

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

A. 510(k) Number:

k060215

B. Purpose for Submission:

Clearance of new device

C. Measurand:

Assayed Controls for urine albumin assays

D. Type of Test:

Not applicable. This submission is for clearance of controls.

E. Applicant:

Eurotrol B.V.

F. Proprietary and Established Names:

AlbuTrol Controls (Low and High)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
Single (Specified) Analyte Controls (Assayed And Unassayed) (JJX)	Class I	21 CFR 862.1660, Quality control material (assayed and unassayed).	75 CLINICAL CHEMISTRY (CH)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

Albutrol is an assayed albumin control intended for professional use in the verification of the precision and accuracy of the HemoCue Urine Albumin and HemoCue Albumin 201 Systems.

3. Special conditions for use statement(s):

For Prescription use only.

4. Special instrument requirements:

HemoCue Albumin Urine Albumin and HemoCue 201 Systems

I. Device Description:

The controls are prepared from human urine and contain other human source material. Components of the controls which are derived from human source material have been tested and found to be nonreactive for HBsAg, anti-HCV and HIV. Each Human Urine Albumin control kit contains 2 bottles of controls (a 1.0 ml fill volume per bottle) with the following target concentrations (Low and High): 25 and 75 mg/L.

J. Substantial Equivalence Information:

Predicate	k023928
Describe the item being compared	
MAS UA Control	

Similarities		
Item	Device	Predicate
Levels	Low and High	Same
Matrix	Human Albumin in human urine	Same

Differences		
Item	Device	Predicate
Constituents	Single, Albumin	Multiple, including microalbumin, specific gravity, pH, glucose, bilirubin, ketones, creatinine, and protein.
Analyzer	HemoCue Urine Albumin and HemoCue Albumin 201 Systems	Multiple commercially marketed analyzers
Procedures	Quantitative	Qualitative and Semi-quantitative

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

None referenced.

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):

The AlbuTrol Low and High controls are prepared from human urine and contain other human source material. The values are assigned from replicate analysis on the factory-calibrated HemoCue Urine Albumin and HemoCue Albumin 201 Systems. Below is information from a representative lot of Albutrol Low and High Controls on the two systems.

HemoCue Urine Albumin system: Low 25 ± 9 mg/L and High 72 ± 23 mg/L

HemoCue Albumin 201 system: Low 25 ± 9 mg/L and High 75 ± 23 mg/L

Opened Vial Stability:

The AlbuTrol Controls are stable for 30 days after opening when stored at 2 to 8°C. Protocols and acceptance criteria for stability testing were described and found to be acceptable.

Unopened Vial Stability:

The AlbuTrol Controls are stable for 9 months when stored at 2 to 8°C. Protocols and acceptance criteria for stability testing were described and found to be acceptable.

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:

Not applicable

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.