510(k) Summary

OCT 16 2006

Submitter:	Radiometer Medical ApS
Address:	Åkandevej 21, DK-2700 Brønshøj, Denmark
Phone:	+45 3827 3827 or +45 3827 3390 (direct)
Fax:	+45 3827 2736
Contact Person:	Ms. Kirsten Rønø
Date Summary Prepared:	September 18, 2006
Device Trade Name(s):	ABL837 FLEX
Common name:	Blood Gas, Co-oximetry, Electrolyte and Metabolite Analyzer
Classification Name:	Creatinine Test System (21 CFR Section 862.1225)

Predicate Devices

ABL800 FLEX (K041874), ABL800 FLEX with FLEXQ Module (K043218), ABL700 Series Upgrade (K002290) all by Radiometer Medical ApS and i-STAT System Creatinine Test (K973292) by i-STAT.

Device Description

The ABL837 FLEX is an analyzer with the capability of measuring creatinine. The wet section of the ABL837 FLEX analyzer is structured as the wet section of the ABL800 FLEX and ABL800 FLEX with FLEXQ Module analyzers, but includes a measuring module comprising the measurement system for the creatinine parameter. This measuring system comprises two electrodes, one of which measures creatine and the other of which measures creatine and creatinine. The creatinine parameter value is determined as a difference measure of the output of these two new electrodes. The two electrodes are developed based on the concept of the existing Radiometer Medical ApS glucose and lactate electrodes.

Intended Use

The ABL837 FLEX analyzer is intended for in vitro testing of samples of heparinized whole blood, plasma and serum for the parameter creatinine.

Statement of Indication for Use

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.

Clinical Interpretation

Creatinine (cCrea): Common causes of low creatinine may be small stature, debilitation, decreased muscle mass, or severe hepatic disease. Common causes of high creatinine may be renal diseases, urinary tract obstruction, rhabdomyolysis, acute necrotizing pancreatitis, diarrhoea, vomiting, or decreased intake.

Performance Test

Several tests have been performed to determine the linearity, precision, detection limits and interference of the creatinine measurements. A comparison test between the ABL837 FLEX and the i-STAT System Creatinine Test has shown that the ABL837 FLEX performs equivalent to the predicate device i-STAT System Creatinine Test.

Summary of Technological Characteristics

The sensors for measuring creatinine are electrochemical sensors.

The ABL837 FLEX analyzer may be interfaced with the RADIANCE STAT analyzer management system software as well as with the hospital LIS/HIS systems through network interfaces.

Conclusion

The ABL837 FLEX analyzer is substantially equivalent in features and characteristics to the predicate devices, ABL800 FLEX (K041874), ABL800 FLEX with FLEXQ Module (K043218), ABL700 Series Upgrade (K002290) all by Radiometer Medical ApS and i-STAT System Creatinine Test (K973292) by i-STAT.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lene Meineche Marnaes
Regulatory Affairs Officer
Akandevej 21
Bronshoj
Denmark, DK-2700

OCT 16 2006

Re: k051968
Trade/Device Name: ABL837 FLEX
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: Class II
Product Code: CGL
Dated: September 18, 2006
Received: September 20, 2006

Dear Ms. Marnaes:

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.

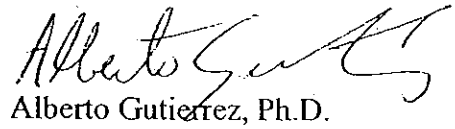
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, 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: K051968

Device Name: ABL837 FLEX

Indications for Use:
The ABL837 FLEX analyzer is intended for in vitro testing of samples of heparinized whole blood, plasma and serum for the parameter Creatinine. 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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