K071644

510(k) Summary

SEP 12 2007

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) 521-7688

Contact Person: Dimitris Demirtzoglou

2) Device name

Proprietary name: ONLINE TDM Phenobarbital

Common name: Enzyme Immunoassay, Phenobarbital

Classification name: Enzyme Immunoassay, Phenobarbital

3) Predicate device

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

4) Device Description

The ONLINE TDM Phenobarbital assay is for the quantitative determination of phenobarbital in human serum or plasma on Roche automated clinical chemistry analyzers. Measurements obtained by this device are used in the diagnosis and treatment of phenobarbital use or overdose and in monitoring levels of phenobarbital. The proposed labeling indicates the Roche Hitachi 912, 917 and Modular P analyzers can be used with the Roche ONLINE TDM Phenobarbital reagent kits.

Phenobarbital is one of the most commonly used drugs for the treatment of grand mal, psychomotor epilepsy, and other forms of focal epilepsy. Monitoring of the serum level of the drug is essential in order to achieve maximal seizure control while maintaining minimal blood levels to avoid negative side effects. As with other anti-convulsant drugs, it is imperative that each patient's dosage be individualized.

5.) Intended Use

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

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510(k) Summary, Continued

6.) Comparison to the Predicate Device

The Roche ONLINE TDM Phenobarbital 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 Phenobarbital (K951595).

The Roche ONLINE TDM Phenobarbital 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 Phenobarbital assay is substantially equivalent to the currently marketed Roche COBAS INTEGRA Phenobarbital assay. The following table summarizes the precision and method comparison results.

	Roche COBAS Integra Phenobarbital **(Predicate)**			**Roche ONLINE TDM** Phenobarbital		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	12.0	23.4	52.0	9.6	24.1	45.2
SD (µg/ml)	0.25	0.51	1.52	0.13	0.18	0.37
CV%	2.1	2.2	2.9	1.3	0.7	0.8
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	12.0	23.4	52.0	9.6	24.1	45.2
SD (µg/ml)	0.26	0.62	2.04	0.34	0.59	0.82
CV%	2.2	2.7	3.9	3.5	2.4	1.8
Method Comparison	Linear Regression: COBAS Integra Phenobarbital Vs. FPIA N=206, Range = 0.8 - 60 µg/ml y = 1.036x – 1.236 r = 0.995			Linear Regression: ONLINE TDM Phenobarbital Vs. COBAS FP Phenobarbital N=53, Range = 3.0 – 52.4 µg/ml y= 1.047x - 0.339 r=0.996		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Roche Diagnostics Corporation
c/o Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
9115 Hague Road
Indianapolis, IN 46250

SEP 12 2007

Re: k071644
Trade/Device Name: Online TDM Phenobarbital
Regulation Number: 21 CFR 862.3660
Regulation Name: Phenobarbital test system
Regulatory Class: Class II
Product Code: DLZ
Dated: June 14, 2007
Received: June 15, 2007

Dear Mr. Demirtzoglou:

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071644

Device Name: ONLINE TDM Phenobarbital

Indication For Use:

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

...vision Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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