K031902

SEP 17 2003

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.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: June 19, 2003

2) Device name

Proprietary name: ONLINE TDM Carbamazepine

Common name: Enzyme immunoassay, Carbamazepine

Classification name: Neuroleptic drugs radioreceptor assay test system

3) Predicate device

We claim substantial equivalence to the currently marketed COBAS INTEGRA Carbamazepine (K951595).

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4) Device Description

The ONLINE TDM Carbamazepine assay is for the quantitative determination of carbamazepine in human serum or plasma on automated clinical chemistry analyzers. In combination with other clinical information, monitoring carbamazepine levels provides physicians with an effective tool to aid in adjusting dosage and achieving optimal therapeutic effect while avoiding both sub-therapeutic and toxic drug levels. The proposed labeling indicates the Roche Hitachi 911, 912, 917 and Modular P analyzers can be used with the Roche ONLINE TDM Carbamazepine reagent kits.

The ONLINE TDM Carbamazepine assay is a homogeneous microparticle agglutination immunoassay. It is a two-reagent system used for the detection of carbamazepine in serum. Kinetic interaction of microparticles (KIMS) will be measured using Roche Diagnostics / Hitachi families of automated analyzers. In this technology biotinylated drug hapten serves as the binding partner to 1.) anti-carbamazepine antibody and 2.) streptavidin coated latex beads. A competitive reaction to a limited amount of specific anti-carbamazepine antibody takes place between the hapten and free carbamazepine in the serum sample. A decrease in the apparent signal is proportional to the amount of drug present in the sample.

5.) Intended Use

The ONLINE TDM Carbamazepine assay is for the quantitative determination of carbamazepine in human serum or plasma on automated clinical chemistry analyzers.

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6.) Comparison to the Predicate Device

The Roche ONLINE TDM Carbamazepine assay is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Roche COBAS INTEGRA Carbamazepine assay (K951595).

The Roche ONLINE TDM Carbamazepine assay was evaluated for several performance characteristics including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche ONLINE TDM Carbamazepine assay is substantially equivalent to the currently marketed Roche COBAS INTEGRA Carbamazepine assay. The following table summarizes the precision and method comparison results.

	Roche ONLINE TDM Carbamazepine			**Roche COBAS INTEGRA Carbamazepine (Predicate)**		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	2.8	8.3	14.1	3.8	8.6	14.7
SD (µg/ml)	0.05	0.13	0.21	0.08	0.17	0.31
CV%	1.7	1.5	1.5	2.2	1.9	2.1
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	2.8	8.3	14.1	3.8	8.6	14.7
SD (µg/ml)	0.15	0.36	0.55	0.12	0.24	0.52
CV%	5.6	4.3	3.9	3.0	2.8	3.6
Method Comparison	Linear Regression: ONLINE TDM Carbamazepine Vs. COBAS INTEGRA Carbamazepine (FPIA) method. N=103, Range = 0.5-11.93 µg/ml y=1.062x - 0.16 r=0.985			Linear Regression: COBAS INTEGRA Carbamazepine Vs. commercially available FPIA method. N=205, Range = 1.6-19.6 µg/ml y=1.061x - 0.124 r=0.995		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 2003

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road, P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k031902
Trade/Device Name: ONLINE TDM Carbamazepine Assay
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: KLT
Dated: June 19, 2003
Received: June 20, 2003

Dear Mr. Kaufman:

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): K031902

Device Name: Roche Diagnostics ONLINE TDM Carbamazepine

Indications for Use: The ONLINE TDM Carbamazepine assay is for the quantitative determination of carbamazepine in human serum or plasma on automated clinical chemistry analyzers. This neuroleptic drug assay test system is a device intended to measure in serum or plasma the dopamine receptor blocking activity of carbamazepine.

(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)

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031902