

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

A. 510(k) Number:

k090283

B. Purpose for Submission:

New device

C. Measurand:

Calibration material for Sodium, potassium, chloride, urea, glucose, creatinine, calcium, and total CO₂.

D. Type of Test:

Calibrator

E. Applicant:

Genchem, Inc.

F. Proprietary and Established Names:

SYNCHRON CX Multi-Analyte Mixture

G. Regulatory Information:

1. Regulation section: 21 CFR 862.1150
2. Classification: Class II
3. Product code: JIX, Calibrator, Multi-Analyte Mixture
4. Panel: Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

SYNCHRON CX Multi-Analyte Mixture Calibrators 1, 2, and 3 are intended to calibrate the Beckman SYNCHRON CX Systems for quantitative determination of sodium, potassium, chloride, urea, glucose, creatinine, calcium, and total CO₂.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only

4. Special instrument requirements:

Beckman[®] SYNCHRON CX[®] Systems.

I. Device Description:

SYNCHRON CX Multi-Analyte Mixture Calibrators 1, 2, and 3 are intended for use with the Beckman SYNCHRON CX Systems to establish reference points for In Vitro Diagnostic testing applications for multiple analytes. Each of the 3 calibrator mixtures (Level 1, 2, and 3) is supplied in ready to use 25 mL bottles.

The calibrators are mixtures of synthetic inorganic chemicals in an aqueous based matrix and contain no blood based components.

J. Substantial Equivalence Information:

1. Predicate device name(s):

HICHEM Calibrators 1, 2, and 3

2. Predicate 510(k) number(s):

k992845

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicate (k992845)
Intended Use	SYNCHRON CX Multi-Analyte Mixture Calibrators 1, 2, and 3 are intended to calibrate the Beckman SYNCHRON CX Systems for quantitative determination of sodium, potassium, chloride, urea,	HiChem Calibrators 1, 2, and 3 are intended to calibrate the Beckman SYNCHRON CX DELTA and CX CE Systems for the quantitative determination of sodium, potassium, chloride, urea, glucose, creatinine, calcium,

Similarities and Differences		
Item	Device	Predicate (k992845)
	glucose, creatinine, calcium, and total CO ₂ .	and total CO ₂ .
Matrix	Aqueous	Aqueous
Analytes	Sodium, potassium, chloride, urea, glucose, creatinine, calcium, and total CO ₂ .	Sodium, potassium, chloride, urea, glucose, creatinine, calcium, and total CO ₂ .
Preparation	Liquid, ready-for-use	Liquid, ready-for-use
Number of Levels	3	3
Packaging	25 mL/level	25 mL/level
Stability	Unopened, until expiration Opened, 30 days	Unopened, until expiration Opened, 30 days
Storage	2-8 °C	2-8 °C

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

Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators.

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:

Sponsor claims traceability to NIST and other analytical standards.

Stability: Stability testing protocols and acceptance criteria were reviewed and found to be acceptable. Test sets are stable unopened until the expiration date printed on the bottle and for 30 days after opening when stored at 2° to 8°C and handled according to instructions. It is recommended that they are not frozen.

Value assignment: The set point values were established based on the gravimetric addition of each of the chemicals to achieve specific concentration of each of the analytes. For value assignment two analyzers were used, with 3 runs, and 3 replicates run for each level. The mean and standard deviation were calculated and the results for each analyte must be within the specifications set by the instrument manufacturer (Beckman Coulter). The analysis for each calibrator constituent must be within $\pm 2SD$ of the assigned value. Quality controls are included in each run of the value assignment process.

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:

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):

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 substantial equivalence decision.