



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

EUROTROL B.V.
MARGHERITA LA MARCA
REGULATORY AFFAIRS MANAGER
KEPLERLAAN 20
EDE 6716 BS
NETHERLANDS

April 22, 2016

Re: K152553
Trade/Device Name: Cuesee Hypoxic
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I, Reserved
Product Code: JJS
Dated: March 22, 2016
Received: March 24, 2016

Dear Ms. La Marca:

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,


Katherine Serrano -S

For: 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

Indications for Use

510(k) Number (if known)
k152553

Device Name
CueSee® Hypoxic

Indications for Use (Describe)

CueSee® Hypoxic is a pre-tonometered bovine hemoglobin (Hb) quality control material for professional use for monitoring blood gas analyzers' performance of Oxygen partial pressure (pO₂).

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. This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92
2. **Submitter**
Eurotrol B.V.
Keplerlaan 20
6716 BS Ede, The Netherlands
T +31 318 695777
F +31 318 695770
E office@eurotrol.com
3. **Submitter Contact**
Margherita La Marca
QA/RA Manager Eurotrol
B.V.
Keplerlaan 20
6716 BS Ede, The Netherlands
T +31 318 695777
F +31 318 695770
E mlamarca@eurotrol.com
4. **Device identification**
Proprietary Name: CueSee® Hypoxic
Common Name: Blood gas control
Classification Name: Class I, reserved
Product code: JJS; Controls for blood-gases, (assayed and unassayed)
(21 CFR 862.1660)
5. **Predicate Device**
Device Name: RNA Medical® Brand QC 823 Range Blood Gas Electrolyte Metabolite Control
Manufacturer: Bionostics, Inc.,
510(k) number: k032453,
Decision Date: 08/28/2003
6. **Intended Use**
CueSee® Hypoxic is a pre-tonometered bovine hemoglobin (Hb) quality control material for professional use for monitoring blood gas analyzers' performance of Oxygen partial pressure (pO₂).
7. **Device description**
CueSee® Hypoxic is prepared from a stroma-free bovine hemoglobin solution and provides the oxygen buffering characteristics of fresh whole blood. The concentrations of total hemoglobin and acid-base levels are within the normal physiological range. Tonometry with a predetermined level of oxygen balanced with nitrogen provides a distinct assay value for partial pressure of oxygen measurements. CueSee® Hypoxic contains no preservatives, viscosity adjusters or other additives that might adversely effect electrode measurements.
CueSee® Hypoxic provides one level in the critical low pO₂ value range, each ampule holding 2.5 mL of solution.
CueSee® Hypoxic is packed in a carton box containing 5 ampules.
8. **Special Instrument Required**
For an appropriate use of CueSee® Hypoxic the use of a blood gas analyzer is required.

9. Predicate Device Comparison

Comparison of CueSee® Hypoxic to the predicate device for substantial equivalence:

	New Device	Predicate Device
	CueSee® Hypoxic	RNA Medical Brand QC 823 Range Blood Gas Electrolyte Metabolite Control
510(k), date		K032453, 08/28/2003
Number of levels	1	2
Analytes	pO ₂	pH, pCO ₂ , pO ₂ , Ca ⁺⁺ , Na ⁺ , K ⁺ , Cl ⁻ , Mg ⁺⁺ , Glucose, Lactate
Value range	pO ₂ : 15 – 25 mmHg	pO ₂ : 8 – 69 mmHg (Level 0)
Container	Clear glass ampules	Clear glass ampules
Filling Volume	2,5 mL	2,5 mL
Color	Blood like	Colorless
Storage temperature	2–8 °C / 35–46°F	2–8 °C / 35–46°F or 9–25 °C / 35–77°F
Indications for Use	Performance assessment of the critical low pO ₂ value range of blood gas analyzers.	Monitoring the performance of blood gas, electrolyte, and metabolite instrumentation.
Matrix/ Materials	Pre-tonometered solution of bovine oxyhemoglobin (O ₂ Hb) of purified stroma-free bovine hemoglobin	Buffered aqueous solution containing electrolytes (Na ⁺ , K ⁺ , Cl ⁻ , Ca ⁺⁺ , Mg ⁺⁺), glucose, and lactate. It has been equilibrated with specific levels of CO ₂ , O ₂ , and N ₂ .
Form	Liquid	Liquid
Open Vial Stability	10 minutes	For pH/blood gas values measure immediately after opening
Values	Lot specific	Lot specific
Shelf life	31 days at 2–8 °C	36 months at 2–8 °C 9 months at 2–25 °C
Where used	Clinical Laboratories, Point of Care testing	Clinical Laboratories, Point of Care testing

Table 1. Predicate Device Comparison

10. Standards and guidelines reference

- CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, Vol 29, No. 20, September 2009;
- Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen (RiLiBAEK), Deutschen Ärzteblatt Jg.110, Heft 12, 22.03.2013, Seite A 575-582.

11. Stability

Real time stability studies have been performed for CueSee® Hypoxic.

The claimed stability is 31 days when the product is stored at 2-8°C. After opening of the ampule, the product is stable for 10 minutes.

12. Value Assignment

Multiple replicates of test samples are measured at the beginning and end of the production run on blood gas analyzers for pO₂ 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 CueSee® Hypoxic.

13. Traceability

The different levels of CueSee® Hypoxic are traceable to the reference material as shown in the table below.

Analyte	Reference Material
pO ₂	NIST SRM: 2658a

Table 2. Traceability of CueSee® Hypoxic.

14. Conclusion

We recommend that CueSee® Hypoxic is substantially equivalent in Intended Use, fundamental scientific technology, features, and characteristics to the predicate device:
RNA Medical Brand QC 823 Range Blood Gas Electrolyte Metabolite Control (K032453)