JUL 9 2003

K031824

510(k) Summary - COBAS Integra Cholesterol Gen.2

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: June 11, 2003
Device Name	Proprietary name: Roche Diagnostics COBAS Integra Cholesterol Gen.2 Common name: Total Cholesterol Assay Classification name: Cholesterol (Total) test system
Device description	The COBAS Integra Cholesterol Gen.2 is an enzymatic colorimetric assay using cholesterol esterase, cholesterol oxidase, and peroxidase to form a red quinone-imine dye. The color intensity of the dye is directly proportional to the cholesterol concentration.
Intended use	The cassette COBAS Integra Cholesterol Gen.2 (CHOL2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of total cholesterol in serum and plasma.
Predicate Device	We claim substantial equivalence to the currently marketed Roche/Hitachi Cholesterol Assay. (K952127).

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

Reagent Summary

The following table describes the similarities and differences between the COBAS Integra Cholesterol Gen.2 and the predicate device.

Topic	Roche Hitachi Cholesterol (K952127)	COBAS Integra Cholesterol Gen.2 (Modified Device)
Intended Use	Enzymatic in vitro test for the direct quantitative determination of cholesterol in human serum and plasma on automated clinical chemistry analyzers.	The cassette COBAS Integra Cholesterol Gen.2 (CHOL2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of total cholesterol in serum and plasma.
Method	Enzymatic, colorimetric test	Same
Sample type	Human Serum and Plasma	Same
Measuring range	3 - 800 mg/dl	0.1 - 800 mg/dl
Expected values	According to the recommendations of the European Atherosclerosis Society and the recommendations of the NCEP Adult Treatment Panel.	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 9 2003

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

Re: k031824
Trade/Device Name: COBAS Integra Cholesterol Gen 2
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: Class I
Product Code: CHH
Dated: June 11, 2003
Received: June 13, 2003

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). 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/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~~ K03 1824

Device Name: COBAS Integra Cholesterol Gen.2

Indications For Use:

The cassette COBAS Integra Cholesterol Gen.2 (CHOL2) contains an in vitro diagnostic reagent system intended for use on COBAS Integra systems for the quantitative determination of total cholesterol in serum and plasma.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in blood and lipid and lipoprotein metabolism disorders.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031824

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)