

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) 845-3362

Contact person: Lisa M. Gerard

Date prepared May 7, 1999

2) Device name **Proprietary name:** COBAS INTEGRA Amikacin MAB
Common name: Enzymatic assay for the determination of Amikacin
Classification name: Amikacin test system

3) Predicate device We claim substantial equivalence to the Roche COBAS INTEGRA Amikacin (K954992).

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510(k) Summary, Continued

4) Device description

The Roche COBAS INTEGRA Amikacin MAB assay contains an in vitro diagnostic reagent system intended for use on the COBAS INTEGRA 700 analyzer for the quantitative determination of amikacin in human serum or heparinized plasma.

The COBAS INTEGRA Amikacin MAB assay determinations are made on the COBAS INTEGRA 700 analyzer using the principle of fluorescence polarization. When a fluorescent molecule, or fluorophore, is irradiated with light of the proper wavelength (the excitation wavelength) some of the light is absorbed. Within a few nano-seconds the absorbed light is emitted, although at a longer wavelength (the emission wavelength). Whether or not the emitted light is polarized depends on the freedom of the fluorophore to rotate in solution. A small molecule, such as fluorescein, can rotate rapidly before light emission occurs, resulting in depolarization of the emitted light. In contrast, a fluorescent macromolecule, such as a fluorescein-labeled protein, will rotate much more slowly. Thus, in the time frame between excitation and emission, the macromolecule will have rotated only very slightly and the emitted light will be polarized.

Fluorescence polarization is a reproducible function of the drug concentration, and is suitable for the quantitative determination of drug concentrations in serum for the purpose of therapeutic drug monitoring.

Surface active agents are used to ensure dissociation of the drug from serum proteins and to prevent nonspecific binding of the tracer.

After completion of the assay, the COBAS INTEGRA 700 will calculate automatically the millipolarization units (mP) of the tracer. After mP values have been calculated for the 6 calibrators, the system calculates a best-fit curve for the calibrators using a nonlinear least squares regression analysis. The concentration of drug in each sample is then interpolated from this curve using its measured mP value.

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510(k) Summary, Continued

5) Intended use The cassette COBAS INTEGRA Amikacin MAB contains and in vitro diagnostic reagent system intended for use on the COBAS INTEGRA 700 analyzer for the quantitative determination of amikacin in human serum or heparinized plasma.

6) Comparison to the predicate device The Roche COBAS INTEGRA Amikacin MAB (AMIKM) 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 (AMIK)(K954992).

The Roche COBAS INTEGRA Amikacin MAB assay contains an in vitro diagnostic reagent system intended for use on the COBAS INTEGRA 700 analyzer for the quantitative determination of amikacin in human serum or heparinized plasma.

Modifications of the Roche COBAS INTEGRA Amikacin MAB assay include:

- changing rabbit polyclonal antibody with mouse monoclonal antibody and
- changing the assay parameters.

The modification has resulted in improved:

- analytical sensitivity and
 - specificity.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 22 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lisa M. Gerard
Regulatory Affairs Consultant
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K991597
Trade Name: Roche COBAS INTEGRA Amikacin
Regulatory Class: II
Product Code: LGJ
Dated: May 7, 1999
Received: May 10, 1999

Dear Ms. Gerard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

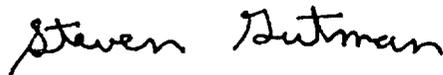
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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 I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number
(if known):

K 991597

Device Name: COBAS INTEGRA Amikacin MAB

Indications for
Use:

The cassette COBAS INTEGRA Amikacin MAB contains and in vitro diagnostic reagent system intended for use on the COBAS INTEGRA analyzer for the quantitative determination of amikacin in human serum or heparinized plasma.

(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)

Jean Coogan

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K991597