McGrath
Regulatory Affairs Specialist
Thermo BioAnalysis
333 Fiske Street
Holliston, MA 01746

Re: K984384
Trade Name: 6.8/7.8 Buffer Pack & Wash Solution Pack
Regulatory Class: II
Product Code: CHL
Dated: December 4, 1998
Received: December 8, 1998

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

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/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

510(k) Number (if known): K984384

Device Name: Reagents on Equivalent Chiron (Ciba-Corning) pH/Blood Gas Analyzers

Indication For Use:

The products encompassed by this request are intended for in vitro diagnostic use and are intended for use in calibrating the electrodes and flushing the sample flow path of the equivalent Chiron (Ciba-Corning) pH/Blood Gas Analyzer. Chiron Diagnostics is the Original Equipment Manufacturer of the analyzers and of the predicate Reagents. The Chiron (Ciba-Corning) pH/Blood Gas Analyzer performs a broad array of blood gas tests. ALKO manufactures the calibration reagents for the analyzer's analyte pH, (concentration of hydrogen ions) which is measured by glass membrane electrodes. ALKO also manufactures the Wash Solution. These Reagents are intended to be used with equivalent Chiron (Ciba-Corning) pH/Blood Gas Analyzers. As such, ALKO products are intended to serve as direct replacements to like named products manufactured by Chiron Diagnostics.

The Buffer Solution 7.3, and Buffer Solution 6.8, are intended to provide calibration points for the pH electrode on the analyzer. The Wash Solution is intended for rinse of the analyzers sample flow path. 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)

Veronica D. Calvin for aum

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984384

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

(Optional Format 1-2-96)

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