DEC 1 9 2002

K024098

510(k) Summary - COBAS Integra Creatinine plus ver.2 Assay

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
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Sherri L. Coenen Date prepared: December 11, 2002
Device Name	Proprietary name: COBAS Integra Creatinine plus ver.2 Common name: creatinine reagent Classification name: enzymatic Method, Creatinine
Device description	The COBAS Integra Creatinine plus ver. 2 Assay is an enzymatic method based on the determination of hydrogen peroxide after conversion of creatinine with the aid of creatininase, creatinase, and sarcosine oxidase. The liberated hydrogen peroxide reacts to form a quinone imine dye, the color intensity of which is directly proportional to the creatinine concentration.
Intended use	The cassette COBAS INTEGRA Creatinine plus ver.2 (CREP2) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of the creatinine concentration in serum, plasma, and urine.
Predicate Device	We claim substantial equivalence to the currently marketed COBAS Integra Creatinine plus Assay. (K003261).

510(k) Summary - COBAS Integra Creatinine plus ver.2,
continued

Reagent Summary

The following table describes the similarities and differences between the COBAS Integra Creatinine plus ver.2 assay and the predicate device.

Topic	COBAS Integra Creatinine plus (K003261)	COBAS Integra Creatinine plus ver.2 (Modified Device)
Intended Use	The cassette COBAS INTEGRA Creatinine plus (CREAP) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of the creatinine concentration in serum, plasma, and urine.	The cassette COBAS INTEGRA Creatinine plus ver.2 (CREP2) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of the creatinine concentration in serum, plasma, and urine.
Method	Enzymatic colorimetric	Same
Sample type	serum, plasma (Li-heparin, K_3-EDTA), urine	Same
Measuring range	Serum/Plasma: 0 - 2700 µmol/L Urine: 0 - 40 mmol/L	Same
Expected values	Serum/Plasma: Females: 45 - 84 µmol/L Males: 59 - 104 µmol/L	Serum/Plasma: *Adults* Females: 45 - 84 µmol/L Males: 59 - 104 µmol/L *Children* Neonates (premature): 29 - 87 µmol/L Neonates (full term): 27 - 77 µmol/L 2 - 12 m: 14 - 34 µmol/L 1 - <3y: 15 - 31 µmol/L 3 - <5y: 23 - 37 µmol/L 5 - <7y: 25 - 42 µmol/L 7 - <9y: 30 - 47µmol/L 9 - <11y: 29 - 56 µmol/L 11- <13y: 39 - 60 µmol/L 13 - <15y: 40 - 68 µmol/L

Reagent Summary,
continued

Topic	COBAS Integra Creatinine plus (K003261)	COBAS Integra Creatinine plus ver.2 (Modified Device)
Expected values, continued	Urine: *First morning urine:* Females: 2.55 - 20.0 mmol/L Males: 3.54 - 24.6 mmol/L *24-hour urine:* Females: 6 - 13 mmol/24h Males: 9 - 19 mmol/24h *Creatinine clearance:* 66 - 143 mL/min	Urine: *First morning urine:* Females: 2.55 - 20.0 mmol/L Males: 3.54 - 24.6 mmol/L *24-hour urine:* Females: 6 - 13 mmol/24h Males: 9 - 19 mmol/24h *Creatinine clearance:* 66 - 143 mL/min

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 19 2002

Ms. Sherri L. Coenen
Regulatory Submissions, Centralized Diagnostics
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k024098
Trade/Device Name: COBAS Integra Creatinine plus ver.2 Assay
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine Test System
Regulatory Class: Class II
Product Code: JFY
Dated: December 11, 2002
Received: December 12, 2002

Dear Ms. Coenen:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): N/A

Device Name: COBAS Integra Creatinine plus ver.2 Assay

Indications For Use:

The cassette COBAS INTEGRA Creatinine plus ver.2 (CREP2) contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative determination of the creatinine concentration in serum, plasma, and urine.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K024098

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)