

OCT 12 2005

September 29, 2005

510(k) Summary

Submitter: Radiometer Medical ApS
Address: Åkandevej 21, DK-2700 Brønshøj, Denmark
Phone: +45 3827 3827 or +45 3827 3390 (direct)
Fax: +45 3827 2736
Contact Person: Ms. Kirsten Rønø
Date Summary Prepared: September 29, 2005
Device Trade Name: AutoCheck6+
Common name: Quality Control
Classification Name: Quality Control Material (Assayed and Unassayed)
(21 CFR Section 862.1660)

Predicate Devices

QUALICHECK5+ (K980135) and AutoCheck5+ (part of K992859 - ABL7000 with AutoCheck Module).

Device Description

AutoCheck6+ is a four level quality control system consisting of part numbers S7835, S7845, S7855, and S7865. Each level consists of 30 ampoules per box.

Intended Use

The AutoCheck6+ is a liquid four ampoule quality control system for checking the precision and accuracy of Radiometer analyzers for pH/Blood Gases, Co-oximetry, Electrolytes, Bilirubin, Glucose, Lactate, and Creatinine.

Technology

AutoCheck6+ is technically similar to the predicate device QUALICHECK5+ and AutoCheck5+. The AutoCheck6+ solutions are aqueous solutions that have the same components as QUALICHECK5+ and AutoCheck5+ and in addition hereto there is added specific amounts of creatine and creatinine and also of the enzyme creatininase (creatinine amidohydrolase) which stabilizes the equilibrium between creatine and creatinine. The measuring of the AutoCheck6+ is performed equivalent to the measuring of the QUALICHECK5+ and AutoCheck5+.

Predicate Devices; Substantial Equivalence

The AutoCheck6+ is substantially equivalent in features and characteristics to the predicate devices QUALICHECK5+ (K980135) and AutoCheck5+ (part of K992859 - ABL7000 with AutoCheck Module) manufactured by Radiometer Medical ApS. The major difference is the addition of the creatinine (cCrea) analyte.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 12 2005

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Kirsten Rønø
Director of Quality and Regulatory Affairs
Radiometer Medical ApS
Åkandevej 21
DK-2700 Brønshøj
Denmark

Re: k051928
Trade/Device Name: AutoCheck6+
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 2, 2005
Received: September 7, 2005

Dear Ms. Rønø:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

September 29, 2005

Indications for Use

510(k) Number: K051928

Device Name: AutoCheck6+

Intended Use:

The AutoCheck6+ is a liquid four ampoule quality control system for checking the precision and accuracy of Radiometer Medical ApS analyzers for pH/Blood Gases, Co-oximetry, Electrolytes, Bilirubin, Glucose, Lactate, and Creatinine.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

Page 1 of 1

510(k) K051928