OCT 1 0 2003

K032279

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) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: July 23, 2003

2) Device name

Proprietary name: ONLINE TDM Amikacin

Common name: Amikacin test system

Classification name: Amikacin serum assay

3) Predicate device

We claim substantial equivalence to the currently marketed COBAS INTEGRA Amikacin (K991597).

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4) Device Description

The ONLINE TDM Amikacin assay is for the quantitative determination of amikacin in human serum or plasma on automated clinical chemistry analyzers. Determination of serum or plasma drug levels is required to achieve optimum therapeutic efficacy and minimize toxicity. The proposed labeling indicates the Roche Hitachi 911, 912, 917 and Modular P analyzers can be used with the Roche ONLINE TDM Amikacin reagent kits.

The ONLINE TDM Amikacin 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 amikacin and rapidly aggregate in the presence of an amikacin antibody solution. When a sample containing amikacin 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 formation is inhibited. Thus, a classic inhibition curve with respect to amikacin concentration is obtained, with the maximum rate of aggregation at the lowest amikacin concentration. By monitoring the change in scattered light or absorbance, a concentration-dependent curve is obtained.

5.) Intended Use

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

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6.) Comparison to the Predicate Device

The Roche ONLINE TDM Amikacin 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 Amikacin assay (K991597).

The Roche ONLINE TDM Amikacin 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. A summary of the evaluation studies is provided in Section IV of this submission. These experiments provide evidence that the Roche ONLINE TDM Amikacin assay is substantially equivalent to the currently marketed Roche COBAS INTEGRA Amikacin assay. The following table summarizes the precision and method comparison results.

	Roche ONLINE TDM Amikacin			**Roche COBAS INTEGRA Amikacin (Predicate)**		
NCCLS Precision, Within run	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	5.43	16.88	33.27	5.3	14.3	27.3
SD (µg/ml)	0.10	0.23	0.47	0.29	0.25	0.58
CV%	1.7	1.4	1.4	5.4	1.8	2.1
NCCLS Precision, Total	Control 1	Control 2	Control 3	Control 1	Control 2	Control 3
Mean (µg/ml)	5.43	16.88	33.27	5.3	14.3	27.3
SD (µg/ml)	0.15	0.37	0.68	0.37	0.36	0.78
CV%	2.8	2.2	2.0	7.0	2.5	2.9
Method Comparison	Linear Regression: ONLINE TDM Amikacin Vs. COBAS INTEGRA Amikacin (FPIA) method. N=89, Range = 0.4 - 39.9 µg/ml y=0.869x + 0.159 r=0.976			Linear Regression: COBAS INTEGRA 700 Amikacin Vs. Abbott TDx (FPIA) method. N=120, Range = 0.30 - 41.8 µg/ml y=0.914x + 0.511 r=0.987		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2003

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k032279
Trade/Device Name: Roche Diagnostics ONLINE TDM Amikacin
Regulation Number: 21 CFR 862.3035
Regulation Name: Amikacin test system
Regulatory Class: Class II
Product Code: KLP
Dated: July 23, 2003
Received: July 24, 2003

Dear Mr. Kaufman:

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

Indications for Use Statement

510(k) Number (if known): K032279

Device Name: Roche Diagnostics ONLINE TDM Amikacin

Indications for Use: The ONLINE TDM Amikacin assay is for the quantitative determination of amikacin in human serum or plasma on automated clinical chemistry analyzers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032279