

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

A. 510(k) Number:

k033910

B. Analyte:

Calibrator

C. Type of Test:

Quantitative

D. Applicant:

Cliniqa Corporation

E. Proprietary and Established Names:

Olympus™ Urine Calibrator

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1150
2. Classification:
II
3. Product Code:
JIX
4. Panel:
75

G. Intended Use:

1. Intended use(s):
Olympus™ Urine Calibrator is intended for use in the calibration of quantitative chemistry assays including Amylase, Calcium, Creatinine, Glucose, Magnesium, Phosphorus, Urea Nitrogen, Uric Acid, and Urinary Total Protein on the Olympus™ series of chemistry analyzers.
2. Indication(s) for use:
Olympus™ Urine Calibrator is intended for use in the calibration of quantitative chemistry assays including Amylase, Calcium, Creatinine, Glucose, Magnesium, Phosphorus, Urea Nitrogen, Uric Acid, and Urinary Total Protein on the Olympus™ series of chemistry analyzers.
3. Special condition for use statement(s):
Not applicable
4. Special instrument Requirements:
Olympus™ series of chemistry analyzers

H. Device Description:

Olympus™ Urine Calibrator is an assayed, liquid, human urine based product containing the constituents listed above. It is supplied ready-to-use in six 5 mL vials.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Urine Chemistry Standard Kit (formerly known as Multi-Chemistry Linearity Standard)
2. Predicate K number(s):
K875285
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Calibration of chemistry test systems	Calibration of chemistry test systems
Constituents	Calcium, creatinine, glucose, magnesium, phosphorus, urea nitrogen	Calcium, creatinine, glucose, magnesium, phosphorus, urea nitrogen
Form	Ready-to-use liquid	Ready-to-use liquid
Differences		
Item	Device	Predicate
Constituents	Amylase, uric acid, urinary total protein	Chloride, potassium, sodium
Matrix	Human urine based	Aqueous based
Levels	1 (single point calibrator)	5

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

None referenced

K. Test Principle:

Not applicable

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*
Not applicable
 - b. *Linearity/assay reportable range:*
Not applicable
 - c. *Traceability (controls, calibrators, or method):*

The assigned values for the constituents are traceable to reference materials or methods from the National Institute of Standards and Technology (NIST) and College of American Pathologists (CAP).

- 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:
The assigned value for each constituent has been established in accordance to Olympus testing protocols and the values are lot-specific. All values were obtained using Olympus chemistry analyzers in conjunction with their respective reagents.

M. Conclusion:

The Olympus™ Urine Calibrator is similar to the predicate device in intended use, the majority of the constituents, and form. The difference in the three constituents and base matrix do not raise new issues of safety and effectiveness. These characteristics are well-established and accepted in the scientific community. Additionally, the value assignment and stability information provided for the calibrator were adequate. I recommend a substantial equivalence determination for the Olympus™ Urine Calibrator.