K062379

JAN 3 1 2007

510(k) Summary

Purpose

In accordance with 21 CFR 907.87, Roche Diagnostics hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

Device Name

Proprietary name: Prealbumin/Ceruloplasmin Control Set

Common name: Precinorm/Precipath PC

Classification name: Multi-Analyte Controls, All Kinds (assayed and unassayed) in Class I

Establishment registration

The establishment registration number for Roche Diagnostics Penzberg is 9610529.

Classification

The FDA has classified Multi-Analyte Controls, All Kinds (assayed and unassayed) in Class I.

Panel	Classification Number	Classification Name	Regulation Citation
75 Clinical Chemistry	JJY	Quality control material (assayed and unassayed)	21 CFR 862.1660

Performance Standards

To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Proposed labeling

Proposed labeling sufficient to describe the device, its intended use, and the directions for use are attached. We believe the proposed version of the device labeling presented in Section V contains all of the technical information required per 21 CFR 809.10.

Substantial equivalence

Prealbumin/Ceruloplasmin Control Set is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Precinorm PUC (K040280).

Substantial equivalence: Similarities

The below tables compare Prealbumin/Ceruloplasmin Control Set with the predicate device, Precinorm PUC (K040280).

Characteristic	Prealbumin/Ceruloplasmin Control Set	Predicate Device Precinorm PUC (K040280).
Intended Use	Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.	Precinorm PUC (Proteins in Urine/CSF) is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.
Stability	Unopened: • Store at 2-8°C until expiration date Reconstituted: • at 15 – 25 °C: up to 8 hrs • at 2-8°C: 2 days • at (-15)-(-25)°C: 2 weeks (freeze only once)	Unopened: • Store at 2-8°C until expiration date Opened: • Stable for 4 weeks at 2-8°C.

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Differences

Characteristic	Prealbumin/Ceruloplasmin Control Set	Predicate Device Precinorm PUC (K040280).
Matrix	Human serum with material of biological origin as specified	Buffered aqueous solution
Format	Lyophilized	Liquid ready-for-use control based on a buffered aqueous solution.
Handling	Reconstitute with exactly 1.0 mL of distilled water and allow to stand closed for 30 minutes to reconstitute, and then mix gently.	Liquid ready-for-use control based on a buffered aqueous solution. Concentrations of control components have been adjusted to represent normal ranges.

Evaluations summary

The Prealbumin/Ceruloplasmin Control Set was evaluated for value assignment and stability. A summary of the evaluation studies is provided in the Performance Characteristics Section of this submission.

Confidentiality

Roche Diagnostics Corporation requests that the FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corporation.
c/o Ms. Corina Harper
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250

JAN 3 1 2007

Re: k062379
Trade/Device Name: Prealbumin/Ceruloplasmin Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: January 10, 2007
Received: January 11, 2007

Dear Ms. Harper:

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). 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) 276-0450. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062379

COBAS INTEGRA Ceruloplasmin: **Ceruloplasmin**

Indications For Use:

Prealbumin/Ceruloplasmin Control Set (Precinorm/Precipath PC) is used for quality control by monitoring accuracy and precision for the quantitative methods as specified in the enclosed value sheet.

Prescription Use XXX 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)

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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