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

A. 510(k) Number:
k051457

B. Purpose for Submission:
New device

C. Measurand:
Calibrator for ceruloplasmin, kappa light chains and lambda light chains

D. Type of Test:
Calibration materials

E. Applicant:
SENTINEL CH. S.r.1.

F. Proprietary and Established Names:
Plasmaproteins Cal 3x

G. Regulatory Information:

1. Regulation section:
   21 CFR § 862. 1150, Calibrator

2. Classification:
   Class II

3. Product Code:
   JIX

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for Use

2. Indication(s) for use:
   The Sentinel Plasmaproteins Cal 3x is a device intended for medical purpose for use in ceruloplasmin, kappa light chains and lambda light chains assay to establish points of reference that are used in the determination of values in the

measurement of ceruloplasmin, kappa and lambda light chains in human serum and plasma.

3. Special condition for use statement(s):
   Prescription Use Only

4. Special instrument Requirements:
   Automated, semi-automated, and manual clinical chemistry systems

I. Device Description:

The Sentinel Plasmaproteins Cal 3x is a liquid, ready-to-use calibrator prepared from plasmatic plasmaproteins in human-based serum. It consists of 4x1 mL bottles of aqueous material containing ceruloplasmin, kappa light chains and lambda light chains in a human serum matrix. This material is stable until the date printed on the label when stored as directed. Calibrator traceability was certified to CRM 470 (Certified Reference Material).

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Calibrator for Automated Systems (C.f.a.s.) Proteins

2. Predicate K number(s):
   k011226

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Plasmaproteins Cal 3x is for use for the calibration of the plasmaprotein tests listed in the Assigned Concentrations Table using immunoturbidimetric methods.	C.f.a.s. (Calibrator for automated systems) Proteins is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.
Matrix	Liquid- ready to use	Liquid- ready to use
Storage	2 to 8^0C	2 to 8^0C

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

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 (controls, calibrators, or method):
   The Sentinel Plasmaproteins Cal 3x calibrator traceability was certified to CRM 470 (Certified Reference Material). The calibrator shelf-life stability was determined by the recovery method on one lot of Plasmaproteins Cal 3x stored at $2 - 8\ ^{0}$ C, compared with the value assigned at manufacturing time. Percent recovery was calculated for each calibrator level by dividing the result in conventional units (mg/dL) of the test calibrators by the assigned value (mg/mL) and multiplying the result by 100. Acceptance criteria is 100±10%. Data support a shelf life of 25 months. Claim will be 24 months.

   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 satisfies the requirement of 21 CFR part 809.10

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.