

## **510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY**

### **A. 510(k) Number:**

k043460

### **B. Purpose for Submission:**

Reason for submission: formulation change – addition of one analyte, change of labeling, and change of manufacturer.

### **C. Measurand:**

Lactic acid has been added to this pre-existing calibrator. The existing formulation may contain up to 20 component calibrators depending on the particular model.

### **D. Type of Test:**

The product is used as a mimic of human serum of known composition used to calibrate the operation of a range Olympus clinical test equipment.

### **E. Applicant:**

Olympus America Inc.

### **F. Proprietary and Established Names:**

Olympus Lyophilized Chemistry Calibrator

### **G. Regulatory Information:**

1. Regulation section:

21CFR862.1150 - Calibrator

2. Classification:

Class II

3. Product code:

JIX

4. Panel:

Chemistry (75)

**H. Intended Use:**

1. Intended use(s):

Olympus Calibrators are intended for use when calibrating Olympus Methods run on the Olympus series of chemistry analyzers.

2. Indication(s) for use:

The Olympus Lyophilized Chemistry Calibrator is a two level general purpose chemistry calibrator designed to provide suitable calibration levels for Olympus analyzers employing the Olympus Methodologies.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

The calibrator is only intended for use with Olympus Chemistry Analyzers.

**I. Device Description:**

The existing calibrator family consists of 2 products. Each product is offered in small and large sizes. As sold, the product consists of a vial of powder and a vial of liquid. Calibrants are present in both vials. The user dissolves the powder in a pre-determined volume of the provided liquid before use.

The first product, referred to as Level I by the submitter, is unaffected by this submission. The submitter proposes the addition of lactate to the 2<sup>nd</sup> or “Level II” product.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Olympus Lyophilized Chemistry Calibrator

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

k032665

### 3. Comparison with predicate:

The currently marketed predicate device claims the presence of a number of analytes. The concentrations of these analytes vary slightly between batches and with the particular product subset. Representative concentrations for analytes common to both the predicate and pre-market device are noted in the table below. The actual, certified concentration is noted on the product insert for each batch.

<b>Similarities (Present in Proposed Device and Predicate)</b>	
<b>Constituent(Level II (reconstituted))</b>	<b>Level II Target Concentration and (Range)</b>
Albumin	4.0 (3.6-4.4) g/dL
Bicarbonate	40 (36-44) mEq/L
Calcium (Arsenazo Application)*	12.0 (11.5-12.5) mg/dL
Calcium (OPC Application)	12.0 (11.5-12.5) mg/dL
Cholesterol	220 (198-242) mg/dL
Creatinine	6.0 (5.4-6.6) mg/dL
Creatinine STAT*	6.0 (5.4-6.6) mg/dL
Glucose	250 (225-275) mg/dL
Glucose STAT*	250 (225-275) mg/dL
Inorganic Phosphorous	5.0 (4.5-5.5) mg/dL
Magnesium	3.0 (2.7-3.3) mg/dL 2.5 (2.25-2.75) mEq/L
Total Protein	7.2 (6.5-7.9) g/dL
Triglyceride	250 (225-275) mg/dL
UIBC	270 (243-297) ug/dL
Urea Nitrogen (BUN)	50 (45-55) mg/dL
Urea Nitrogen STAT*	50 (45-55) mg/dL
Uric Acid	8.0 (7.2-8.8) mg/dL

\*These assays not available for AU5200 Analyzer

<b>Differences</b>		
<b>Constituent(Level II (reconstituted))</b>	<b>Proposed Level II Target Concentration and (Range)</b>	<b>Predicate (K032665)</b>
Lactate	40 (35 – 45) mg/dL	Not Present

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

Guidance for Industry: Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators. Web Link: <http://www.fda.gov/cdrh/ode/calibrator.pdf>

**L. Test Principle:**

The product under submission is used to calibrate or verify the performance of Olympus Clinical Analyzers. The calibrator is treated as a typical sample. Processing is done per instrument instructions.

**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 predicate and pre-market devices serve as calibrators for specific Olympus clinical laboratory equipment. The stability and traceability of the component analytes are the primary criteria for acceptance.

Traceability is handled via the selection and documentation of the source material. The majority of the constituent calibrants can be traced to the National Institute of Standards and Technology. Two calibrants can be traced to 3<sup>rd</sup> party standard suppliers, New England Reagent Laboratories and Certified Reference Material. Lactic acid concentration is calculated via an Olympus colorimetric kit.

Stability is measured by:

- Open vial aging which mimics handling by the users of the product. These studies involve verifying concentration of the reconstituted analytes when the product is stored capped but unsealed at 2 °C to 8 °C.
- Accelerated Stability Testing which involves storing tested samples at elevated temperatures (37 °C) in an effort to predict their long-term performance.

The reported stability is within the error limits stated with the product. The measured stability is consistent with the shelf life claimed on the product insert.

*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.