ABL835 FLEX analyzer with pleural pH

Section 5

MAR 2 4 2011

510(k) Summary

1. Submitter Information
A. Establishment Registration: 3002807968
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D. Date Prepared: February 3, 2011

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4. Device Identification
A. Trade/Proprietary Name: ABL835 FLEX analyzer
B. Classification: Class II (21CFR § 862.1120)
C. Product Code: CHL.
D. Subsequent Codes: CEM, JGS, JFP, CGZ, CGA, KHP, CIG, MQM, GHS, GKR, KQI, JIX, JJY

5. Device Description
ABL835/ABL830/ABL825/ABL820/ABL815/ABL810/ABL805 FLEX analyzers are several models of the same analyzer for the measurement of blood gas, pH, electrolyte, metabolite, co-oximetry, and expired air for the parameters pO2 and pCO2.
An additional indication, namely the measurement of pH in pleura fluids, has been introduced for the ABL835 FLEX analyzer.
This additional indication is based on a further development of the software used in all ABL800 FLEX (and ABL700 before that).

6. Intended Use (added with this submission)
In vitro testing of pleural fluid samples for the pH parameter.

7. Substantial Equivalence
Predicate:
A. Trade/Proprietary Name: Roche Omni C
B. Classification: Class II (21CFR § 862.1120)
C. Product Code: CHL.
D. K-Number: 050423

ABL835 FLEX analyzer with pleural pH

Item	SE Device	Predicate Device
	ABL835 FLEX analyzer with pleural pH	**Roche analyzer K050423**
Indications for use	New indication for measuring of pH in pleural fluids	Same
Blood Gas Measurement	pH by potentiometry	Same
Calibration Method	Two-Point liquid calibration	Same
User interface	Menu driven touch screen	Same
Sensors	Traditional, discrete amperometric and potentiometric sensors installed in the analyzer	Same
Calibration and QC solutions	Discrete bottles and ampoules	Same
Pleural fluid pH measuring range	7.0 – 7.5	Same

The ABL835 FLEX analyzer is substantially equivalent to the predicate device Roche Omni C (K050423) regarding the measurement of pH in pleural fluid.

ABL835 FLEX analyzer with pleural pH

8. Performance Characteristics:

Precision study:
Repeatability and Device/Method Precision is evaluated according to "NCCLS Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition, EP5-A2, Vol. 24, No. 25".

Performance Claims for Precision Performance, Repeatability (S_0) and Total Precision (S_x)

pH	Number of Observations	Mean	Repeatability (S_0)	Total Precision (S_x)
7.1	244	7.150	0.013	0.029
7.3	248	7.290	0.009	0.019
7.5	248	7.517	0.005	0.027

The test verifies that the use of this new pleural fluid measuring mode produces pH results with acceptable precision.

Method Comparison:
Method comparison study has been conducted according to NCCLS guideline AP9-A2 "Method Comparison and Bias Estimation Using Patient Samples".

The slope of the linear fit to the data is 1.063 for the ABL835, and the intersection with the Y-axis is at −0.446. The linear fit intersects the identity line X = Y (and thus the Roche data) at pH 7.079. Furthermore, the graph clearly shows coherence between the ABL835 data and the Roche data in the sense that the X=Y line, representing the Roche data, lies within the 95% confidence interval of the linear regression, in the entire pathological range from pH 7.0 to 7.5, and the difference in slope of 6.3% is well within the 10% acceptance.

At the critical decision interval for pleural fluid treatment, namely around pH 7.3, the ABL835 device measures 0.0138 above the Roche analyzer. This bias is considered acceptable, taking into account the nature of the sample material, and the fact that the clinical decision point is not defined more accurately than is the case. This means that the difference of 0.0138 pH-units could be contained in the rounding of the data. Finally, the placement of the critical decision point varies regionally; at some hospitals pH 7.2 is considered the critical decision point.

Summarizing our findings, we find that the results of this test clearly demonstrate that the ABL835 analyzer correctly measures pH in pleural fluid, since the measurements show a good agreement with those of the predicate device.

Linearity:

The data to prove the linear fit of the method has been taken from the method comparison study.

