RADIOMETER AMERICA INC.

MEDICAL DIVISION

810 SHARON DRIVE, WESTLAKE, OHIO 44145
800-736-0600, 440-871-8900
FAX 440-835-2633

NOV 2 4 1999

SUBJECT: **510(K) SUMMARY NUMBER: K991417**

FROM:
Vince Sigmund
Manager of Customer Relations & Technical Support
Radiometer America Inc.
810 Sharon Drive
Westlake, Ohio 44145
(440)871-8900, Ext. 209 or 1-800-736-0600
Fax (440)871-2633

DATE: **May 11, 1999**

PRODUCT:
Trade Name: ABL735
Common Name: pH/Blood Gas/Co-oximetry/Electrolyte/Metabolyte Analyzer
Classification Name: Blood Gas and Blood pH Test System

PREDICATE DEVICE: **Radiometer ABL700 (K980130), for neonate bilirubin testing the Unistat (Leica Inc., K922770) and the Advanced Bilirubin Stat Analyzer Model BR2 (Advanced Instruments Inc., K790608) and for adult bilirubin testing the Vitros (Johnson and Johnson Clinical Diagnostics, formerly Kodak Clinical Diagnostics, K840606; K840880).**

PRODUCT DESCRIPTION: **ABL735 is an automated pH/Blood Gas/Co-oximetry/Electrolyte/Metabolyte Analyzer that is 44cm X 70cm X 50cm (HWD) and weighs 30kg. It measures on whole blood in approximately 60 seconds.**

INTENDED USE: **The ABL735 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 parameters (total hemoglobin, oxygen saturation and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, *F*HHb, and *F*HbF).**

TECHNOLOGICAL CHARACTERISTICS VERSUS PREDICATE DEVICE: **Similar to the ABL700 Series**

SUBSTANTIAL EQUIVALENCE: **The ABL735 is substantially equivalent in features and characteristics to the current ABL700 Series (K980130) marketed by Radiometer America Inc.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 24 1999

Mr. Vince Sigmund
Manager, Customer Relations/Technical Support
Radiometer America, Inc.
810 Sharon Drive
Westlake, Ohio 44145

Re: K991417
Trade Name: ABL735 Analyzer
Regulatory Class: II
Product Code: CHL, CGZ, JGS, CIG, JFP, CGA, CEM, MQM, CKK
Regulatory Class: I
Product Code: KHP
Dated: October 25, 1999
Received: October 26, 1999

Dear Mr. Sigmund:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991417

Device Name:_____

Indications For Use:

The ABL735 is intended for in vitro testing of samples of whole blood for the parameters pH,pO2, pCO2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and coOoximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions fO2Hb, fCOHb, fMetHb, fHHb, and fHbF).

Joan Cogan
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991417

(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)

(Optional Format 1-2-96)