DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 17, 2015

RADIOMETER MEDICAL APS.
LASSE POST MOLLER
REGULATORY AFFAIRS SPECIALIST
AAKANDEVEJ 21
BROENSHOEJ 2700 DENMARK

Re: K142898
Trade/Device Name: ABL800 FLEX with AQURE connectivity
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: CHL, CEM, JGS, JFP, CGZ, CGA, KHP, CGL, CIG, MQM, KQI, GHS, GKR
Dated: May 13, 2015
Received: May 20, 2015

Dear Lasse Moller:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Katherine Serrano -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k142898

Device Name
ABL800 FLEX with AQURE connectivity

Indications for Use *(Describe)*
The ABL800 FLEX analyzers are intended for In Vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, cK+, cNa+, cCa2+, cCl-, cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF). In addition the ABL800 FLEX is intended for In vitro testing of samples of expired air for the parameters pO2 and pCO2, and for In vitro testing of pleura samples for the pH parameter.

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

pO2: The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

pCO2: pCO2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (cK+): the measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

Sodium (cNa+): the measurements of the concentration of sodium ions in plasma are used to monitor the electrolyte balance.

Calcium (cCa++): the measurements of the concentration of calcium ions in plasma are used to monitor the electrolyte balance.

Chloride (cCl-): the measurements of the concentration of chloride ions in plasma are used to monitor the electrolyte balance.

Glucose (cGlu): The glucose measurements measure the concentration of glucose in plasma. The glucose measurements are used to screen for, diagnose and monitor diabetes, pre-diabetes and hyper and hypoglycemia.

Lactate (cLac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements serve as a marker of critical imbalance between tissue oxygen demand and oxygen supply.

Bilirubin (ctBil): The bilirubin measurements measure the total concentration of bilirubin in plasma. ctBil is used to assess the risk of hyperbilirubinemia.

Total Hemoglobin (ctHb): ctHb is a measure of the potential oxygen-carrying capacity of the blood.

Oxygen Saturation (sO2): sO2 is the percentage of oxygenated hemoglobin in relation to the amount of hemoglobin capable of carrying oxygen. sO2 allows evaluation of oxygenation.

Fraction of Oxyhemoglobin (FO2Hb): FO2Hb is a measure of the utilization of the potential oxygen transport capacity; that is the fraction of oxyhemoglobin in relation to all hemoglobins present (tHb) including dyshemoglobins.

Fraction of Carboxyhemoglobin (FCOHb): FCOHb is the fraction of carboxyhemoglobin. It is incapable of transporting

oxygen.

Fraction of Methemoglobin (FMetHb): FMetHb is the fraction of methemoglobin. It is incapable of transporting oxygen.

Fraction of Deoxyhemoglobin in Total Hemoglobin (FHHb): FHHb is the fraction of deoxyhemoglobin in total hemoglobin. It can bind oxygen then forming oxyhemoglobin.

Fraction of Fetal Hemoglobin (FHbF): Fetal hemoglobin consist of two α-chains and two β-chains, and has a higher oxygen affinity than adult Hb.

Creatinine (cCrea): The creatinine measurements measure the concentration of creatinine in blood. Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

Pleural pH: 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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June 17, 2015

Section 06. 510(k) Summary

1. Administrative

Device Information

Device Name:	ABL800 FLEX with AQURE connectivity
Common Name:	Blood gases and blood pH test system
Product Code:	CHL (CGZ, CGA, CGL, CEM, CIG, GKR, GHS, JFP, JGS, KHP, KQI, MQM)
Registration Number:	21 CFR 862.1120
Classification:	Class II
Classification Panel:	Clinical Chemistry

Submitter

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2. Description of Device Modification

ABL800 FLEX with AQURE connectivity is a stationary, automated system intended for in vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, cK+, cNa+, cCa2+, cCl-, cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF).

The modification consists of integration with the Medical Device Data System (MDDS) called AQURE system. The software enables the initiation of device actions on connected ABL800 series analyzers.