The data points from the 58 samples lie sufficiently distributed in the pathological range, and form a straight line, when plotting the ABL835 pH values against the Roche pH values. An R^2 value of 0.994 is found when doing a linear regression on the data, plotting randomly selected single ABL835 measurements against the Roche average of two measurements.

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Summarizing our findings, we find that the results of this test clearly demonstrate that the ABL835 analyzer correctly measures pH in pleural fluid, since the measurements show a good agreement with those of the predicate device.

Conclusion:
Taken the results from the performance studies and the comparison of the new device with the predicate devices into consideration, we believe that the ABL835 with pleural pH is as safe and effective as the predicate devices.

Calibration and Quality Control
Since the measuring technology for pH in pleural fluid is the same as in blood no new calibration or quality controls have been introduced for the new indication.
The existing calibration and QC solutions are listed below.

Calibration
The following are the calibration solution relevant for the pH electrode.

S1820 Calibration Solution 1
Use: For calibration of the pH, electrolyte and metabolite electrodes in the ABL835 FLEX analyzer.

S1830 Calibration Solution 2
Use: For calibration of the pH, electrolyte and metabolite electrodes in the ABL835 FLEX analyzer.

Quality Controls
QUALICHECK5+/AutoCheck5+
Use: This quality control system can be used for quality control of the ABL835 FLEX analyzer from Radiometer.

Parameter	S7730/S7735 Level 1	S7740/S7745 Level 2	S7750/S7755 Level 3	S7760/S7765 Level 4
PH	7.1	7.4	7.6	6.8

QUALICHECK3+/AutoCheck3+
Use: This quality control system can be used for quality control of the ABL835 FLEX analyzer from Radiometer.

Parameter	S7330/S7335 Level 1	S7340/S7345 Level 2	S7350/S7355 Level 3	S7360/S7365 Level 4
PH	7.1	7.4	7.6	6.8

Range+ QUALICHECK
Use: Range+ QUALICHECK quality control systems can be used for quality control of the ABL77, ABL700 Series and ABL800 FLEX Series analyzers from Radiometer.

Parameter	S7930 Level 1	S7940 Level 2	S7950 Level 3
PH	6.8	7.0	7.8

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Technology
The technology has not been altered for the new indication of measuring pH in pleural fluids.

Potentiometric Method
The potential of an electrode chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation).
The electrode chain consisting of a sample, electrode, reference electrode, voltmeter, membranes and electrolyte solutions.

The reference electrode maintains a stable, fixed potential against which other potential differences can be measured. The potential is not altered by sample composition.

The pH electrode (E777) is a pH-sensitive glass electrode. The pH-sensitive glass membrane is located at the tip and seals the inner buffer solution with a constant and known pH

Modes of Operation
The instrument is an automated, random access, stat instrument. The specimens are withdrawn from a sampling device and drawn into the closed fluid transport system within the instrument for analysis.
The FLEXQ (K043218) allows the capability of automatic sampling from up to three blood samplers. Automatic measurements are accomplished via bar coding on the patient samples. The required tests for the identified sample are retrieved from a networked server. If required, manual introduction of a blood sample may be performed as well.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 24 2011

Radiometer Medical ApS
c/o Soren Bogestrand
Regulatory Affairs Specialist
Akandevej 21
Bronshoj, Denmark DK-2700

Re: k110416
Trade Name: Radiometer Medical ApS ABL835 FLEX analyzer
Regulation Number: 21 CFR §862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system.
Regulatory Class: Class II
Product Code: CHL
Dated: February 3, 2011
Received: February 14, 2011

Dear Mr. Bogestrand:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

ABL835 FLEX analyzer

Intended Use:

The ABL835 FLEX analyzer is intended for:

- in vitro testing of pleural fluid samples for the pH parameter

Indications for use:

The pH measurement of pleural fluid can be a clinically useful tool in the management of patients with parapneumonic effusions.

Critical values: pH >7.3 is measured in uncomplicated parapneumonic effusions. All pleural effusions with a pH of <7.3 are referred as complicated parapneumonic effusions; they are exudative in nature.

Prescription Use __X__	And/Or	Over the Counter Use _____
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k): K110416