JUN 1 2 1998

K981795

510(k) Summary
for ALKO Reagents on
ABL™ 50, 500, 510, 520,
600, 610 and 620 pH/ Blood Gas Analyzers

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 ABL™ pH/ Blood Gas Analyzers. Radiometer Medical/Copenhagen 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 ABL™ pH/ Blood Gas Analyzers. The ABL™ pH/Blood Gas Analyzers perform a broad array of blood gas and co-oximetery tests. ALKO manufactures the calibration reagents for the analyzer's analyte pH (concentration of hydrogen ions) which is measured by the glass membrane electrode. ALKO also manufactures the Cleaning, Rinse, Hypochlorite and Salt Bridge Solution. The ALKO Reagents are intended to serve as direct replacements to like named products manufactured by Radiometer Medical /Copenhagen. The Calibration Solutions, pH 7.4/**3** and Calibration Solution, pH 6.8/**4** are buffered solutions for calibration of the pH electrode. The Salt Bridge Solution /**2** provides a liquid junction through the reference electrode and the sample during calibration and measurement. The Cleaning Solution/**1**, Rinse Solution /**5** and Hypochlorite solution are all used to clean and rinse the analyzers electrodes, and sample flow path.

- ALKO product A943-791 (Calibration Solution, pH 7.4/ **3**) is equivalent to Radiometer Medical/Copenhagen product S1565 / 943-791 (Calibration Solution, pH 7.4/ **3**).

- ALKO Product A943-792 (Calibration Solution, pH 6.8/ **4**), is equivalent to Radiometer Medical/Copenhagen S1575 / 943-792 (Calibration Solution, pH 6.8/ **4**).

- ALKO product A943-794 (Salt Bridge Solution /**2**) is equivalent to Radiometer Medical/Copenhagen product S4915 / 943 -794 (Salt Bridge Solution /**2**).

- ALKO product A943-795 (Cleaning Solution /**1**) is equivalent to Radiometer Medical/Copenhagen product S5345 / 943 -795 (Cleaning Solution /**1**).

- ALKO product A943-793 (Rinse Solution /**5**) is equivalent to Radiometer Medical/Copenhagen product S4901 / 943 -793 (Rinse Solution /**5**).

- ALKO product A943-906 (Hypochlorite Solution) is equivalent to Radiometer Medical/Copenhagen product S5362 / 943 -906 (Hypochlorite Solution).

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

- Through a method comparison where results obtained on an equivalent ABL™ p/H Blood Gas Analyzer, calibrated with ALKO products and compared with results obtained on the same analyzer calibrated with Radiometer Medical/Copenhagen products; and

- Through a precision study where ALKO products were installed on an equivalent ABL™ p/H Blood Gas Analyzer and samples were measured one run per day for twenty days. A summary of the results of these studies follows:

PERFORMANCE CHARACTERISTICS

Precision Data

Precision data were collected from the analyses of three levels of control materials measured one run per day for twenty days on an ABL™ 500 pH/pCO2/pO2 analyzer calibrated with all ALKO reagents.

Level 1

Analyte		N	Mean	STD	CV%	Min	Max
pH	Total	60	7.155	0.0025	0.0344	7.149	7.159
	Run to Run	20	7.155	0.0023	0.0325	7.149	7.157
pCO2	Total	60	73.5	0.8096	1.1022	72.2	75.8
	Run to Run	20	73.5	0.7140	0.9720	72.5	75.6
pO2	Total	60	76.4	1.2870	1.6848	73.9	79.2
	Run to Run	20	76.4	0.9898	1.2951	74.8	78.7

Level 2

Analyte		N	Mean	STD	CV%	Min	Max
pH	Total	60	7.370	0.0022	0.0301	7.365	7.381
	Run to Run	20	7.370	0.0015	0.0209	7.367	7.374
pCO2	Total	60	44.2	0.5873	1.3296	43.4	47.5
	Run to Run	20	44.2	0.3177	0.7193	43.8	45.1
pO2	Total	60	102.2	1.8308	1.7906	98.7	109.9
	Run to Run	20	102.2	1.5290	1.4955	99.5	105.3

Level 3

Analyte		N	Mean	STD	CV%	Min	Max
pH	Total	60	7.576	0.0026	0.0345	7.571	7.586
	Run to Run	20	7.576	0.0020	0.0267	7.572	7.579
pCO2	Total	60	20.3	0.4511	2.2171	17.4	20.8
	Run to Run	20	20.3	0.3096	1.5214	19.2	20.8
pO2	Total	60	157.4	3.6420	2.3146	149.0	165.3
	Run to Run	20	157.4	3.1385	1.9946	151.0	163.3

Accuracy by Correlation with Radiometer ABL™ Reagents

Correlation data were obtained from 51 blood samples for pH/pCO2/pO2, measured on two ABL™ 500 analyzers, one calibrated with all ALKO reagents as compared with the other one calibrated with all Radiometer reagents. A Linear Regression Analysis was performed using the Radiometer data as the Independent X Variable and ALKO Data as the Dependent Y Variable in the equation Y = a + bX.

Analyte	N	Slope	Intercept	R Squared *	Range
pH	51	1.0068	-0.04888	0.9998	6.816 - 7.987
pCO2	51	1.0106	-0.14954	0.9995	5.1- 152.7
pO_2	51	0.9961	0.46989	0.9995	12.6 - 285.0

*R Squared= Correlation Coefficient Squared

I hope you find this information useful and informative.

5/19/98
(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 12 1998

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

Re: K981795
Calibration Solutions pH 7.4, pH 6.8 and Cleaning, Salt Bridge, Rinse and Hypochlorite Solutions
Regulatory Class: II
Product Code: JIX, CHL
Dated: May 19, 1998
Received: May 21, 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 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.

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):

Device Name: Reagents on Equivalent ABL™ 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 cleaning / flushing the sample flow path of the equivalent ABL™ pH/Blood Gas Systems. Radiometer Medical/Copenhagen is the Original Equipment Manufacturer of the analyzers and of the predicate Reagents. The ABL™ pH/Blood Gas Analyzers perform a broad array of blood gas and co-oximetery 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 Cleaning, Rinse, Hypochlorite and Salt Bridge Solution. These Reagents are intended to be used with equivalent ABL™ pH/Blood Gas Analyzers. As such, ALKO products are intended to serve as direct replacements to like named products manufactured by Radiometer Medical/Copenhagen.

The Calibration Solution, pH 7.4/ **3** and Calibration Solution, pH 6.8/ **4** are intended to provide calibration points for the pH electrode on the analyzer. The Salt Bridge Solution /**2** provides a liquid junction through the reference electrode during calibration and measurement. The Cleaning Solution /**1**, Rinse Solution /**5** and Hypochlorite Solution are intended for maintenance of the analyzers electrodes and 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)

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

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

(Optional Format 1-2-96)