510(k) Summary – COBAS INTEGRA Ceruloplasmin

JAN 3 1 2007

K062114

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Purpose

Due to a misinterpretation caused in part by an error on the FDA classification database available on line, which had erroneously listed Ceruloplasmin as exempt until June 2005, this test system was erroneously considered by us to be exempt during its original application to the COBAS INTEGRA and Roche Hitachi families of analyzers. It was erroneously listed by us as exempt in the reagent lists accompanying the FDA-cleared premarket notification submissions for the COBAS INTEGRA 800 and Roche Hitachi 917 analyzers. The COBAS INTEGRA family of analyzers was cleared under K951595 and the Roche/Hitachi family of analyzers under K953239/A005.

In order to correct this error, Roche now submits a traditional 510(k) featuring performance data on the Integra 700 analyzer. The assay has already been applied to all Integra family members and to the Roche/Hitachi family of analyzers using the Application Validation Protocol submitted as part of this 510(k).

Submitter name, address, contact

Roche Diagnostics
9115 Hague Rd
Indianapolis IN 46250
(317) 521-3723

Contact person: Corina Harper

Date prepared: Jul 17, 2006

Device Name

Proprietary name: COBAS INTEGRA Ceruloplasmin

Common name: Ceruloplasmin

Classification name: Ceruloplasmin immunological test system

Device Description

The COBAS INTEGRA Ceruloplasmin cassette (CERU) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA SYSTEMS for the quantitative immunological determination of human ceruloplasmin in serum and plasma. The calibrator and control were cleared via K954992.

Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

The test principle is an immunoturbidimetric assay. The calibrator is Serumproteins T Standard and the recommended control material is the Serumproteins T Control.

Intended use

The COBAS INTEGRA Ceruloplasmin cassette (CERU) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA SYSTEMS for the quantitative immunological determination of human ceruloplasmin in serum and plasma (test CERU3, 0-666).

Predicate Device

We claim substantial equivalence to the DakoCytomation assay for Polyclonal Rabbit Anti-Human Ceruloplasmin cleared as K812486.

Substantial equivalency – Similarities

The table below indicates the similarities between the COBAS INTEGRA Ceruloplasmin test and its predicate device (Polyclonal Rabbit Anti-Human Ceruloplasmin cleared as K812486).

Feature	Predicate device: Polyclonal Rabbit Anti-Human Ceruloplasmin (K812486)	COBAS INTEGRA Ceruloplasmin
General		
Intended Use/ Indications for Use	Polyclonal Rabbit Anti-Human Ceruloplasmin is intended for the quantitative determination of Ceruloplasmin in human sample material by turbidimetry and nephelometry.	The COBAS INTEGRA Ceruloplasmin cassette (CERU) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA SYSTEMS for the quantitative immunological determination of human ceruloplasmin in serum and plasma (test CERU3, 0-666).
Specimen type	Serum, plasma	Same
Test principle		
Reference method	turbidimetry and nephelometry	turbidimetry
Reagent information		

Stability - shelf life and on-board	2-8 °C until expiration date Stability of prediluted antibody: 28 days at 2-8 °C On board stability: 28 days 2-8 °C until expiration date	2-8 °C until expiration date COBAS INTEGRA 400/400+ On board in use 8 weeks at 10 to 15° C COBAS INTEGRA 700/800 On board in use 8 weeks at 8°C
Calibrator	Human Serum Protein Calibrator Interval: each lot or 28 days	Serum Proteins T Standard Interval: each lot
Quality control	Human Serum Protein Low and High	Serum Proteins T Control Interval: 24 hrs recommended
Traceability	Information not available.	Standardized against IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619) for 14 serum proteins.
Performance characteristics		
Measuring range	0.06-1.3 g/L	0.06-1.26 g/L
Lower Detection Limit	0.02 g/L	0.017 g/L
Expected values	0.2-0.6 g/L	Same

Substantial equivalency – Differences

The table below indicates the similarities between the COBAS INTEGRA Ceruloplasmin test and its predicate device (DakoCytomation assay for Polyclonal Rabbit Anti-Human Ceruloplasmin cleared as K812486). 1

Feature	**Predicate device: Polyclonal Rabbit Anti-Human Ceruloplasmin (K812486)**	**COBAS INTEGRA Ceruloplasmin**
Reagent information		
R1 R2	Purified immunoglobulin fraction of rabbit antiserum provided in liquid. In 0.1 mol/L NaCl, 15 mmol/L NaN3	R1: Accelerator Polyethylene glycol (PEG) 50 g/L, in phosphate buffer stabilized with 0.09% sodium azide in vial A (liquid)

		R2=SR: Anti-ceruloplasmin T antiserum (rabbit) specific for human ceruloplasmin >0.42 g/L in phosphate buffer stabilized with 0.09% sodium azide in vial C (liquid)
Instrument	COBAS MIRA, Hitachi and other instruments	COBAS Integra family of analyzers, Roche/Hitachi family (including cobas c6000 series)
Performance characteristics		
Precision	Within run total CV% 1.0% @ 0.27 g/L 1.4% @ 0.34 g/L 1.6% @ 0.62 g/L	Within run total CV%: 3.88% @ 0.2 g/L 2.66% @ 0.35 g/L
Linearity	0.06-0.69 g/L	0.06-1.26 g//L
Endogenous interferences	Hemolysis no interferences up to 10 g/L Icterus no interferences up to 600 mg/L Triglycerides no interferences up to 25 g/L Intralipid at 10 g/L	Hemolysis: no significant interferences Icterus: no significant interferences Lipemia: no significant interferences Rheumatoid factors: no significant interferences up to 400 IU/mL
Exogenous Interferences		Gammopathy, in particular IgM, may cause unreliable results in rare cases
Method comparison	y = COBAS INTEGRA Ceruloplasmin x = DAKOCytomation Anti Human Ceruloplasmin Passing-Bablok results: y = 1.0x – 0.0 g/L; r =0.987	

Proposed Labeling

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

Validation and Design Control

Development activities were conducted under appropriate design control procedures and the overall product specifications were met. The Declaration of Conformity with Design Controls and Results of Risk Analysis are provided in Section 5.1. Analytical Performance.

Confidentiality

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

Closing

Therefore, we trust the information provided in this Traditional 510(k) will support a decision of substantial equivalence of the COBAS INTEGRA Ceruloplasmin test system to the predicate.

If you have any questions or require further information, please do not hesitate to contact this office.

- Phone: (317) 521-3831
- FAX: (317) 521-2324
- email: corina.harper@roche.com

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: k062114
Trade/Device Name: COBAS INTEGRA Ceruloplasmin Model 2055953
Regulation Number: 21 CFR 866.5210
Regulation Name: Ceruloplasmin Immunological Test System
Regulatory Class: Class II
Product Code: CHN
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): K062114

COBAS INTEGRA Ceruloplasmin: **Ceruloplasmin**

Indications For Use:

COBAS INTEGRA:

In vitro test for the quantitative immunological determination of ceruloplasmin in human serum and plasma on COBAS INTEGRA systems.

Measurements of Ceruloplasmin aid in the diagnosis of copper metabolism disorders.

Roche/Hitachi cobas c systems:

In vitro test for the quantitative determination of ceruloplasmin in human serum and plasma on Roche/Hitachi cobas c systems.

Measurements of Ceruloplasmin aid in the diagnosis of copper metabolism disorders.

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

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062114