

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

A. 510(k) Number:

k051452

B. Purpose for Submission:

Notification of intent to manufacture and market the device: Sentinel Clin Chem Cal.

C. Measurand:

Amylase and Cholinesterase Calibrator

D. Type of Test:

Calibrator

E. Applicant:

Sentinel CH. S.r.l.

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:

The Sentinel Clin Chem Cal is a device intended for medical purposes for use in pancreatic amylase and cholinesterase assays to establish points of reference that are used in the determination of values in the measurement of pancreatic amylase and cholinesterase in human serum and plasma.

3. Special conditions for use statement(s):

For Prescription Use Only

4. Special instrument requirements:

Abbott Aeroset and Architect Systems

I. Device Description:

The Sentinel Clin Cal is a lyophilized calibrator prepared with human serum. Porcine pancreatic amylase and human cholinesterase are added to the base serum. The product consists of 4 X 3 mL bottles of lyophilized material containing pancreatic amylase and cholinesterase in a human serum matrix. The values of the calibrator are lot-dependent.

All human source material was tested and found to be non-reactive for HBsAg, HCV, and HIV-1/2.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Calibrator for Automated Systems

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

k033501

3. Comparison with predicate:

Characteristics	New Device	Predicate
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Constituents	Pancreatic Amylase, Cholinesterase	Contains additional analytes
Intended Use	For the calibration of clinical chemistry tests	Same
Storage	2-8°C	2-8°C
Reconstituted Stability	2 days at 2-8°C 14 days at -20°C when stored in small volumes (300-600µL) and frozen only once.	8 hours at 15-25°C 2 days at 2-8°C 4 weeks when stored at – (15 °C) to - (25 °C) and frozen only once.

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):

Sentinel Clin Chem Cal is traceable to the International Federation of Clinical Chemistry (IFCC) for Pancreatic Amylase and Deutsche Gesellschaft für Klinische Chemie (DGKC) for Cholinesterase.

Analyte	Method
Pancreatic Amylase	IFCC EPS/37°C
Cholinesterase	DGKC Butyrylthiocholine37°C

Values were assigned in house on commercially marketed clinical chemistry analyzers. During each testing run, two levels of control material (low and high) were assayed to ensure the assays were meeting their expected performance.

On three consecutive days, three replicates of the product were assayed on a commercially marketed analyzer. The average of all replicates was calculated (X1).

Five vials of freshly reconstituted product were assayed in five replicates on a commercially marketed analyzer. The average of all replicates was calculated (X2).

The assigned value (Xm) was determined to be the mean of the two averages:
 $X_m = (X_1 + X_2) / 2$.

Shelf Life: The Sentinel Clin Chem Cal is stable for 24 months based on real time stability studies.

Reconstituted: Real time stability studies show the Sentinel Clin Chem Cal is stable for 2 days at 2-8°C and 14 days at -20°C when stored in small volumes (300-600µL) 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.