AUG 1 1 2005

K050869

510(k) Summary
As required by 807.92
For RADIANCE v2.5 modification to **ABL800 FLEX** (K041874)
Prepared on March 30, 2005

Submitted by: Radiometer Medical ApS
Akandevej 21
DK-2700 Bronshoj, Denmark

Tel. 45 38 27 38 27 Fax: 45 38 27 27 36

Contact Person: Kirsten Rono

Device Trade Name: **RADIANCE** 2.5 modification to **ABL800 FLEX**

Common Name: Blood Gas, Co-0ximetry, Electrolyte and Metabolite Analyzer

Classification: Blood gases and blood pH test system, Class II Sec. 21 CFR 862.1120

Predicate Device: **ABL800 FLEX** K041874

Manufactured by: Radiometer Medical ApS
Akandevej 21
DK-2700 Bronshoj, Denmark

Description of the Device: **RADIANCE** v2.5 is a Windows-based software application that runs on an independent server and, when added to **ABL800 FLEX**, enables remote data entry and control of compatible blood-gas analyzers connected to a laboratory information system (LIS) and/or a hospital information system (HIS).

Intended Use for the Device: The **ABL800 FLEX** with **RADIANCE** v2.5 modification is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry paramenters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *FCOHb*, *F*MetHb, *F*HHb and *F*HbF). In addition, the **ABL800 Flex** with **RADIANCE** v2.5 modification is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The **ABL800 FLEX** with **RADIANCE** v2.5 modification includes an AutoCheck Module to perform automated analysis of quality control fluids

Substantial Equivalence to Predicate Device: **ABL800 FLEX** modified by the addition of **RADIANCE** v2.5 has many similarities to the predicate device which previously

received 510(k) clearance. It has the same intended use and the same fundamental scientific technology. Design control information ensures substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 1 2005

Ms. Kirsten Rønø
Director of Quality and Regulatory Affairs
Radiometer Medical ApS
Åkandevej 21
Brønshøj
Denmark DK-2700

Re: k050869
Trade/Device Name: ABL800 Flex modified by RADIANCE v2.5
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO2, pO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, CIG, GHS, KQI, KHP, MQM
Dated: July 12, 2005
Received: July 12, 2005

Dear Ms. Rønø:

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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 Statement

510(k) Number (if known) K050869

Device Name **ABL800 FLEX** modified by **RADIANCE** v2.5

Indications for Use

Indications : The **ABL800 FLEX** with **RADIANCE** v2.5 modification is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry paramenters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *FCOHb*, *F*MetHb, *F*HHb and *F*HbF). In addition, the **ABL800 Flex** with **RADIANCE** v2.5 modification is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The **ABL800 FLEX** with **RADIANCE** v2.5 modification includes an AutoCheck Module to perform automated analysis of quality control fluids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K050869