AUG - 5 2003

K032336

510(k) Summary - Tina-quant CRP (Latex)

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: July 25, 2003
Device Name	Proprietary name: Roche Diagnostics Tina-quant CRP (Latex) Common name: Tina-quant CRP (Latex) Classification name: C-reactive protein immunological test system
Device description	The Tina-quant CRP (Latex) is a particle-enhanced immunoturbidimetric assay. Anti-CRP antibodies coupled to latex microparticles react with antigen in the sample to form an antigen/antibody complex which is measured turbidimetrically.
Intended use	Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on automated clinical chemistry analyzers.
Predicate Device	We claim substantial equivalence to the currently marketed Roche Diagnostics Tina-quant CRP (Latex) HS assay. (K003400).

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

Reagent Summary

The following table describes the similarities and differences between the Tina-quant CRP (Latex) and the predicate device.

Topic	Tina-quant CRP (Latex) HS (K003400)	Tina-quant CRP (Latex) (Modified Device)
Intended Use	Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on automated clinical chemistry analyzers.	Same
Method	Particle-enhanced immunoturbidimetric assay	Same
Sample type	Serum Plasma: Li-/Na-heparin, Na-/K_3-EDTA, citrate plasma	Serum Plasma: Li-/Na-heparin, Na-/K_2-/K_3-EDTA
Measuring range	• Roche/Hitachi 902: 0.1 - 20 mg/L • Roche/Hitachi 904/911/912/917/Modular P: 0.2 - 20 mg/L 0.1 - 300 mg/L with rerun	• Roche/Hitachi 902: 1 - 265 mg/L • Roche/Hitachi 717/Modular D: 1 - 265 mg/L 1 - 398 mg/L with rerun • Roche/Hitachi 904/911/912: 1 - 260 mg/L 1 - 520 mg/L with rerun • Roche/Hitachi 917/Modular P: 1 - 280 mg/L 1 - 560 mg/L with rerun
Expected values	< 0.5 mg/dl	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG - 5 2003

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

Re: k032336
Trade/Device Name: Tina-quant CRP (Latex)
Regulation Number: 21 CFR 866.5270
Regulation Name: C. reactive protein immunological test system
Regulatory Class: Class II
Product Code: DCN
Dated: July 25, 2003
Received: July 29, 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). 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 K032336

Device Name: Tina-quant CRP (Latex)

Indications For Use:

Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on automated clinical chemistry analyzers.

Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(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)

Division Sign-Off For Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032336