FEB 2 8 2001

K003865

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

Contact person: Jennifer Tribbett

Date prepared: February 14, 2001

2) Device name

Proprietary name: Cobas Integra Amphetamines

Common name: Amphetamines test system

Classification name: Enzyme immunoassay, amphetamines

3) Predicate device

We claim substantial equivalence to the currently marketed Abuscreen OnLine Amphetamines assay (K933052).

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4) Device description

The Cobas Integra Amphetamines is an in vitro diagnostic test for the semi-quantitative and qualitative detection of amphetamines, methamphetamines and their metabolites in human urine at a cutoff concentration of 500 ng/mL.

Principle of procedure

Cobas Integra Amphetamine assay is based on the kinetic interaction of microparticles in a solution (KIMS) as measured by changes in light transmission. In the absence of sample drug, free antibody binds to drug-microparticle conjugates, causing the formation of particle aggregates. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases.

When a urine sample contains the drug in question, this drug competes with the particle-bound drug derivative for free antibody. Antibody bound to sample drug is no longer available to promote particle aggregation, and subsequent particle lattice formation is inhibited. As the aggregation reaction proceeds in the absence of sample drug, the absorbance increases. Conversely, the presence of sample drug diminishes the increasing absorbance in proportion to the concentration of drug in the sample. Sample drug content is determined relative to the value obtained for a known cutoff concentration of drug.

5) Intended use

The Cobas Integra Amphetamines is an in vitro diagnostic test for the semi-quantitative and qualitative detection of amphetamines, methamphetamines and their metabolites in human urine at a cutoff concentration of 500 ng/mL.

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6) Comparison to the predicate device

The Roche Cobas Integra Amphetamines 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 Abuscreen OnLine Amphetamines (K933052).

The Cobas Integra Amphetamine assay contains an in vitro diagnostic reagent system intended for use on the Integra 400, 700 and 800 analyzers for the semi-quantitative and qualitative detection of amphetamines, methamphetamines and their metabolites in human urine at a cutoff concentration of 500 ng/mL.

The Cobas Integra Amphetamine assay contains the same raw components as the currently marketed Abuscreen OnLine Amphetamines assay (K933052) at the same 500 ng/mL cutoff concentration. Differences between this application and the cleared assay include:

- Application on the Cobas Integra Analyzers
- Increased sensitivity to methamphetamines, "designer drugs" such as MDMA, and their metabolites, and
- 500 ng/mL cutoff concentration only, no 1000 ng/mL cutoff

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 2 8 2001

Ms. Jennifer Tribbett
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, Indiana 46250-0457

Re: K003865
Trade Name: Roche Cobas® Integra Amphetamines
Regulatory Class: II
Product Code: DKZ
Dated: February 14, 2001
Received: February 15, 2001

Dear Ms. Tribbett:

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.

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" (21CFR 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): K003865

Device Name: Cobas Integra Amphetamines

Indications for Use: COBAS INTEGRA Amphetamines (AMPS) is an in vitro diagnostic test for the semi-quantitative and qualitative detection of amphetamines, methamphetamines and their metabolites in human urine at a cutoff concentration of 500 ng/mL.

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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 [illegible]ff)
Division [illegible] Laboratory Devices
510(k) N[illegible] K003865