K042485

OCT 2 9 2004

510(k) Summary

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 9115 Hague Road Indianapolis, IN 46250 317-521-3723 Contact Person: Theresa M. Ambrose Date Prepared: September 9, 2004
Device Name	Proprietary name: Tina-Quant CRP (Latex) HS Test System (C-reactive protein (latex) high sensitive) Common name: hsCRP test system Classification name: Cardiac C-reactive Protein, Antigen, Antiserum, and Control
Predicate device	The Tina-quant® CRP (latex) HS Test System is substantially equivalent to the currently marketed Roche Tina-quant® CRP (latex) HS Test System cleared under K003400. For purposes of the extended intended use, we claim equivalence to the currently marketed Dade Behring N High Sensitivity CRP (K033908)
Device Description	The Tina-quant® CRP (latex) HS Test System is a latex particle-enhanced immunoturbidimetric test for the measurement of C-reactive protein in human serum or plasma.

Intended use	The Tina-quant® CRP (Latex) High Sensitive Immmunoturbidimetric assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on Roche automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Highly sensitive measurement of CRP may also be used as an aid in the assessment of the risk of future coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may also be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.
Comparison to predicate device	The below table compares Tina-Quant® CRP (Latex) HS with the predicate devices, Tina-Quant® CRP (Latex) HS (K003400), and Dade-Behring N High Sensitivity CRP (K033908).

Substantial equivalence: comparison table

Characteristic	Tina-Quant® CRP (Latex) HS (modified intended use)	Predicate device Tina-Quant® CRP (Latex) HS (K003400)	Predicate device Dade-Behring N High Sensitivity CRP (K033908)
Intended Use	The Tina-quant® CRP (Latex) High Sensitive Immmunoturbidimetric assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on Roche automated clinical chemistry analyzers. Highly sensitive measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Measurement of CRP may also be used as an aid in the assessment of the risk of future coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may also be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.	Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on automated clinical chemistry analyzers.	N *High Sensitivity* CRP is an in vitro diagnostic reagent for the quantitative determination of C-reactive protein (CRP) in human serum, and heparin and EDTA plasma by means of particle-enhanced immunonephelometry using BN Systems. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes

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Predicate device (continued)

Characteristic	Tina-Quant® CRP (Latex) HS (modified intended use)	Predicate device Tina-Quant® CRP (Latex) HS (K003400)	Predicate device Dade-Behring N High Sensitivity CRP (K033908)
Indications for Use	Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Highly sensitive measurement of CRP may also be used as an aid in the assessment of the risk of coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.	For the quantitative determination of C-reactive protein in human serum and plasma. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases.	In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders, and associated diseases. Measurements may also be used as an aid in the identification of individuals at risk for future cardiovascular disease. High sensitivity CRP (hsCRP) measurements, when used in conjunction with traditional clinical laboratory evaluation of acute coronary syndromes, may be useful as an independent marker of prognosis for recurrent events, in patients with stable coronary disease or acute coronary syndromes
Assay principle	Same as K003400	Latex particle-enhanced immunoturbidimetric test	Particle-enhanced agglutination with nephelometric detection
Instrument	Same as K003400	Roche/Hitachi family of analyzers	Dade-Behring BN Systems (nepholometric systems)

