K032049

AUG 2 2 2003

Roche ONLINE Valproic Acid Assay

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) 845-2000

Contact Person: Mike Flis

Date Prepared: June 27, 2003

2) Device name

Roche ONLINE TDM Valproic Acid

3) Predicate device

We claim substantial equivalence to the Roche Valproic II Assay [K930734].

4) Device Description

The assay is a homogeneous immunoassay based on the principle of measuring changes in scattered light or absorbance which result when activated microparticles aggregate. The microparticles are coated with valproic acid and rapidly aggregate in the presence of a valproic acid antibody solution. When a sample containing valproic acid is introduced, the aggregation reaction is partially inhibited, slowing the rate of the aggregation process. Antibody bound to sample drug is no longer available to promote microparticle aggregation, and subsequent particle lattice formulation is inhibited. Thus, a classic inhibition curve with respect to valproic acid concentration is obtained, with the maximum rate of aggregation at the lowest valproic acid concentration. By monitoring the change in scattered light or absorbance, a concentration-dependent curve is obtained.

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510(k) Summary, Continued

5) Intended use

For the quantitative determination of valproic acid in human serum or plasma on automated clinical chemistry analyzers.

6) Comparison to predicate device

The Roche ONLINE TDM Valproic Acid 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 Valproic Acid Assay is substantially equivalent to the currently marketed Roche Valproic Acid II Assay. The following table presents the precision and method comparison results.

Roche ONLINE TDM Valproic Acid				**Roche Valproic Acid II, (Predicate)**		
Versus Roche Valproic Acid II Assay (predicate device) N = 75 Y = 0.969X+3.003 R = 0.992 Range = 11.3 to 144.2 µg/mL				Versus Abbott TDx Valproic Acid Assay N= 77 Y= 1.08X-0.61 R= 0.972 Range = 2.6 to 119.8 µg/mL		
NCCLS Precision:	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	34.8	74.1	118.9	20.6	65.2	118.5
CV% (within run)	0.8	0.6	0.6	2.3	1.5	1.3
CV% (total)	2.1	2.4	1.9	3.4	2.3	1.7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 2 2003

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250

Re: k032049
Trade/Device Name: Roche ONLINE TDM Valproic Acid Assay
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: LEG
Dated: June 27, 2003
Received: July 11, 2003

Dear Mr. Flis:

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,

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

Roche Diagnostics Corporation

510(k) Number (if known):
Device Name: Roche ONLINE TDM Valproic Acid Assay
Indications for Use:

The Roche ONLINE TDM Valproic Acid assay contains an in vitro diagnostic reagent system indicated for the quantitative determination of valproic acid in human serum or plasma on automated clinical chemistry analyzers. Valproic acid is primarily used in the treatment of petit mal seizures and other generalized and partial complex seizures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032049

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

(Optional Format 1-2-96)