K060738

AUG 16 2006

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) 521-7688

Contact Person: Dimitris Demirtzoglou

2) Device name

Proprietary name: ONLINE TDM N-acetylprocainamide

Common name: Enzyme Immunoassay, N-acetylprocainamide

Classification name: Enzyme Immunoassay, N-acetylprocainamide

3) Predicate device

We claim substantial equivalence to the currently marketed COBAS INTEGRA N-acetylprocainamide (K951595).

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510(k) Summary, Continued

4) Device Description

The ONLINE TDM N-acetylprocainamide assay is for the quantitative determination of N-acetylprocainamide in human serum or plasma on Roche automated clinical chemistry analyzers. The proposed labeling indicates the Roche Hitachi 911, 912, 917 and Modular P analyzers can be used with the Roche ONLINE TDM N-acetylprocainamide reagent kits.

The assay is based on a homogeneous enzyme immunoassay technique used for the quantitative analysis of N-acetylprocainamide in human serum or plasma.6,7 The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the sample can be measured in terms of enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically. Endogenous serum G6PDH does not interfere because the coenzyme functions only with the bacterial (Leuconostoc mesenteroids) enzyme employed in the assay.

5.) Intended Use

The ONLINE TDM N-acetylprocainamide assay is for the quantitative determination of N-acetylprocainamide in human serum or plasma on Roche automated clinical chemistry analyzers.
N-acetylprocainamide measurements are used in monitoring levels of N-acetylprocainamide to ensure proper procainamide therapy.

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510(k) Summary, Continued

6.) Comparison to the Predicate Device

The Roche ONLINE TDM N-acetylprocainamide 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 N-acetylprocainamide (K951595).

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

	Roche ONLINE TDM N-acetylprocainamide			Roche COBAS FP N-acetylprocainamide **(Predicate)**		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	1.7	4.0	8.2	5.4	11.5	20.9
SD (µg/ml)	0.07	0.08	0.17	0.09	0.18	0.60
CV%	3.9	2.0	2.1	1.6	1.6	2.9
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	1.7	4.0	8.2	5.4	11.5	20.9
SD (µg/ml)	0.08	0.16	0.26	0.15	0.27	0.68
CV%	5.0	4.0	3.2	2.8	2.3	3.2
Method Comparison	Linear Regression: ONLINE TDM N-acetylprocainamide Vs. COBAS FP N-acetylprocainamide N=54, Range = 0.5 -16.3 µg/ml y = 1.03 x + 0.09 r = 0.995 SD (md 95) = 0.389			Linear Regression: COBAS FP N-acetylprocainamide Vs. COBAS FARA II N=153, Range = 0.5 - 29 µg/ml y=0.978x + 0.059 r=0.997		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2006

Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
Roche Diagnostics Operations, Inc.
9115 Hague Road
Indianapolis, IN 46250

Re: k060738
Trade/Device Name: ONLINE TDM N-acetylprocainamide
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: LAN
Dated: July 20, 2006
Received: July 24, 2006

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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060738

Device Name: ONLINE TDM N-acetylprocainamide

Indications For Use:

The ONLINE TDM N-acetylprocainamide assay is for the quantitative determination of N-acetylprocainamide in human serum or plasma on Roche automated clinical chemistry analyzers. Measurements obtained from this device are used in the diagnosis and treatement of N-acetylprocainamide overdose and in monitoring the levels of N-acetylprocainamide to help ensure appropriate therapy.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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