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K121468

510(k) summary of Premarket Notification k121468
Eurotrol B.V.
GAS-ISE Metabolites and epoc Calibration Verification Fluids
June 20, 2012

510(k) Summary

Submitter: Eurotrol B.V.
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Date of Preparation: June 13, 2012

Proprietary Name: Eurotrol GAS-ISE metabolites or epoc Calibration Verification Fluids

Classification Name: Multi-analyte controls, all kinds (assayed) (21 CFR 862.1660, Product Code JJY)

Common Name: Blood gas, electrolyte and metabolite control

Intended Use

- Eurotrol GAS-ISE Metabolites

Eurotrol GAS-ISE Metabolites is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System. Eurotrol GAS-ISE Metabolites was designed to test the following analytes: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine and tCO2. Eurotrol GAS-ISE Metabolites is also developed to verify calibration, operating temperature and other performance characteristics. **Eurotrol GAS-ISE Metabolites is for professional use only.**

- epoc Calibration Verification Fluids

epoc Calibration Verification Fluids is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System. epoc Calibration Verification Fluids was designed to test the following analytes: pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Urea, Creatinine and tCO2. epoc Calibration Verification Fluids is also developed to verify calibration, operating temperature and other performance characteristics. **epoc Calibration Verification Fluids is for professional use only.**

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Substantial Equivalence

Eurotrol GAS-ISE metabolites and epoc Calibration Verification Fluids are substantially equivalent in function, safety and efficacy to the currently marketed device RNA Medical® Brand CVC 123 Calibration Verification Controls, as produced by Bionostics Inc.

Comparison of Eurotrol GAS-ISE metabolites and epoc Calibration Verification Fluids to predicate devices for substantial equivalency:

	Device	**Predicate Device**
	- Eurotrol GAS-ISE Metabolites - epoc Calibration Verification Fluids	**RNA Medical® Brand CVC 123 Calibration Verification Controls**
510(k), date	K121468	K032453
Number of levels	- Eurotrol GAS-ISE Metabolites: 3 - epoc Calibration Verification Fluids: 5	5
Analytes	pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, BUN, Creatinine, Mg++.	pH, pO2, pCO2, Na+, K+, Ca++, Cl-, Glucose, Lactate, Mg++.
Container	Clear glass ampules	Clear glass ampules
Filling Volume	2,5 mL	2,5 mL
Color	Clear	Clear
Storage temperature	2 - 8°C/35 - 46°F	2 - 8°C/35 - 46°F
Indications for Use	Eurotrol GAS-ISE Metabolites is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System. Eurotrol GAS-ISE Metabolites was designed to test the following analytes: pH, pO2, pCO2, Na+, K+, Ca++, Mg++, Cl-, Glucose, Lactate, Urea, Creatinine and tCO2. Eurotrol GAS-ISE Metabolites is also developed to verify calibration, operating temperature and other performance characteristics. epoc Calibration Verification Fluids is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System. epoc Calibration Verification Fluids was designed to test the following analytes: pH, pO2, pCO2, Na+, K+, Ca++, Mg++, Cl-, Glucose, Lactate, Urea, Creatinine and tCO2. epoc Calibration Verification Fluids is also developed to verify calibration, operating temperature and other performance characteristics.	Confirming the calibration and linearity of blood gas, electrolyte, and metabolite instrumentation for the analytes and analyzers listed on the Expected Values Chart, incl. the epoc® Blood Analysis System.

	Device	Predicate Device
	- Eurotrol GAS-ISE Metabolites - epoc Calibration Verification Fluids	**RNA Medical® Brand CVC 123 Calibration Verification Controls**
Matrix/Materials	Salts in a physiologically buffered aqueous matrix.	Buffered aqueous solution containing electrolytes, glucose, and lactate. It has been equilibrated with specific levels of CO2, O2, and N2.
Form	Liquid	Liquid
Open Vial Stability	30 seconds after opening the ampule	Immediate introduction to the analyzer
Values	Lot specific	Lot specific
Shelf life	12 months at 2-8°C	36 months at 2-8°C 9 months at 8-25°C

Table 1. Comparison with predicate.

Device Description

Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids are assayed blood gas, electrolyte and metabolite reference materials, to verify the precision and accuracy of the epoc® Blood Analysis System. Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids are filled in 3 mL clear glass ampules.

Eurotrol GAS-ISE Metabolites provides three different physiologically relevant levels. epoc Calibration Verification Fluids provides five different physiologically relevant levels.

10 ampules of the same level of Eurotrol GAS-ISE Metabolites are packed in a carton box. 5 ampules, 1 ampule per level, of epoc Calibration Verification Fluids are packed in a carton box. A product insert with Intended Use is inserted in each product box of GAS-ISE Metabolites and epoc Calibration Verification Fluids.

Special Instruments Required

For an appropriate use of Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids the use of epoc® Blood Analysis System including BGE/BGEM test cards is required.

Traceability

The different levels of Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids are traceable to the reference materials as shown in the table below.

Analyte	Reference Material
pH	NIST SRM: 186 I/II, 185, 187, 191 and 192
pCO2	NIST SRM: 1674b, 2625a, 2658a and 2659a
pO2	NIST SRM: 1674b, 2625a, 2658a and 2659a
Na+	NIST SRM 956b
K+	NIST SRM 956b
Ca++	NIST SRM 956b
Cl-	NIST SRM 956b

Analyte	Reference Material
Glucose	NIST SRM 965c
Lactate	Biomed DuoCal Multi 10260
Urea	Precipath U plus 159955 + Precinorm U plus 157249
Creatinine	NIST SRM 967a

Table 2. Tracebalility of the analytes of Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids to reference materials.

Value assignment

Multiple replicates of test samples are measured at the beginning and end of the production run on various analyzers for metabolites and on blood gas analyzers for blood gas and pH values.

Values are assigned on the epoc® system using BGEM cards for metabolites, blood gas and pH values. Values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot. Ranges are assigned using pre-determined intervals. Value assignment is performed for each lot of Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids.

Stability

Real time stability was performed for the Eurotrol GAS-ISE metabolites or epoc Calibration Verification. The claimed stability is 12 months at 2-8°C or 1 week at room temperature for unopened ampule and 30 seconds for open ampules.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

JUN 22 2012

Eurotrol B.V.
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The Netherlands

Re: k121468
Trade/Device Name: Eurotrol GAS-ISE Metabolites; epoc Calibration Verification Fluids
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: May 16, 2012
Received: May 17, 2012

Dear Ms. Kooijmans:

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).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k121468

Device Name: _Eurotrol GAS-ISE Metabolites and epoc Calibration Verification Fluids_____

Indications for Use:

- Eurotrol GAS-ISE Metabolites
Eurotrol GAS-ISE Metabolites is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System.
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- epoc Calibration Verification Fluids
epoc Calibration Verification Fluids is an assayed blood gas, electrolyte and metabolite material, to verify the precision and accuracy of the epoc® Blood Analysis System.
epoc Calibration Verification Fluids was designed to test the following analytes: pH, pO2, pCO2, Na+, K+, Ca++, Mg++, Cl-, Glucose, Lactate, Urea, Creatinine and tCO2. epoc Calibration Verification Fluids is also developed to verify calibration, operating temperature and other performance characteristics.

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

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

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

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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