RADIOMETER AMERICA INC.

MEDICAL DIVISION

810 SHARON DRIVE, WESTLAKE, OHIO 44145
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JAN 1 0 2000

SUBJECT: 510(K) SUMMARY NUMBER: K992859

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 871-2510

DATE: November 22, 1999

PRODUCT:

Trade Name: ABL700 with AutoCheck Module
Common Name: pH/Blood Gas/Co-oximetry/Electrolyte/Metabolyte Analyzer
Classification Name: Blood Gas and Blood pH Test System

PREDICATE DEVICE: RADIOMETER ABL700 Series (K980130, RADIOMETER Qualicheck 5+ (K980135) and AVL9181 Electrolyte Analyzer (K972673).

PRODUCT DESCRIPTION:

The ABL700 Series Analyzer with the AutoCheck module is an ABL700 Analyzer with the added capability of performing automated analysis of quality control fluids. The AutoCheck module is designed to work with a quality control fluid system named AutoCheck 5+. The AutoCheck 5+ is an ampouled four level quality control fluid system. The composition of the various levels of Quality control fluids in AutoCheck 5+ correspond to the composition of the corresponding levels of Qualicheck 5+ system (K980135).

The AutoCheck 5+ ampoules comprise a cap on the top of the ampoules designed to break the top of an ampoule when it is to be used. Furthermore, each ampoule has a bar code containing information on the specific level and lot of the quality control fluid.

Installing an AutoCheck module into an existing ABL700 Series Analyzer includes physically installing the module and loading upgraded software which controls the function of the AutoCheck module. The AutoCheck module comprises an ampoule carrousel carrying 20 ampoules of quality control fluid and further comprises a bar code reader for reading the bar code located on each ampoule. When installed into the ABL700 Series Analyzer, the AutoCheck module automatically performs the quality control of the analyzer. Thus, when a quality control is due, the analyzer warns the user and if the user accepts, the quality control is performed. The software selects the appropriate ampoule, the AutoCheck module opens the ampoule by pressing the cap through the top of the ampoule, the quality control fluid is automatically introduced into the analyzer inlet and the measurements are performed. The upgraded software controls all steps. If required, a manual quality control may be performed as well.

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The automatic inlet of sample loaded into a carrousel is a principle, which is well known from various types of analyzers. Thus, it is well known in coagulation and/or urine analyzers that the samples to be measured are loaded with a sample carrousel. Also, the AVL9181 Electrolyte Analyzer (K972673) for measuring electrolytes in i. a. whole blood, serum, or plasma comprises a built-in autosampler. For further details of performing the automatic quality control in the ABL700 Series Analyzer with the AutoCheck module I refer to the enclosed sections of the Operator's Manual.

INTENDED USE: **The ABL700 Series Analyzer with the AutoCheck module 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. The AutoCheck Module is an added functionality to perform automated analysis of quality control fluids.**

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

SUBSTANTIAL EQUIVALENCE: **The ABL700 Series Analyzer with the AutoCheck module 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

JAN 1 0 2000

Mr. Vincent M. Sigmund
Product Manager, Quality Services
Radiometer America Inc.
810 Sharon Drive
Westlake, Ohio 44145

Re: K992859
Trade Name: ABL700 with AutoCheck Module
Regulatory Class: II
Product Code: CHL, JFP, CGZ, CGA, KHP, CEM, JGS, GKF
Regulatory Class: I
Product Code: JJS, KHP
Dated: December 22, 1999
Received: December 23, 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

RADIOMETER AMERICA INC.
MEDICAL DIVISION

EXHIBIT III

510(k) NUMBER (IF KNOWN): K992859

DEVICE NAME: ABL700 with AutoCheck Module

INDICATIONS FOR USE:

The ABL700 Series Analyzer with the AutoCheck module 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. The AutoCheck Module is an added functionality to perform automated analysis of quality control fluids.

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K992859

(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)**