SEP 1 3 2000

K002290

RADIOMETER COPENHAGEN

July 25, 2000

510(k) Summary - ABL700 Series Upgrade

000766

Submitter:	Radiometer Medical A/S
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Contact Person	Mrs. Kirsten Rønø

Trade Name	ABL700 Series
Common name	Blood Gas, Co-oximetry, Electrolyte and Metabolite Analyzer
Classification Name	Blood gases and blood pH test system

Predicate Devices
RADIOMETER ABL 700 Series (K980130) and ABL735 (991417).

Device Description
The ABL700 Series upgrade is a modification of the predicate ABL700 and ABL735 devices. The software is upgraded, thereby allowing for additional indications.

The additional indications are:

- the capability of measuring pO_2 and pCO_2 on samples of expired air.

The ABL700 Series upgrade has the same technological characteristics as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 3 2000

Ms. Kirsten Rønø
Head of Regulatory Affairs
Radiometer Medical A/S
Akandevej 21
DK-2700 Bronshoj,
Denmark

Re: K002290
Trade Name: ABL700 Series (upgrade)
Regulatory Class: II
Product Code: CHL, JFP, CGA, CGZ, KHP, CEM, CIG, JGS, GKF
Dated: July 25, 2000
Received: July 27, 2000

Dear Ms. Rønø:

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.

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" (21CFR 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K002290
Device Name: ABL700 Series (upgrade)
Indications for Use:

The ABL700 Series 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, FCOHb, FMetHb, FHHb and FHbF). In addition the ABL700 Series is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002290

(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