K012361

NOV 2 9 2001

510(k) Summary

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) 576-7643
Contact Person: Helen T. Torney

Date Prepared: November 12, 2001

2) Device name

Proprietary name:	Tina-quant Complement C3c Test System
Common name:	Complement C3c Test
Classification name:	Complement components immunological test system

3) Predicate device

We claim substantial equivalence to the currently marketed Tina-quant Complement C3c Test System on Roche COBAS Integra Analyzers (K591595).

510(k) Summary, Continued

4) Device Description

The Tina-quant Complement C3c ver.2 Test System is based on the activation of the complement system which takes place via a classical and an alternative route. The two pathways come together in a joint terminal path. As a complement factor C3 is a factor common to both pathways, the concentration of C3 and its degradation products (including C3c) can be evaluated as a parameter for activation of the complement system. Human C3c forms a precipitate with a specific antiserum which is determined turbidimetrically.

5) Intended use

For the in vitro quantitative immunological determination of human complement C3c in serum and plasma.

6.) Substantial equivalence

The table below indicates the similarities between the modified Tina-quant Complement C3c ver.2 Test System on COBAS Integra analyzers and the predicate, Tina-quant Complement C3c Test System on COBAS Integra analyzers (K951595). In summary, the Tina-quant Complement C3c 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 C3c ver.2	Tina-quant Complement C3c (cleared K951595)
Intended Use	For the in vitro quantitative immunological determination of human complement C3c in serum and plasma.	For the in vitro quantitative immunological determination of human complement C3c in serum.
Indication for Use	Measurements of these proteins aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.	Measurements of these proteins aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.
Sample Type	Human serum and plasma	Human serum
Analytical Sensitivity	0.11 g/L (11 mg/dL)	0.262 g/L (26mg/dL)
Wavelength	340/659 nm	340/659 nm
Analyzer	COBAS Integra analyzers	COBAS Integra analyzers

Topic	Modified Tina-quant Complement C3c ver.2	Tina-quant Complement C3c (cleared K951595)
Measuring Range	0.11-6.0 g/L (11-600 mg/dL)	0.55-8-9 g/L (55-890 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: k012361
Trade/Device Name: Tina-Quant Complement C3c ver.2 Test System
Regulation Number: 21 CFR 866.5240
Regulation Name: Complement components immunological test system
Regulatory Class: Class II
Product Code: CZW
Dated: November 12, 2001
Received: November 14, 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): K012361
Device Name: **Tina-quant Complement C3c ver.2 Test System**

Indications for Use:
For the in vitro quantitative immunological determination of human complement C3cin serum and plasma. Measurements of these proteins aid in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan S. Altare

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K012361

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

(Optional Format 1-2-96)