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

A. 510(k) Number:
K031921

B. Analyte:
Chemistry calibration verifiers for Beckman Coulter Synchron Systems containing the following constituents: albumin, BUN, calcium, creatinine, lactate, magnesium, phosphorus, total protein, triglycerides, glucose, iron, sodium, potassium, chloride.

C. Type of Test:
N/A

D. Applicant:
Cliniqa Corporation

E. Proprietary and Established Names:
LiniCAL Chemistry Calibration Verifiers, Levels A-E for Beckman Coulter Synchron Systems.

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1660
2. Classification:
   Class I
3. Product Code:
   JJY
4. Panel:
   CH

G. Intended Use:

1. Indication(s) for use:
   The LiniCAL Chemistry Calibration Verifiers, Levels A-E for Beckman Coulter Synchron Systems is intended for use as an assayed quality control material for analysis.
2. Special condition for use statement(s):
   N/A
3. Special instrument Requirements:
   N/A

H. Device Description:

The LiniCAL Chemistry Calibration Verifiers are human serum-based, containing constituents of human origin. They are used in the clinical laboratory to verify calibration and/or assess linearity of the Beckman Coulter Synchronm Systems. Five assayed levels of albumin, BUN, calcium, creatinine, lactate, magnesium, phosphorus, total protein, triglycerides, glucose, iron, sodium, potassium, and chloride are provided to allow monitoring of the reportable range.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   LiniCAL Protein @ Calibration Verifiers Levels A-E for Beckman Coulter Immage System.
2. Predicate K number(s):
   K013332
3. Comparison with predicate:
   Both devices are human serum-based products that are manufactured using the same processes. They differ in that the constituents in the predicate device are alpha-1-acid-glycoprotein, alpha-1-antitrypsin, alpha-2-macroglobulin, antithrombin III, beat-2-macroglobulin, and ceruloplasmin, and the constituents in the subject device are of albumin, BUN, calcium, creatinine, lactate, magnesium, phosphorus, total protein, triglycerides, glucose, iron, sodium, potassium, and chloride

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):*
     N/A
   - *d. Detection limit:*
     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
    c. *Other clinical supportive data (when a and b are not applicable):*
    N/A
4. Clinical cut-off:
    N/A
5. Expected values/Reference range:
    N/A

M. Conclusion:

Based upon the information provided, I recommend that the Cliniqa LiniCAL Chemistry Verifiers, Levels A-E for Beckman Coulter Synchron Systems be found substantially equivalent to predicate devices according to 21 CFR 862.1660.