510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE TEMPLATE

A. 510(k) Number: K031577

B. Analyte: Protein 2 Calibration verifiers A – E for Beckman Coulter Array Protein Systems containing the following analytes; Alpha-1-Acid Glycoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, Antithrombin III, Beta-2-Macroglobulin and Ceruloplasmin.

C. Type of Test: n/a

D. Applicant: CLINIQA

E. Proprietary and Established Names: Quality Control Material

F. Regulatory Information:
    1. <u>Regulation section</u>: 21 CFR 862.1660

    2. <u>Classification:</u> Class 1

    3. <u>Product Code:</u> JJY

    4. <u>Panel:</u> 75

G. Intended Use:
    1. <u>Indication(s) for use:</u> The LiniCAL Protein 2 Calibration Verifiers Levels A – E for Beckman Coulter Array Protein Systems is intended for use as an assayed quality control material for analysis.

    2. <u>Special condition for use statement(s):</u> none

    3. <u>Special instrument Requirements</u>: none

H. Device Description: The Protein 2 Calibration Verifiers are used in the clinical laboratory to verify calibration and/or assess linearity of the Beckman Coulter Array Protein Systems. Five assayed levels of Alpha-1-Acid Glycoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, Antithrombin III, Beta-2-Macroglobulin and Ceruloplasmin are provided to allow monitoring of the reportable range.

I. Substantial Equivalence Information:
    1. <u>Predicate device name(s):</u> LiniCAL Protein 2 Calibration Verifiers Levels A-E for Beckman Immage

2. Predicate K number(s): K023250

3. Comparison with predicate: Both devices are serum based products containing Alpha-1-Acid Glycoprotein, Alpha-1-Antitrypsin, Alpha-2-Macroglobulin, Antithrombin III, Beta-2-Macroglobulin and Ceruloplasmin and are manufactured using the same processes. The difference between the two products is the constituent concentration has been optimized for this 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: N/A

M. Conclusion: Based upon the information provided, I recommend that the CliniqaLiniCAL Protein 2 Calibration verifiers Levels A-E for Beckman Coulter Array Protein Systems be found substantially equivalent with predicate devices according to 21 CFR 862.1660.