k122729

Section 5. 510(k) Summary

1. Administrative

NOV 16 2012

Device Information	
Device Name:	ABL90 Flex
Common Name:	Blood gases and blood pH test system
Product Code:	CHL (JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX)
Registration Number:	21 CFR 862.1120
Classification:	Class II
Classification Panel:	Clinical Chemistry

Submitter	
Company Name:	Radiometer Medical ApS
ER Number:	3002807968
Address:	Aakandevej 21 2700 Broenshoej Denkmark
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2. Description of Device Modification

The ABL90 FLEX is a portable, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2 , pCO2, potassium, sodium, calcium, chloride, glucose, lactate, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO2Hb, FCOHb, F MetHb, FHHb and FHbF).
The labelling and the software has been modified to assure that the Operator does not use glucose results obtained from samples with a pO_2 level below 25 mmHg.

3. Intended Use

The ABL90 FLEX analyzer is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate, and oximetry in heparinised whole blood. The ABL90 FLEX analyzer is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting. These tests are only performed under a physician's order.

4. Indications for use

pH, pO_2 and pCO_2: pH, pCO_2 and pO_2 measurements are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Potassium (cK^+): potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.

Sodium (cNa^+): sodium measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.

Calcium (cCa^{2+}): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride (cCl^-): chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such a cystic fibrosis and diabetic acidosis.

Glucose (*c*Glu): glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

Total Hemoglobin (*c*tHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO_2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO_2Hb: oxyhemoglobin as a fraction of total hemoglobin.

*F*COHb: carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.

*F*MetHb: methemoglobin as a fraction of total hemoglobin.

*F*HHb: reduced hemoglobin as a fraction of total hemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): FHbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

5. Substantial Equivalence

The ABL90 FLEX with the modification described above is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K120197 ABL90 Flex, Radiometer Medical ApS

Predicate: ABL90 Flex (K120197)	
Similarities	**Differences**
Intended Use The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinised whole blood. The ABL90 FLEX is intended for use by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care setting.	Added caution to manual: Low *p*O2 levels can influence the linearity of glucose measurements, and can therefore result in falsely low glucose results. Please note that glucose performance is not specified when the *p*O2 is less than 25 mmHg (3.33 kPa). The linearity of the glucose is dependent on the oxygen tension of the sample. This dependence is due to the co-reaction of glucose and oxygen by the enzyme glucose oxidase. Low pO_2 levels can influence the linearity of the glucose sensor. The following table outlines the glucose linearity as a function of the pO_2.

<table>
<tr><th colspan="2">Predicate: ABL90 Flex (K120197)</th></tr>
<tr><th>Similarities</th><th>Differences</th></tr>
<tr><td>Blood Gas Measurement
pH, pO_2, pCO_2 by potentiometry</td><td>Added information to manual:
<table><tr><th colspan="2">Impact of the pO_2 level on Glucose linearity and specifications of the ABL90 FLEX analyzer</th></tr><tr><td>If the pO_2 level in a sample is:</td><td>Then cGlu linearity specifications only apply to cGlu values between:</td></tr><tr><td><25 mmHg (3.33 kPa)</td><td>Linearity not specified. Glu is not usable.</td></tr></table></td></tr>
<tr><td>Electrolyte Measurement
cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry</td><td>Software changes:
- Suppression of glucose results when pO_2 < 25 mmHg
- Message: "Glu not usable"</td></tr>
<tr><td>Metabolite Measurement
cGlu, cLac by amperometry</td><td></td></tr>
<tr><td>Oximetry Measurement
ctHb, sO_2 FO_2Hb, FHHb, FCOHb, FMetHb, FHbF</td><td></td></tr>
<tr><td>Hemoglobin Measurement
Spectrophotometry</td><td></td></tr>
<tr><td>Identical Performance Characteristics</td><td></td></tr>
<tr><td>Two-Point liquid calibration</td><td></td></tr>
<tr><td>Menu driven touch screen</td><td></td></tr>
<tr><td>Software operating system Microsoft XPE</td><td></td></tr>
<tr><td>Sample Introduction Aspiration</td><td></td></tr>
<tr><td>Dimensions (length x width x depth)</td><td></td></tr>
<tr><td>External Power Source
230/120 V mains</td><td></td></tr>
</table>

6. Design Control Activities

The risk associated with a negative bias on glucose results obtained from samples with low pO_2 level was assessed in a risk analysis. An interference study confirmed that this could lead to an unacceptable negative bias of more than 10% on glucose values in the upper reportable range.

