JUN 2 2 1999

K991440

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 April 23, 1999

2) Device name

Proprietary name: Roche COBAS INTEGRA Serum Barbiturates

Common name: Homogeneous fluorescence immunoassay for the determination of barbiturates in plasma, serum and urine

Classification name: Enzyme Immunoassay, Barbiturates test system

3) Predicate device

We claim substantial equivalence to the Roche COBAS INTEGRA Serum Barbiturates (K982551).

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4) Device description

The COBAS INTEGRA Serum Barbiturates assay is an in vitro diagnostic reagent for use on the COBAS INTEGRA systems for the detection of barbiturates and their metabolites in plasma, serum or urine. This reagent system is intended for use in toxicological screenings where the analytical result is used in the management of barbiturate use or overdose.

The COBAS INTEGRA Serum Barbiturates assay is based on fluorescence polarization (FP) methodology. Fluorescence polarization measures the change in angle of polarized light emitted by a fluorescent molecule. This change in polarization is dependent on molecule rotation, which is dependent on molecule size. FP utilizes a homogeneous competitive binding immunoassay with particle-bound fluorescein-labeled drug derivative to detect barbiturates and their metabolites in unknown samples.

In the absence of sample drug, free antibody (R1) binds to fluorescein-labeled drug derivative (R3), causing the fluorescein-labeled drug derivative to rotate slowly. The large complex rotates more slowly than the free fluorescein-labeled drug derivative in solution, thereby causing the light emitted to remain highly polarized.

When a urine sample contains the drug in question, this drug competes with the fluorescein-labeled drug derivative for antibody. The small fluorescein-labeled drug derivative molecules will rotate rapidly in solution and the emitted light will be depolarized. The large molecules (antibody bound to fluorescein labeled drug) will rotate slowly and the light emitted will remain highly polarized.

Large molecules = slow rotation = polarized light retained = high polarization
Small molecules = rapid rotation = depolarized light = low polarization

Unknown sample drug content is determined relative to the value obtained from samples of known drug content, which have been used to establish a standard curve. The presence of drug decreases polarization in proportion to the concentration of drug in the sample.

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510(k) Summary, Continued

5) Intended use	The cassette COBAS INTEGA Serum Barbiturates contains an in vitro diagnostic reagent intended for use on the COBAS INTEGRA analyzer for the detection of barbiturates and their metabolites in human serum, heparinized plasma or urine.
6) Comparison to the predicate device, similarities	The Roche COBAS INTEGRA Serum Barbiturates and the predicate device use the same reagents, on the same analyzer. The Roche COBAS INTEGRA Serum Barbiturates assay has been modified to include parameters for urine samples. The assay performance characteristics for urine and serum samples are extremely similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 2 1999

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

Re: K991440
Trade Name: Roche COBAS INTEGRA Serum Barbiturates (SBARB)
Regulatory Class: II
Product Code: DIS
Dated: April 23, 1999
Received: April 26, 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.

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 Gutman

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): K991440

Device Name: Roche COBAS INTEGRA Serum Barbiturates

Indications for Use: The cassette COBAS Integra Serum Barbiturates contains and in vitro diagnostic reagent system intended for use on the COBAS INTEGRA analyzer for the detection of barbiturates and their metabolites in human serum, heparinized plasma or urine. This reagent system is intended for use in toxicological screenings where the analytical result is used in the management of barbiturate use or overdose.

(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)

Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K991440