

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

A. 510(k) Number:

k070971

B. Purpose for Submission:

New device with the addition of new analytes to a multi-analyte calibrator material

C. Measurand:

Amylase, cholinesterase, creatinine, lithium, alpha-hydroxybutyrate, and dibucaine-inhibited cholinesterase

D. Type of Test:

Calibrator materials

E. Applicant:

Sentinel CH.

F. Proprietary and Established Names:

Sentinel Clin Chem Cal

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1150, Calibrator

2. Classification:

Class II

3. Product code:

JIX, Multi-Analyte Calibrator

4. Panel:

75, Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Clinical Chemistry- The Sentinel Clin Chem Cal is a device intended for medical purposes for use in Pancreatic amylase, cholinesterase, creatinine, lithium, alpha-hydroxybutyrate dehydrogenase and “cholinesterase dibucaine-inhibited” assays to establish points of reference that are used in the determination of values in the measurement of pancreatic amylase, cholinesterase, creatinine, lithium, alpha-hydroxybutyrate dehydrogenase and “cholinesterase dibucaine-inhibited” in human specimens.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Abbott Aeroset and Abbott Architect Analyzers

I. Device Description:

The Sentinel Clin Chem Cal is an *in vitro* diagnostic device intended for use in pancreatic amylase, cholinesterase, creatinine, lithium, alpha-hydroxybutyrate dehydrogenase and “cholinesterase dibucaine-inhibited” assays to establish points of reference that are used in the determination of values in the measurement of pancreatic amylase, cholinesterase, creatinine, lithium, alpha-hydroxybutyrate dehydrogenase and “cholinesterase dibucaine-inhibited” in human specimens. The device consists of lyophilized material in human based serum. The human serum used has been tested and found to be non-reactive for HBsAg, anti-HIV 1/2 and anti-HCV.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Sentinel Clin Chem Cal

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

k051452

3. Comparison with predicate:

| Similarities | | |
|--------------|--|-----------|
| Item | Device | Predicate |
| Intended use | Clin Chem Cal must be used only for the calibration of clinical chemistry test. | Same |
| Storage | 2 to 8° C | Same |
| Stability | 2 days when stored at 2 to 8° C. 14 days at -20°C if aliquoted in small volumes | Same |

| Differences | | |
|-------------|---|---|
| Item | Device | Predicate |
| Components | Cholinesterase Cholinesterase Dibucaine-Inhibited Pancreatic Amylase Creatinine Alpha beta hydroxybutyrate dehydrogenase Lithium | Cholinesterase, Pancreatic α -amylase, Creatinine, Alpha beta hydroxybutyrate dehydrogenase, Acid phosphatase, Albumin, α -amylase, Alkaline phosphatase, Alanine aminotransferase, Asparate aminotransferase, Direct bilirubin, Calcium, Cholesterol, Creatine kinase, Iron, γ - glutamytransference, Glucose, Lactate, Lactate dehydrogenase, Lipase, Magnesium, Phosphorus, Salicylate, Triglycerides, Total protein, Uric Acid, UIBC, Urea |

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

FDA's Guidance for Industry, Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators, February 22, 1999.

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):*

The Sentinel Clin Chem Cal is traceable to the following:

| Analytes | Method | Standardization |
|--|--|------------------------------|
| Cholinesterase | Deutsche Gesellschaft für Klinische Chemie (DGKC) Butyrylthiocholine 37 ° | ε Hexacyano-ferrate (III) |
| Cholinesterase Dibucaine-Inhibited | Deutsche Gesellschaft für Klinische Chemie (DGKC) Dibucaine.inhibited liquid | ε Hexacyano-ferrate (III) |
| Pancreatic Amylase | International Federation of Clinical Chemistry (IFCC) EPS / 37° | p-Nitrophenol |
| Creatinine | Enzymatic Colorimetric | NIST, SRM909b |
| Lithium | Colorimetric Substituted Porphyrin | NIST, SRM909b |
| Alpha-hydroxybutyrate dehydrogenase | DGKC/37 ° | ε NADH |

Values are assigned in-house on commercially marketed clinical chemistry analyzers. Each testing run evaluates triplicates of the following: two levels of control materials (low and high), an aliquot of internal master lot and two aliquots of two pools of calibrator materials. Four runs on at least two different days are performed. The mean and the standard deviation of the two calibrator pools were calculated. The assigned value was determined to be the mean of the two calibrator pools barring any outlier and imprecision of less than 4.5%.

The sponsors' results support the shelf-life stability claim of up to 24 month and a reconstituted stability material claim of 2 days at 2 to 8°C or 14 days at -20°C when stored in small volumes and frozen once.

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.