#/ Hazard	Validations and Verifications activities descriptions	Pre-determined Acceptance criteria	Testing results summary	Meet the acceptance criteria or not?
41/Too low Glucose result in the upper reportable range obtained from samples with low pO2 level 48/Unacceptable bias on Glucose results obtained from	Interference study at different pO_2 levels and at different glucose levels covering the reportable range of the analyser using fresh heparinized samples.	Bias: <10% for glucose when pO_2 is > 25 mmHg when compared to the reference method	30 days 5-7 different pO_2 levels 5 different glucose levels 10 analyzers 5 tests of each sample on each analyzer 3 runs Total of 3150 measurements The results are valid under the	Passed The acceptance criterion is met under the condition that all glucose results are suppressed when the pO_2 level of the

#/ Hazard	Validations and Verifications activities descriptions	Pre-determined Acceptance criteria	Testing results summary	Meet the acceptance criteria or not?
samples with pO2 levels above 25 mmHg 49/Too low Glucose result in the lower and medium reportable range obtained from samples with low pO2 level			condition that all glucose results are suppressed when the pO_2 level of the sample is below 25 mmHg all acceptance criteria are met: Bias < 10%	sample is below 25 mmHg.

cGlu= 36 mg/dL (2 mmol/L)			cGlu= 108 mg/dL (6 mmol/L)			cGlu= 180 mg/dL (10 mmol/L)			cGlu= 450 mg/dL (25 mmol/L)			cGlu= 720 mg/dL (40 mmol/L)		
ave pO_2 [mmHg]	$Bias_{ABL735}$		ave pO_2 [mmHg]	$Bias_{ABL735}$		ave pO_2 [mmHg]	$Bias_{ABL735}$		ave pO_2 [mmHg]	$Bias_{ABL735}$		ave pO_2 [mmHg]	$Bias_{ABL735}$	
	[mg/dL]	[%]		[mg/dL]	[%]		[mg/dL]	[%]		[mg/dL]	[%]		[mg/dL]	[%]
17.9	0.72	2.36	14.9	0.90	0.77	14.8	-7.56	-4.15	16.1	-37.26	-8.30	13.5	-81.0	-11.20
28.4	0.54	1.78	30.5	1.08	0.97	26.4	-3.42	-1.91	27.4	-7.74	-1.79	25.6	-9.36	-1.32
-	-	-	-	-	-	-	-	-	-	-		33.3	-46.8	-6.67
46.8	1.62	4.95	43.0	1.80	1.75	43.8	2.52	1.45	41.6	-0.18	-0.05	44.9	24.8	3.65
62.1	0.54	1.46	55.5	1.44	1.29	60.7	-1.08	-0.63	60.2	1.62	0.36	59.0	29.7	4.43
77.0	0.54	1.43	80.8	1.26	1.27	75.4	-0.72	-0.37	74.7	-0.9	-0.21	76.2	27.0	4.03
-	-	-	-	-	-	-	-	-	-	-	-	97.6	4.86	0.70

The labelling and the software has been modified to assure that the Operator does not use glucose results obtained from samples with a pO_2 level below 25 mmHg.
The verification and validation activities for the software change have been conducted and it has been concluded that the device is effective and safe.

7. Performance Data
The performance data submitted in the original submission (K092686) still apply.

8. Conclusion
The ABL90 FLEX with the modification described above is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate ABL90 Flex (K120197).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 16, 2012

Radiometer Medical ApS
c/o Martin Gabler
Akandevej 21
Bronshoj 2700 Denmark

Re: k122729
Trade/Device Name: ABL90 FLEX
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO2, PO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, CEM, CGA, CGZ, GHS, GKR, JFP, JGS, JIX, KQI, KHP,JJY
Dated: October 16, 2012
Received: October 22, 2012

Dear Mr. Gabler

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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* Diagnostics and Radiological Health 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,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

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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 Diagnostics and Radiological Health (OIR)

Yueng Chan
Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)

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Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood.)

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

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