## Section 5. 510(k) Summary

JUL 3 1 2013

### 1. Administrative

**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<br>2700 Broenshoej<br>Denmark |
| Phone: | +45 3827 3827 |
| Fax: | +45 3827 2727 |

### 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 modification consists of Data Management software called AQURE system. The software enables display of test results, receivable of data from connected devices at the point-of-care or laboratory, transfer of test results to the HIS/LIS and initiation of device actions.

### 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. Substantial Equivalence

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

510(k) Number/Device Manufacturer:
K092686 ABL90 FLEX SERIES, Radiometer Medical ApS
K120197 ABL90 FLEX, Radiometer Medical ApS
K122729 ABL90 FLEX, Radiometer Medical ApS

| Similarities | | |
|---|---|---|
| **Issue** | **SE Device** | **Predicate Device (K092686, K120197 and K122729)** |
| Intended Use | Same | 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. |
| Blood Gas Measurement | Same | pH, $pO_2$, $pCO_2$ by potentiometry |
| Electrolyte Measurement | Same | $cK^+$, $cNa^+$, $cCa^{2+}$, $cCl^-$ by potentiometry |
| Metabolite Measurement | Same | cGlu, cLac by amperometry |
| Oximetry Measurement | Same | ctHb, $sO_2$, $FO_2Hb$, FHHb, FCOHb, FMetHb, FHbF by spectrophotometry |
| Performance Characteristics | Same | Identical Performance Characteristics |
| Calibration | Same | Two-Point liquid calibration |
| User Interface | Same | Menu driven touch screen |
| Software operating system | Same | Microsoft XPE |
| Sample Introduction | Same | Aspiration |
| Dimensions (height x width x depth) | Same | 17.7 x 9.8 x 11.4 in |
| Weight | Same | 11.1 kg |
| Ethernet | Same | 1 x RJ45 connector,<br>100Base-Tx Fast Ethernet |
| USB | Same | Three connectors for USB port |
| Software version | Same | Software version 2.8 (K122729) |

| Differences | | |
|---|---|---|
| **Issue** | **SE Device** | **Predicate Device (K092686)** |
| AQURE system | Send Operator data (new, changed) to ABL90 Flex Analyzer | Local Operator Administration at the analyzer |
| | Data management software.<br>The software functionalities are:<br>• Remote display of test results<br>• Receivable of data from connected devices at the point-of-care or laboratory<br>• Transfer of test results to the HIS/LIS | Analyzer functionalities are:<br>• Local display of test results<br>• Direct transfer of test results to the HIS/LIS |
| | **SE Device** | **Predicate Device (K120197)** |
| | Initiation of device actions, see section *12.02 Device actions for ABL90 FLEX analyzers* | Remote access to the analyser by the Netop host/client OTS software supporting the following functions:<br>• Perform calibrations,<br>• Perform replacements,<br>• Perform QC measurements,<br>• Edit data in the log files, and<br>• Approve patient results. |

**5. Performance Data**

No performance characteristics are affected by the change. The performance data submitted in the original submission (K092686) still apply.

**6. Conclusion**

The ABL90 FLEX with AQURE described above is substantially equivalent in Intended Use, fundamental scientific technology, and characteristics to the predicate ABL90 Flex (K092686, K120197 and K122729). For the implementation of the change design control principles (risk management, verification and validation) have been applied which indicated that the change is of no impact to the performance of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2013

Radiometer Medical ApS
C/O Gitte Juel Friis
Aakandevej 21
2700 Broenshoej
DENMARK

Re: K130144
Trade/Device Name: ABL90 Flex
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, KHP, GKR, GHS, KQI, JJY, JIX
Dated: June 27, 2013
Received: July 1, 2013

Dear Gitte Juel Friis:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, Ph.D.

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

510(k) Number (if known): k130144

Device Name: ABL90 Flex Analyzer

Indications for Use:
**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.

**Indications for use:**
**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.

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

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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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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# Indications for Use

510(k) Number (if known): k130144

Device Name: ABL90 Flex Analyzer

Indications for Use:
**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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