OCT 2 1 2005

510(k) Summary

Submitter's Name/Address
Sentinel CH. S.r.l.
via Principe Eugenio, 5
20155 Milan, Italy

Contact Person
Davide Spada
Application Specialist
+39 02 345514.1
Fax +39 02 345514.64

Date of Preparation of this Summary:	August 30, 2005
Device Trade or Proprietary Name:	Sentinel Ceruloplasmin
Device Common/Usual Name or Classification Name:	ceruloplasmin
Classification Number/Class:	JFR/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: K051456

Test Description:

Sentinel Ceruloplasmin is an in vitro diagnostic assay for the quantitative determination of ceruloplasmin in serum or plasma. The Sentinel Ceruloplasmin assay is a two-reagent format based on the immunological reaction between anti-ceruloplasmin antibonds specific for ceruloplasmin. The turbidity of the immunocomplex is proportional to the concentration of the analyte in the sample.

Substantial Equivalence:

The Sentinel Ceruloplasmin assay is substantially equivalent to the Roche Ceruloplasmin assay (which was exempted from the Premarket Notification) on the Roche/Hitachi 911 Analyzer (Previously named Boehringer Mannheim Hitachi 911 Analyzer, K921661). These assays yield similar Performance Characteristics.

Similarities:

- Both assays are in vitro clinical chemistry methods.
- Both assays can be used for the quantitative determination of analyte name.
- Both assays yield similar clinical results.
- Both assays have the same reference range.

Differences:

There is a difference between the assay ranges.

Intended Use:

The Sentinel Ceruloplasmin assay is used for the quantitation of ceruloplasmin in serum or plasma.

Performance Characteristics:

Comparative performance studies were conducted using the AEROSET® System. The Sentinel Ceruloplasmin assay method comparison yielded acceptable correlation with the Roche Ceruloplasmin assay on the Roche/Hitachi 911 Analyzer. The Passing & Bablok regression was: slope = 1.0256, and Y-intercept = -1.0205 mg/dL. Precision studies were conducted using the Sentinel Ceruloplasmin assay. Within-run and between-run studies were performed using three levels of control material. The total %CV for Level 1 is 3.69%, Level 2 is 5.33%, and Level 3 is 4.53%. The Sentinel Ceruloplasmin assay is linear up to 110 mg/dL. The limit of quantititation (sensitivity) of the Sentinel Ceruloplasmin assay is 2 mg/dL. These data demonstrate that the performance of the Sentinel Ceruloplasmin assay is substantially equivalent to the performance of the Roche Ceruloplasmin assay on the Roche/Hitachi 911 (Previously named Boehringer Mannheim Hitachi 911 Analyzer, K921661).

Conclusion:

The Sentinel Ceruloplasmin assay is substantially equivalent to the Roche Ceruloplsmin assay on the Roche/Hitachi 911 Analyzer as demonstrated by results obtained in the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sentinel CH. S.r.l.
c/o Mr. Davide Spada
Application Specialist
Via Principe Eugenio, 5
20155 Milano, Italy

OCT 2 1 2005

Re: k051456
Trade/Device Name: Sentinel Ceruloplasmin
Regulation Number: 21 CFR 866.5210
Regulation Name: Ceruloplasmin Immunological Test System
Regulatory Class: Class II
Product Code: JFR
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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051456

Device Name: Sentinel Ceruloplasmin

Indications For Use:

The Sentinel Ceruloplasmin assay is used for the quantitation of ceruloplasmin (copper-transporting serum protein) levels in human serum or plasma. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorder.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k051456