Reagent Stability	Same as K003400	• Unopened kit: up to the stated expiration date at 2-8 °C • On board the analyzer (opened and refrigerated): 90 days	• Unopened kit: up to the stated expiration date at 2-8 °C • Opened: 4 weeks at stored in closed vial. Do not freeze
Sample type	Same as K003400	Human serum and plasma	Human serum, and heparin and EDTA plasma
Traceability/ standardization	Same as both predicates	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)	IFCC/BCR/CAP reference preparation CRM 470 (RPPHS 91/0619)
Measuring range	Same as K003400	0.1 – 20 mg/l without dilution 0.1 -300 mg/l extended range with dilution and rerun	0.175 – 1100 mg/L with dilution
Lower Detection Limit	Same as K003400	0.03 mg/L	0.175 mg/L
Within-run precision (%CV)	Same as K003400	Control material • 0.43% at 4.27 mg/L • 0.41% at 11.62 mg/L Human serum • 1.34% at 0.55 mg/L • 0.28% at 12.36 mg/L	• 2.5 % at 0.5 mg/L • 3.8 % at 1.3 mg/L • 2.1 % at 2.1 mg/L • 2.6 % at 14 mg/L • 3.9 % at 24 mg/L • 5.7% at 56 mg/L
Between-run precision (%CV)	Same as K003400	Control material • 2.70 % at 4.34 mg/L • 3.45% at 11.90 mg/L Human serum • 5.70% at 0.52 mg/L • 2.51% at 10.98 mg/L	• 3.1 % at 0.5 mg/L • 3.8 % at 1.1 mg/L • 3.4 % at 2.1 mg/L • 4.0 % at 15 mg/L • 2.3 % at 26 mg/L • 4.4% at 62 mg/L
Functional Sensitivity (CV < 10%)	Same as K003400	0.11 mg/L	Not available.

Limitations: interferences	Same as K003400	No significant interference up to • I index of 60 (60 mg/dL bilirubin) • H index of 1000 (1000 mg/dL hemoglobin) • L index of 1000 at CRP > 5mg/L (lipemia; intralipid) • L index of 800 at CRP > 4mg/L • L index of 500 at CRP > 2 mg/L • Rheumatoid factors < 1200 IU/mL No high dose hook effect up to 1000 mg/L In rare cases, gammopathy, in particular IgM Waldenstrom's macroglobinemia may cause unreliable results	No interference from • Bilirubin up to 230 mg/L • Hemoglobin up to 36 g/L • Triglycerides up to 7.4 g/L Highly lipemic samples that cannot be clarified by centrifugation (10 min at 15000 X G) must not be tested. Particles that are formed in incompletely clotted serum or plasma or due to protein denaturation must be removed by centrifugation prior to testing.
Limitations: Result Interpretation	Same as K003400	Increases in CRP values are non-specific and should not be interpreted without a complete clinical history. When using CRP to assess the risk of coronary heart disease results should be compared to previous values. For diagnostic purposes, results should always be assessed in conjunction with the patient's medical history and other findings.	Increases in CRP values are non-specific and should not be interpreted without a complete clinical history.
Expected values	Same as both predicates (both sets of information are provided)	Adults: < 5.0 mg/L Neonates 0-3 weeks: 0.1 – 4.1 mg/L Children (2 months-15 years) 0.1 – 2.8 mg/L	Relative risk/average hsCRP: Low < 1 mg/L Average 1.0-3.0 mg/L High >3.0 mg/L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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OCT 2 9 2004

Theresa M. Ambrose, Ph.D., DABCC, FACB, RAC
Regulatory Principal
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k042485
Trade/Device Name: Tina-Quant® CRP (Latex) HS
Regulation Number: 21 CFR 866.5270
Regulation Name: C-reactive protein immunological test system
Regulatory Class: Class II
Product Code: NQD
Dated: September 10, 2004
Received: September 13, 2004

Dear Dr. Ambrose:

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): N/A K042485

Device Name: Tina-Quant® CRP (Latex) HS

Indications For Use:

The Tina-quant® CRP (Latex) High Sensitive Immmunoturbidimetric assay is for the in vitro quantitative determination of C-reactive protein (CRP) in human serum and plasma on Roche automated clinical chemistry analyzers. Measurement of CRP is of use for the detection and evaluation of inflammatory disorders and associated diseases, infection and tissue injury. Highly sensitive measurement of CRP may also be used as an aid in the assessment of the risk of future coronary heart disease. When used as an adjunct to other laboratory evaluation methods of acute coronary syndromes, it may also be an additional independent indicator of recurrent event prognosis in patients with stable coronary disease or acute coronary syndrome.

Prescription Use __X___ (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)

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Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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