DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 13, 2015

RADIOMETER MEDICAL ApS
METTE HARPSOEE
REGULATORY AFFAIRS SPECIALIST
AKANDEVEJ 21
2700 BRONSHOJ, DENMARK

Re: K150226
Trade/Device Name: Hematocrit and Metabolite QUALICHECK
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJS
Dated: March 27, 2015
Received: March 30, 2015

Dear Mette Harpsoee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150226

Device Name
Hematocrit and Metabolite QUALICHECK

Indications for Use *(Describe)*
This Hematocrit and Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are: cGlucose, cLactate, Hct

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

1. Submitter and contact information

Submitter

Company Name: Radiometer Medical ApS
ER Number: 3002807968
Address: Aakandevej 21
2700 Broenshoej
Denmark
Phone: +45 3827 3827
Fax: +45 3827 2727

Contact Person

Name: Mette Skytte Harpsoee
Function: Regulatory Affairs Specialist
E-mail: mette.skytte@radiometer.dk
Phone: +45 3827 3114
Fax: +45 3827 2727

Date prepared

Date: May 7, 2015

2. a. Device Information

Device Name: Hematocrit and Metabolite QUALICHECK
Common Name: Quality Control

Classification:

Classification name	CFR Section	Device Class	Product Code
Controls for blood-gases, (assayed and unassayed)	862.1660	I, reserved	JJS

2. b. Device Description

Hematocrit and Metabolite QUALICHECK is a two-level quality control system consisting of:

- Hematocrit and Metabolite QUALICHECK, Level 1 (S7170), 944-039
- Hematocrit and Metabolite QUALICHECK, Level 2 (S7180), 944-040

The system consists of 30 ampoules per box. One ampoule contains 2 mL of solution.

The quality control solution is an aqueous solution containing an organic buffer, acid, salts, metabolites, and a preservative.

3 Intended Use

This Hematocrit and Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.

Analytes are: *c*Glucose, *c*Lactate, Hct

4. Predicate device: QUALICHECK5+ (K980135)
Substantial Equivalence
The Hematocrit and Metabolite QUALICHECK is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate:

510(k) Number/Device Manufacturer:
K980135 QUALICHECK5+, Radiometer Medical ApS

Similarities		
Issue	**SE Device**	**Predicate: QUALICHECK5+ (K980135)**
Form	Same	Liquid
Base matrix	Same	Aqueous solution
Preservatives	Same	ProClin 950
Parameters	*c*Glucose, *c*Lactate, Hct	pH, pCO_2, pO_2, cNa^+, cK^+, cCa^{2+}, cCl^-, *c*Glucose, *c*Lactate, *c*tHb, sO_2, FO_2Hb, *F*COHb, *F*MetHb, *F*HbF, *c*tBil
Intended Use	This Hematocrit and Metabolite QUALICHECK solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges.	For In Vitro Diagnostic Use. This QUALICHECK5+ solution is an assayed quality control system for evaluating the accuracy and precision of all parameters listed on the insert specifying the control ranges. For professional use.
Storage	2 °C to 25 °C until expiration date.	2 °C to 25 °C until expiration date, including up to a total of 15 days at up to 32 °C.

Differences		
Issue	**SE Device**	**Predicate: QUALICHECK5+ (K980135)**
Levels	Two levels	Four levels
Target ranges	Target ranges, see Section *12.02 Target values*	Target ranges, see Section *12.02 Target values*
Compatible analyzers	• ABL77 • ABL555 • ABL605/615/625 • ABL80 FLEX • ABL80 BASIC • EML105	• ABL5 • ABL500/505/510/520/555 • ABL600/605/610/615/620/625 • ABL700/705/710/715/720/725/730/735 • ABL805/810/815/820/825/830/835/800BASIC • ABL80 - CO-OX • ABL80 - OSM • ABL90 FLEX • EML100/105

5. Stability

Stability claims are based on real time stability studies. Control solutions are stable for 2 years at 2 °C to 25 °C. Multiple test points were tested, with six measurements at each test point. All study results met the acceptance criteria.

In-use Stability: The contents should be used immediately after opening.

6. Value Assignment

To determine the true value for each parameter and thereby the assigned values and control ranges for Hematocrit and Metabolite QUALICHECK, the following sampling and measurements are performed:

Hct:

- 6 trays are sampled randomly from the Hematocrit and Metabolite QUALICHECK batch. Each tray contains 1000 ampoules.
- 5 ampoules are sampled from each of the 6 trays
- 30 ampoules are sampled from the reference batch
- Measurements are performed on at least 2 validated ABL555
- Measurements of Hct are performed alternately on the reference ampoule and the sample ampoule. This is repeated 5 times on each ABL555 – 60 measurements in total
- Measurement results are recorded and analyzed in a validated Excel spreadsheet

Glucose and lactate:

- 6 trays are sampled randomly from the Hematocrit and Metabolite QUALICHECK batch. Each tray contains 1000 ampoules.
- 5 ampoules are sampled from each of the 6 trays
- 30 ampoules are sampled from the reference batch
- Measurements are performed on at least 2 validated EML105
- Measurements of glucose and lactate are performed alternately on the reference ampoule and the sample ampoule. This is repeated 5 times on each EML105 – 60 measurements in total
- Measurement results are recorded and analyzed in a validated Excel spreadsheet

Calculation of true value is described in the test instruction for each level. Assigned values are calculated from the true values by validated algorithms. Control ranges are based on the assigned values ± validated 95% confidence intervals.

7. Conclusion

The Hematocrit and Metabolite QUALICHECK is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate device: QUALICHECK5+ (K980135).