APR 2 8 2003

K030428

Roche ONLINE Phenytoin 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: February 6, 2003

2) Device name

Roche ONLINE Phenytoin

3) Predicate device

We claim substantial equivalence to the Roche CEDIA Phenytoin II Assay [K963840].

4) Device Description

The Roche ONLINE Phenytoin assay contains an in vitro diagnostic reagent system indicated for the quantitative determination of phenytoin, an anti-convulsant drug, in human serum or plasma on automated clinical chemistry analyzers. Measurements obtained by the device are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to ensure appropriate therapy. The proposed labeling indicates the Roche/Hitachi 911, 912, 917, and Modular P analyzers can be used with the Roche ONLINE Phenytoin reagent kits.

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510(k) Summary, Continued

5) Intended use

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

6) Comparison to predicate device

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

Roche ONLINE Phenytoin				**Roche CEDIA Phenytoin II, (Predicate)**		
Versus Abbott TDx Phenytoin Assay N = 106 Y = 0.99X-0.865 R = 0.992 Range = 1.68 to 40.0 µg/mL				Versus Abbott TDx Phenytoin Assay N= 108 Y= 0.99X-1.43 R= 0.993 Range = 1.1 to 40.0 µg/mL		
NCCLS Precision:	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	6.49	13.39	22.87	6.3	14.8	26.8
CV% (within run)	2.7	1.4	1.5	3.2	2.0	1.3
CV% (total)	6.1	4.5	4.3	5.1	3.1	2.3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 8 2003

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k030428
Trade/Device Name: Roche ONLINE Phenytoin Assay
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenlhydantoin Test System
Regulatory Class: Class II
Product Code: DIP
Dated: February 6, 2003
Received: February 10, 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

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Roche Diagnostics Corporation

510(k) Number (if known): K030428
Device Name: Roche ONLINE Phenytoin Assay
Indications for Use:

The Roche ONLINE Phenytoin assay contains an in vitro diagnostic reagent system indicated for the quantitative determination of phenytoin, an anti-convulsant drug, in human serum or plasma on automated clinical chemistry analyzers. Measurements obtained by the device are used in the diagnosis and treatment of phenytoin overdose and in monitoring levels of phenytoin to ensure appropriate therapy.

(Division Sign-Off)
Division of Clinical Laboratory Dev
510(k) [illegible] K030428

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)