510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

A. 510(k) Number: K033162

B. Analyte: LiniCAL Chemistry Calibration verifiers A – E for Olympus AU Systems containing the following analytes; Albumin, Blood Urea Nitrogen, Calcium, Creatinine, Magnesium, Phosphorus, Total Protein, Triglycerides, Glucose, Iron, Sodium, Chloride, and Potassium at five useful concentrations.

C. Type of Test: n/a

D. Applicant: CLINIQA

E. Proprietary and Established Names: Quality Control Material

F. Regulatory Information:

1. Regulation section: 21 CFR 862.1660

2. Classification: Class 1

3. Product Code: JJY

4. Panel: 75

G. Intended Use:

1. Indication(s) for use: The CLINIQA Chemistry Calibration Verifiers Levels A – E for Olympus AU Systems are assayed, liquid, quality control products which may be used to evaluate the performance of the Olympus AU Systems for Albumin, Blood Urea Nitrogen, Calcium, Creatinine, Magnesium, Phosphorus, Total Protein, Triglycerides, Glucose, Iron, Sodium, Chloride, and Potassium use as an assayed quality control material for analysis.

2. Special condition for use statement(s): none

3. Special instrument Requirements: none

H. Device Description: The CLINIQA Chemistry Calibration Verifiers Levels A – E are used in the clinical laboratory to verify calibration and/or assess linearity of the Olympus AU Systems. Five assayed levels Albumin, Blood Urea Nitrogen, Calcium, Creatinine, Magnesium, Phosphorus, Total Protein, Triglycerides, Glucose, Iron, Sodium, Chloride, and Potassium are provided to allow monitoring of the reportable range.

I. Substantial Equivalence Information:

1. Predicate device name(s): CLINIQA LiniCAL Chemistry Calibration Verifiers Levels A – E for Beckman Coulter Synchron Systems

2. Predicate K number(s): K031921

3. Comparison with predicate: Both devices are serum based products containing Albumin, Blood Urea Nitrogen, Calcium, Creatinine, Magnesium, Phosphorus, Total Protein, Triglycerides, Glucose, Iron, Sodium, Chloride, and Potassium at five useful concentrations and are manufactured using the same processes. The differences between the two products are the constituents and their target concentrations which have been optimized for each test system.

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

K. Test Principle: N/A

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:* N/A
   b. *Linearity/assay reportable range:* N/a
   c. *Traceability (controls, calibrators, or method):* None provided
   d. *Detection limit (functional sensitivity:* N/A
   e. *Analytical specificity:* N/A
   f. *Assay cut-off:* N/A
2. Comparison studies:
   a. *Method comparison with predicate device:* N/A
   b. *Matrix comparison:* N/A
3. Clinical studies:
   a. *Clinical sensitivity:* N/A
   b. *Clinical specificity:* N/A
4. Clinical cut-off: N/A
5. Expected values/Reference range: See the package insert for specific calibrator concentrations.

M. Conclusion: Based upon the information provided, I recommend that the LiniCAL Chemistry Calibration verifiers A – E for Olympus AU Systems containing the following analytes; Albumin, Blood Urea Nitrogen, Calcium, Creatinine, Magnesium, Phosphorus, Total Protein, Triglycerides, Glucose, Iron, Sodium, Chloride, and Potassium levels A – E , be found substantially equivalent with predicate devices according to 21 CFR 862.1660.