## Section 5. 510(k) Summary

AUG 06 2010

**1. Submitter Information**
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D. Date Prepared: August 26, 2009

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**4. Device Identification**
A. Trade/Proprietary Name: ABL90 FLEX
B. Classification: Class II (21CFR § 862.1120)
C. Product Code: 75CHL.
D. Subsequent Codes: CEM, JGS, JFP, CGZ, CGA, KHP, GHS, GKR, KQI, JIX, JJY

**5. Device Description**
The ABL90 FLEX system consists of a modular analyzer incorporating a user interface module with a large colour touch screen interfacing the analyzer electronic and fluidic modules. The user interface module contains the analyzer CPU and all of the required electronic interfaces for external communication and data storage.

Sensors that measure pH, $pO_2$, $pCO_2$, potassium, sodium, calcium, chloride, glucose and lactate are contained in a sensor cassette that connects to the sample inlet. This cassette attaches to the front of the instrument.

An oximetry module measures ctHb, $sO_2$, *F*O2Hb, *F*COHb, *F*MetHb and *F*HHb. This module consists of a spectrometer, an ultrasonic hemolyzer and thermostatic components integrated into the instrument.

The system also includes a solution pack for the calibration and automatic quality control of the sensor and oximetry system. The solution pack includes calibration and quality control reagents individually packaged in sealed foil pouches.

The instrument and consumables incorporate "smart chip" technology for unique identification and lot-specific calibration and quality control data.

**6. Intended Use**
The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in 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.

**7. Substantial Equivalence**
The ABL90 FLEX is substantially equivalent in features and characteristics to the predicates: the ABL80 FLEX Co-Ox, the ABL800 FLEX, the ABL735, the NPT7 and the QUALICHECK5$^+$.

510(k) Number/Device Manufacturer:
K08370 ABL80 FLEX Co-OX, SenDx Medical, Inc.
K050869 Modification to ABL800 FLEX, Radiometer Medical ApS
K041874 ABL800 FLEX, Radiometer Medical ApS
K002290 ABL735 Series, Radiometer Medical A/S
K982928 NPT7, Radiometer America Inc.
K980135 QUALICHECK5$^+$, Radiometer America Inc.

With the ABL800 FLEX, ABL735 Series and the ABL90 FLEX, the principles of operation are similar for all parameters except $pO_2$:
Amperometry: Glucose, Lactate
Potentiometry: pH, $pCO_2$, sodium, potassium, calcium, chloride,
Spectrophotometry: ctHb, $sO_2$, $FO_2Hb$, *F*COHb, *F*MetHb and *F*HHb.

With the NPT7 and the ABL90 FLEX, the same optical measurement principle is used for $pO_2$, viz. phosphorescence quenching.

**8. Performance Data**
The following data has been generated for the ABL90 FLEX

A. Method Comparison
B. Precision
C. Linearity/Assay Reportable Range
D. Limit of Quantitation
E. Calibration/Quality Control
F. Analytical Specificity - Interferences
G. User Testing
H. Stability

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Radiometer Medical APS
c/o Martin Gabler
Regulatory Affairs
Akandevej 21,
Bronshoj
Denmark DK-2700

JUN 0 2 2011

Re: k092686
Trade/Device Name: ABL90 Flex
Regulation Number: 21 CFR 862.1600
Regulation Name: Potassium test system.
Regulatory Class: II
Product Code: CEM, CGA, CGZ, CHL, GHS, GKR, JFP, JGS, JIX, KQI, JJY, KHP
Dated: July 29, 2010
Received: August 2, 2010

Dear Mr. Gabler:

This letter corrects our substantially equivalent letter of August 6, 2010.

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

# Indication for Use

510(k) Number: k092686

Device Name: ABL90 FLEX

Indication For Use:

The ABL90 FLEX is a portable, automated analyzer that measures pH, blood gases, electrolytes, glucose, lactate and oximetry in heparinized 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.

These tests are only performed under a physician's order:

pH, pO2 and pCO2 : pH, pCO2 and pO2 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 (cCa2+): calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

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

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

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

Glucose (cGlu): 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 (cLac): 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 (ctHb): total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.

sO2: oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus reduced hemoglobin.

FO2Hb: oxyhemoglobin as a fraction of total hemoglobin.

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

FMetHb: methemoglobin as a fraction of total hemoglobin.

FHHb: reduced hemoglobin as a fraction of total hemoglobin.

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

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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