K012359

510(k) Summary

NOV 2 9 2001

Introduction

According to the requirements established in the Food and Drug Administration's guidance document entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7643

Contact Person: Helen T. Torney
Date Prepared: July 23, 2001

2) Device name

Proprietary name: Tina-quant Complement C4 Test System
Common name: Complement C4 Test
Classification name: Complement components immunological test system.

3) Predicate device

We claim substantial equivalence to the currently marketed Tina-quant Complement C4 Test System on Roche COBAS Integra Analyzers (K951595)

4) Device Description

The Tina-quant Complement C4 Test System is based on the activation of the complement system which takes place via a classical and alternative route. Complement factor C4 participates in activation by the classical route. Human C4 forms a precipitate with a specific antiserum which is determined turbidimetrically.

5) Intended use

In vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human complement C4 in serum and plasma.

6.) Substantial equivalence

The table below indicates the similarities between the modified Tina-quant Complement C4 ver.2 Test System on COBAS Integra analyzers and the predicate, Tina-quant Complement C4 Test System Roche (K951595). In summary, the Tina-quant Complement C4 ver.2 Test System described in this submission is, in our opinion, substantially equivalent to the predicate device.

Comparison of Proposed and Predicate Device

Topic	Modified Tina-quant Complement C4 ver. 2	Tina-quant Complement C4 (cleared K951595)
Intended Use	In vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human complement C4 in serum and plasma	For the in vitro quantitative immunological determination of human complement C4 in serum and plasma.
Indication for Use	Aid in detecting the presence and level of C4 found in autoimmune diseases, infections and inflammatory disorders.	Aid in detecting the presence and level of C4 found in autoimmune diseases, infections and inflammatory disorders.
Analyzer	COBAS Integra analyzers	COBAS Integra analyzers
Sample Type	Human serum and plasma	Human serum
Analytical Sensitivity	0.04 g/L (4 mg/dL)	0.012 g/L (1.2mg/dL)
Wavelength	340/659 nm	340/659 nm
Measuring Range	0.04-1.35 g/L (4-135 mg/dL)	0.06-0.9 g/L (6-90 mg/dL)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 9 2001

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

Re: k012359
Trade/Device Name: Tina-Quant Complement C4 ver.2 Test System
Regulation Number: 21 CFR 866.5240
Regulation Name: Complement components immunological test system
Regulatory Class: Class II
Product Code: DBI
Dated: October 12, 2001
Received: October 15, 2001

Dear Ms.Torney:

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); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K012359
Device Name: **Tina-quant Complement C4 ver.2 Test System**

Indications for Use:
In vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human complement C4 in serum and plasma. Aid in detecting the presence and level of C4 found in autoimmune diseases, infections and inflammatory disorders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan C Alfaro

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012359

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

(Optional Format 1-2-96)