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

A. 510(k) Number:

k110251

B. Purpose for Submission:

Add **Lactate** (lactic acid) and **Magnesium** to the previously cleared Synchron Systems Multi Calibrator for albumin, BUN, calcium, cholesterol, creatinine, glucose, inorganic phosphorus, total protein, triglycerides and uric acid.

C. Measurand:

Calibrator for Lactate (Lac) and Magnesium (Mg)

D. Type of Test:

Not applicable

E. Applicant:

Beckman Coulter, Inc.

F. Proprietary and Established Names:

SYNCHRON Multi Calibrator

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1150, Calibrator

2. Classification:

   Class II

3. Product code:

   JIX, Calibrator, Multi-Analyte Mixture

4. Panel:

   75, Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See Indications for use below.

2. Indication(s) for use:

   The SYNCHRON MULTI CALIBRATOR, used in conjunction with SYNCHRON reagents, is intended for use on SYNCHRON Systems for the calibration of Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid.

3. Special conditions for use statement(s):

   Prescription use.

4. Special instrument requirements:

   Beckman Coulter SYNCHRON CX, LX and UniCel DxC family of analyzers and SYNCHRON reagents.

I. Device Description:

The SYNCHRON MULTI CALIBRATOR is a liquid, ready-to-use multi-analyte, in vitro diagnostic calibrator. The SYNCHRON Multi Calibrator is prepared in a human serum matrix which is stabilized by the use of ethylene glycol. During manufacture, the multiple constituents are spiked into the matrix at the desired concentration levels.

The analytes in this calibrator are traceable using prEN ISO 17511 to the following:

Measurand	**Traceable to:**
Albumin (ALB)	NIST 927a
Calcium (CA)	NIST SRM 915
Cholesterol (CHOL)	NIST 911b
Glucose (GLU)	NIST SRM 917a
Lactate	Manufacturer's working calibrator
Magnesium (MG)	NIST SRM 929
Inorganic Phosphorus (PHOS) / (PHS) / (PO4)	NIST SRM 3139a
Total Protein (TP)	NIST SRM 927a
Triglyceride (TG) / (TG-B)	Manufacturer's working calibrator
Urea, Blood Urea Nitrogen (BUN)	NIST SRM 912a
Uric Acid	NIST SRM 913b

Creatinine was removed from the SYNCHRON MULTI CALIBRATOR and is now separate (k095240). The traceability was changed from NIST traceable to Isotope

Dilution Mass Spectrometry, (k071277).

All serum or plasma donor units used in the preparation of this material were tested by FDA approved methods and found to be negative for HIV, and HCV antibodies, as well as non-reactivity for HBs Ag. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infections agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   SYNCHRON MULTI CALIBRATOR

2. Predicate K number(s):

   k883181

3. Comparison with predicate:

Similarities		
Item	Device	Predicate k883181
Intended Use	Same	Calibration of Synchron Systems
Matrix base	Same	Human serum and stabilized with ethylene glycol
Format	Same	Liquid, ready-to-use
Levels	Same	1
Open vial stability	Same	20 days at 2-8°C
Real time stability	Same	24 months
Storage	Same	-15 to -20°C
Packaging	Same	6x20 mL bottles

Differences		
Item	Device	Predicate
Calibrator analytes	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Glucose, Inorganic Phosphorus, Lactate, Magnesium, Total Protein, Triglycerides, and Uric Acid.	Albumin, Blood Urea Nitrogen (Urea), Calcium, Cholesterol, Creatinine, Glucose, Inorganic Phosphorus, Total Protein, Triglycerides, and Uric Acid.

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

None were referenced.

L. Test Principle:

Not applicable

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):

Traceability: Lactate is gravimetrically prepared and is traceable to an older lot of calibrator. Magnesium is traceable to NIST 929.

Value Assignment: Value assignment of the lactate calibrator is established by comparing lactate recovery to the previous lot of calibrator and by evaluating lactate recovery against a commercially available set of standards. Bottle value assignment occurs by performing multiple runs over multiple days with the new lot using multiple SYNCHRON Systems—CX5 CE, CX9 Pro, LX20 Pro, DxC800, and two lots of SYNCHRON reagents. Magnesium value assignment is accomplished using an anchor pool, traceable to the NIST 929 reference method. Bottle value assignment occurs by performing multiple runs over multiple days on multiple SYNCHRON Systems using two lots of SYNCHRON reagents.

Stability: Real time stability study data supports the manufacturer labeling that the Beckman Coulter SYNCHRON Multi-Calibrator is stable for 24 months when stored unopened at -15 to -20 °C. Real time stability study data supports an open vial stability claim of 20 days at 2-8°C. Calibrators are not stored on board the instruments.

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.