MAY 1 8 2001

510(k) Summary

K010978

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.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis IN 46250
(317) 576-3544

Contact person: Kay A. Taylor

Date prepared: May14, 2001

2) Device Name

Proprietary name: Tina-quant Alpha-1-Antitrypsin

Common name: Alpha-1-Antitrypsin immunological test system

Classification name: Alpha-1-Antitrypsin, Antigen, Antiserum, Control

3) Predicate Device

Roche Diagnostics claims substantial equivalency to the currently marketed Roche/Hitachi Tina-quant Alpha-1-Antitrypsin reagent (K972640).

4) Device Description

The alpha-1-antitrypsin determination is based upon an immunoturbidimetric method using a serum or plasma sample. Human anti-1-antitrypsin forms a precipitate with a specific anti-serum that is determined turbidimetrically at 340 nm.

5) Intended Use

In vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human α1-antitrypsin in serum and plasma.

6) Substantial equivalence – similarities and differences

Similarities:

The Roche/Hitachi Tina-quant Alpha-1-Antitrypsin reagent is the same reagent that was previously cleared for use on the Roche/Hitachi family of analyzers utilizing the premarket notification process (K972640).

Differences:

This submission is being provided for the purpose of extending the application of the Tina-quant Alpha-1-Antitrypsin reagent to the COBAS Integra system (AAT2).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 8 2001

Ms. Kay A. Taylor
Regulatory Affairs, Laboratory Systems
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K010978
Trade Name: Roche Diagnostics Tina-quant® Alpha-1-Antitrypsin Reagent
Regulation Number: 21 CFR§ 866.5130
Regulatory Class: II
Product Code: DEM
Dated: March 12, 2001
Received: March 13, 2001

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

K010978

INDICATIONS FOR USE STATEMENT

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

Device Name: Tina-quant Alpha-1-Antitrypsin Reagent

Indications For Use:

In vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the quantitative immunological determination of human α1-antitrypsin in serum and plasma.

The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010978

(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)