3. Intended Use

The ABL800 FLEX analyzers are intended for In Vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, cK+, cNa+, cCa2+, cCl-, cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF). In addition the ABL800 FLEX is intended for In vitro testing of samples of expired air for the parameters pO2 and pCO2, and for In vitro testing of pleura samples for the pH parameter.

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

pO2: The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

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rate.

Potassium (cK+): the measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

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Pleural pH: 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.

4. Substantial Equivalence
ABL800 FLEX with AQURE connectivity is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
Radiometer Medical ApS.
ABL800 FLEX - K041874

5. Registration history
ABL800 FLEX was originally cleared with K041874, and then modified with the FLEXQ Module - an optional capability of automatic sampling from of up to three queued blood samplers in K043218. Connectivity to the RADIANCE-system was cleared with K050869, the suggested predicate. K051968 introduced the parameter creatinine to the device. K100777 and K110416 introduced the possibility to measure the pH in pleural fluids.

ABL90 FLEX was cleared for integration with AQURE in K130144. Currently, remote control functionality to other devices than ABL90 FLEX is not available in the US. The functionality is not available to the customer and any information regarding this functionality is either re-moved from the manual or is indicated as unavailable. The device actions for the other analyzers have a note added stating “This feature is not available in the USA”.

Similarities		
Issue	**SE Device**	**Predicate Device (K041874)**
Intended Use	Same	The ABL800 FLEX analyzers are intended for In Vitro testing of samples of whole blood for the parameters pH, pO2, pCO2, cK+, cNa+, cCa2+, cCl-, cGlu, cLac, cCrea, ctBil, and co-oximetry parameters (ctHb, sO2, and the hemoglobin fractions FO2Hb, FCOHb, FMetHb, FHHb and FHbF). In addition the ABL800 FLEX is intended for In vitro testing of samples of expired air for the parameters pO2 and pCO2, and for In vitro testing of pleura samples for the pH parameter.
Blood Gas Measurement	Same	pH, pCO_2 by potentiometry, pO_2 by amperometry
Electrolyte Measurement	Same	cK^+, cNa^+, cCa^{2+}, cCl^- by potentiometry
Metabolite Measurement	Same	cGlu, cLac, cCrea by amperometry
Oximetry Measurement	Same	ctHb, sO_2, FO_2Hb, FHHb, FCOHb, FMetHb, FHbF, ctBil 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	Height: 548 mm (21.95 in.) with the vertical screen Width: 700 mm (27.6 in.) Depth: 476 mm (18.5 in.)
Weight	Same	ABL805: 32,9 kg ABL830/20/10: 32,9 kg ABL835/25/15: 33,9 kg ABL837/27/17: 36,2 kg
Ethernet	Same	1 x RJ45 connector, 32-bit PCI bus interface, Novell NE 2000 compatible, onboard 10-Base T, fully compliant with IEEE 802.3 10 Mbps CSMA/CD standards.
USB	Same	Pin header for two USB (Universal Serial Bus) ports

Similarities		
Issue	**SE Device**	**Predicate Device (K041874)**
Software version	Same	Software version 6.13

Differences		
Issue	**SE Device**	**Predicate Device (K041874)**
AQURE system	Send Operator data (new, changed) to ABL800 FLEX Analyzer	Local Operator Administration at the analyzer
	Initiation of device actions through AQURE system. See section 13.02 Device actions for ABL800 FLEX analyzers	Remote access to the analyser by the Netop host/client OTS software supporting the following functions: • Perform calibrations, • Perform replacements, • Perform QC measurements, • Edit data in the log files, and Approve patient results.

5. Performance Data
No performance characteristics are affected by the change. The performance data submitted in the original submission (K041874 as modified by K043218, K050869, K051968, K100777 and K110416) still apply.

6. Summary of Design Control activities
We conducted an FMEA risk analysis and mitigated all identified hazards to As Low As Reasonably Practicable (ALARP) as per ISO 14971, and verified software mitigations by using test protocols. Results met predefined acceptance criteria.

7. Conclusion
ABL800 FLEX with AQURE connectivity described above is substantially equivalent in Intended Use, fundamental scientific technology, and characteristics to the predicate ABL800 FLEX (K041874 as modified by K043218, K050869, K051968, K100777 and K110416). 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.