

# RADIOMETER AMERICA INC.

EXHIBIT VI

MEDICAL DIVISION

811 SHARON DRIVE, WESTLAKE, OHIO 44145-1598  
800-736-0600, 216-871-8900  
FAX 216-892-8117

OCT - 6 1997

**SUBJECT:** 510(k) SUMMARY

**FROM:** Donald L. Baker  
Director of Marketing and Regulatory Affairs  
Radiometer America Inc.  
810 Sharon Drive  
Westlake, Ohio 44145  
(440)871-8900, Ext. 287 or 1-800-736-0600  
Fax (440)871-8117

**DATE:** September 5, 1997

**PRODUCT:** Trade Name - ABL555  
Common Name - Blood Gas, Electrolyte and Metabolite Measuring System  
Classification Name - Blood Gas

## PREDICATE

**DEVICE:** ABL505 and EML105

## PRODUCT

**DESCRIPTION:** ABL555 is an automated blood gas, electrolyte and metabolite analyzer that is 40 cm x 55 cm x 40 cm (WHD) and weighs 37.5 kg. It measures on whole blood in approximately 54 seconds.

## INTENDED

**USE:** ABL555 is a stand alone, blood gas, electrolyte and metabolite analyzer that measures pH,  $pCO_2$ ,  $pO_2$ ,  $Na^+$ ,  $K^+$ , and glucose on whole blood.

## TECHNOLOGICAL CHARACTERISTICS

### VERSUS PREDICATE

**DEVICE:** ABL555 (with glucose) is technologically similar to the current version ABL505.

## SUBSTANTIAL EQUIVALENCE:

ABL555 is substantially equivalent in features and characteristics to the current ABL505 marketed by Radiometer America Inc. (K914166). The major difference is the addition of the glucose analyte and the elimination of the  $Ca^{++}$  and  $Cl^-$  electrodes.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 6 1997

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Donald L. Baker  
Director of Marketing and Regulatory Affairs  
Radiometer America, Inc.  
811 Sharon Drive  
Westlake, Ohio 44145-1598

Re: K973367  
ABL555 Analyzer  
Regulatory Class: II  
Product Code: CHL, JGS, CEM, CGA  
Dated: September 5, 1997  
Received: September 8, 1997

Dear Mr. Baker:

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 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 (Pre-market 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 pre-market 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.

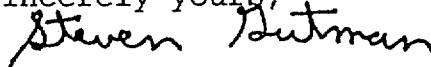
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsmamain.html>".

Sincerely yours,



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


Page \_\_\_ of \_\_\_

510(k) Number (if known): \_\_\_\_\_

Device Name: ABL555

Indications For Use:

ABL555 is a stand alone, blood gas, electrolyte and metabolite analyzer that measures pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, and glucose on whole blood.

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K973367

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

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

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