K060586

MAY 11 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

Date Prepared: February 28, 2006

2) Device name

Proprietary name: ONLINE TDM Vancomycin

Common name: Enzyme Immunoassay, Vancomycin

Classification name: RADIOIMMUNOASSAY, VANCOMYCIN

3) Predicate device

We claim substantial equivalence to the currently marketed COBAS INTEGRA Vancomycin (K954992).

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510(k) Summary, Continued

4) Device Description

The ONLINE TDM Vancomycin assay is for the quantitative determination of vancomycin 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 Vancomycin reagent kits.

The assay is based on a homogeneous enzyme immunoassay technique used for the quantitative analysis of vancomycin in human serum or plasma.8 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 Vancomycin assay is for the quantitative determination of vancomycin in human serum or plasma on Roche automated clinical chemistry analyzers.

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6.) Comparison to the Predicate Device

The Roche ONLINE TDM Vancomycin 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 Vancomycin assay (K954992).

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

	Roche ONLINE TDM Vancomycin			**Roche COBAS INTEGRA** Vancomycin **(Predicate)**		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	6.8	21.0	39.1	3.8	8.6	14.7
SD (µg/ml)	0.34	0.29	0.45	0.08	0.17	0.31
CV%	4.9	1.4	1.1	2.2	1.9	2.1
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	6.8	21.0	39.1	3.8	8.6	14.7
SD (µg/ml)	0.40	0.60	1.04	0.12	0.24	0.52
CV%	5.8	2.9	2.7	3.0	2.8	3.6
Method Comparison	Linear Regression: ONLINE TDM Carbamazepine Vs. COBAS INTEGRA Carbamazepine (FPIA) method. N=55, Range = 5.0-67.2 µg/ml y=1.038x - 0.094 r=0.991			Linear Regression: COBAS INTEGRA Carbamazepine (FPIA) Vs. COBAS FARA II N=193, Range = 1.41-68.1 µg/ml y=0.958x - 0.386 r=0.995		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
Roche Diagnostic Corp.
9115 Hague Rd.
Indianapolis, IN 46250

MAY 11 2006

Re: k060586
Trade/Device Name: ONLINE TDM Vancomycin
Regulation Number: 21 CFR§862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: March 6, 2006
Received: March 7, 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): K060586

Device Name: ONLINE TDM Vancomycin

Indications For Use:

The ONLINE TDM Vancomycin assay is for the quantitative determination of vancomycin in human serum or plasma on Roche automated clinical chemistry analyzers. Measurements obtained by this device are used in the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to 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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