

MEDICAL DIVISION

811 SHARON DRIVE, WESTLAKE, OHIO 44146-1698
800-736-0800, 216-871-8900
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JAN 16 1998

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:** December 19, 1997**PRODUCT:** Trade Name - ABL555
Common Name - Blood Gas, Electrolyte and Metabolite Measuring System
Classification Name - Blood Gas**PREDICATE****DEVICE:** ABL555, EML105, i-STAT Model 100, and Corning 348**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^+ , Hct, and the option of one of the following parameters: Cl^- or Ca^{2+} or glucose or lactate.**TECHNOLOGICAL CHARACTERISTICS****VERSUS PREDICATE****DEVICE:** ABL555 (with lactate and Hct) is technologically similar to the current version ABL555.**SUBSTANTIAL EQUIVALENCE:**

ABL555 is substantially equivalent in features and characteristics to the current ABL555 marketed by Radiometer America Inc. (K973367). The major difference is the addition of the lactate analyte and hematocrit.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 16 1998

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

Re: K974818
ABL555 Blood Gas, Electrolyte, and Metabolite
Measuring System
Regulatory Class: II
Product Code: MMI
Dated: October 30, 1997
Received: October 31, 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 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.

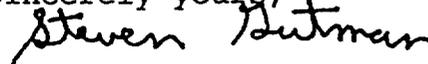
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

510(k) Number (if known): K974818

Device Name: ABL555

Indications For Use:

ABL555 is a stand alone, blood gas, electrolyte and metabolite analyzer that measures pH, pCO₂, pO₂, Na⁺, K⁺, Hct, and the option of one of the following parameters: CL⁻ or Ca²⁺, or Glucose or Lactate.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974818

(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)