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510(k) Summary

Submitter's Name/Address
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Date of Preparation of this Summary: May 28, 2005

Device Trade or Proprietary Name: Sentinel Plasmaproteins Cal 3x

Device Common/Usual Name or Classification Name: Calibrator

Classification Number/Class: JIX/Class II

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K051457

Test Description:

The Sentinel Plasmaproteins Cal 3x is a device intended for medical purposes for use in ceruloplasmin, kappa light chain, and lambda light chain assays to establish points of reference that are used in the determination of values in the measurement of ceruloplasmin, kappa light chains, and lambda light chains in human serum and plasma.

Intended Use:

Sentinel Plasmaproteins Cal 3x must be used only for the calibration of plasmaprotein tests using the immunoturbidimetric methods.

Description of the Calibrator Material:

Sentinel Plasmaproteins Cal 3x contains analytes (plasmatic plasmaproteins) in human serum matrix. The analytes consist of ceruloplasmin, kappa light chains, and lambda light chains.

Assigned Values and Value Assignment Process:

The Sentinel Plasmaproteins Cal 3x value assignment is assessed by testing the new lot of calibrator with approved reagent calibrated with a Master lot stored at -20 °C.

In the assignment testing, five replicates per three runs are assessed for Kappa light chains, Lambda light chains and Ceruloplasmin assays. The assigned value is calculated as the average of all the replicates for each assay.

Quality control materials are used to verify the assay performance at every step of the test. Fresh reagents and new calibrations are used at each run.

Directions for Use:

Refer to Draft Calibrator Labeling

Performance Characteristics:

1. **Precision/Reproducibility**

   N/A

2. **Linearity/assay reportable range**

   N/A

3. **Traceability (controls, calibrators, or method)**

   The Sentinel Plasmaproteins Cal 3x is traceable to the following referenced standards:

Short Name	Analyte	Method	Standardization
Cerul	Ceruloplasmin	Turbidimetric	CRM 470
Kappa	Kappa Light Chains	Turbidimetric	CRM 470
Lambd	Lambda Light Chains	Turbidimetric	CRM 470

4. Detection limit (functional sensitivity)

N/A

5. Analytical specificity

N/A

6. Assay cut-off

N/A

7. Calibrator Shelf-life Stability

The calibrator shelf-life stability was determined by the recovery method on one lot of Plasmaproteins Cal 3x stored at 2 – 8 °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/dL) and multiplying the result by 100. Acceptance criteria is 100 ± 10 %. At each testing point. Data support a shelf life of 25 months. Claim will be 24 months. Results are reported in the table below.

Plasmaproteins Cal 3x lot P0387	Assigned Value	Found 1 Month at 2-8 °C	% Rec	Found 25 Months at 2-8 °C	% Rec
Kappa light chains (mg/dL)	590	592	100.3%	599	101.5%
Lambda light chains (mg/dL)	356	354	99.4%	353	99.2%
Ceruloplasmin (mg/dL)	90	90	100.0%	89	98.9%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 25 2005

Mr. Davide Spada
Applicantion Specialist
SENTINEL CH. S.r.l
Via Principe Eugenio, 5
20155 Milano- Italy

Re: k051457
Trade/Device Name: Sentinel Plasmaproteins Cal 3x
Regulation Number: 21 CFR 862. 1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIX
Dated: May 28, 2005
Received: June 2, 2005

Dear Mr. Spada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051457

Device Name: Sentinel Plasmaproteins Cal 3x

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Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K051457