K980130

FEB - 9 1998

16

RADIOMETER AMERICA INC.

MEDICAL DIVISION

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

EXHIBIT VI

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)871-2633

DATE: January 5, 1998

PRODUCT: Trade Name: ABL700 Series
Common Name: Blood Gas, Co-oximetry, Electrolyte and Metabolite Measuring System
Classification Name: Blood Gas

PREDICATE DEVICE: ABL625 and ABL555

PRODUCT DESCRIPTION: ABL700 Series, is an automated blood gas, co-oximetry electrolyte and metabolite analyzer that is 44 cm x 70 cm x 50 cm (HWD) and weighs 30 kg. It measures on whole blood in approximately 60 seconds.

INTENDED USE: ABL700 Series is a stand-alone blood gas analyzer that measures pH, pCO_2, pO_2, cNa^+, cK^+, cCa^{2+}, cCL^-, Glucose, Lactate, and Co-oximetry parameters on human arterial/venous and capillary whole blood, and pO_2 and pCO_2 on expired air.

TECHNOLOGICAL CHARACTERISTICS VERSUS PREDICATE DEVICE: ABL700 Series is technologically similar to the ABL625 and ABL555.

SUBSTANTIAL EQUIVALENCE:
ABL700 Series is substantially equivalent in features and characteristics to the current ABL625 (K962334) and ABL555 (K973367) marketed by Radiometer America Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K980130
ABL700 Series Analyzer
Regulatory Class: I & II
Product Code: CHL, JFP, CGZ, CGA, KHP, CEM, JGS
Dated: January 5, 1997
Received: January 14, 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 (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/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

RADIOMETER AMERICA INC.
MEDICAL DIVISION

EXHIBIT V

510(k) NUMBER (IF KNOWN): K980130

DEVICE NAME: ABL700 Series

INDICATIONS FOR USE:

ABL700 Series is a stand-alone blood gas analyzer that measures pH, pCO_2, pO_2 , cNa^+, cK^+, cCa^{2+}, cCL^-, Glucose, Lactate, and Co-oximetry parameters on human arterial/venous and capillary whole blood, and pO_2 and pCO_2 on expired air.

P. Bernhardt (for A. Montgomery)
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980130

(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)