510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k152553

B. Purpose for Submission:

New Device

C. Measurand:

Quality control material for blood gases

D. Type of Test:

Not applicable

E. Applicant:

Eurotrol B.V.

F. Proprietary and Established Names:

CueSee Hypoxic

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660, Quality Control Material (Assayed and Unassayed)

2. Classification:

   Class I, reserved

3. Product code:

   JJS

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use statements below

2. Indication(s) for 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).

3. Special conditions for use statement(s):

   For prescription use only

4. Special instrument requirements:

   Not applicable

I. 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 affect 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Bionostics Roche Blood Gas Electrolyte Metabolite Control

2. Predicate 510(k) number(s):

   k032453

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device k032453
Intended Use	Quality control material for monitoring blood gas analyzers' performance of Oxygen partial pressure (pO2).	Same
Values	Lot specific	Same

Differences		
Item	Candidate Device	Predicate Device k032453
Matrix	Pre-tonometered solution of bovine oxyhemoglobin (O2Hb) 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 CO2, O2, and N2.
Analytes used for	pO2	pH, pCO2, pO2, Ca++, Na+, K+, Cl+, Mg++, Glucose, Lactate
Storage temperature	2–8 °C / 35–46°F	2–8 °C / 35–46°F until expiration date or 9–25 °C / 35–77°F for up to 9 months.
Open vial stability	10 minutes	For pH/blood gas values measure immediately after opening
Shelf life	31 days at 2–8 °C	36 months at 2–8 °C or 9 months at 2–25 °C
Levels	one level	two levels

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP25-A; Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, Vol 29, No. 20, September 2009.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

Analyte	Reference Material
pO2	NIST SRM:, 2658a

Stability:

The shelf life testing protocol and acceptance criteria for the CueSee Hypoxic control was reviewed and found to be adequate. The real time stability study shows results up to 31 days when stored at 2-8°C supporting the shelf life claim of 31 days from date of manufacture when stored at 2-8°C prior to opening.

The open vial stability testing protocol and acceptance criteria for the CueSee Hypoxic control was reviewed and found to be adequate. The open vial stability study shows results up to 10 minutes after opening supporting the open vial stability claim of 10 minutes.

Value Assignment:

Value assignment protocols and acceptance criteria for the CueSee Hypoxic were reviewed and found to be adequate. Values are determined by taking the mean of multiple determinations performed on randomly selected samples from each lot on

Radiometer ABL 835 Flex analyzer, Abbott i-STAT CG4+ system, and epoc Blood analysis system. Value assignment is performed for each lot of control. An example of one lot of control is listed below:

Instrument	Mean (mmHg)	SD (mmHg)	Control range (mmHg)
Radiometer ABL 835 Flex	19.2	4	7.2 - 31.2
Abbott iSTAT CG4+ System	18	4	6 - 30
epoc Blood Analysis System	14.8	5	0.0 – 29.8

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

*b. Clinical specificity**:***

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:**

Not applicable

5. Expected values/Reference range:

Representative control mean and range for the control solution has been provided in the labeling.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.