K023296

NOV 25 2002

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: October 1, 2002

2) Device name

Proprietary name: COBAS INTEGRA ONLINE DAT II Cocaine II

Common name: Cocaine and cocaine metabolite test system

Classification name: Enzyme immunoassay, cocaine and cocaine metabolites

3) Predicate device

We claim substantial equivalence to the currently marketed Roche COBAS INTEGRA Cocaine Metabolite assay (K951595).

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4) Device Description

The cassette COBAS INTEGRA Cocaine II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semiquantitative and qualitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine at cutoff concentrations of 150 ng/ml and 300 ng/ml. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

Principal of procedure

The COBAS INTEGRA ONLINE DAT II Cocaine II 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, soluble drug-polymer conjugates bind to antibody-bound microparticles, causing the formation of particle aggregates.

When a urine sample containing the drug in question is present, this drug competes with the conjugate-bound drug derivative for microparticle-bound 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.

Negative Sample

drug-polymer conjugate + antibody-bound microparticle = particle aggregates
(↑ absorbance)

Positive Sample

sample drug + antibody-bound microparticle = particle aggregation inhibited
drug-polymer conjugate + antibody bound microparticle = particle aggregates

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5.) Intended Use

The cassette COBAS INTEGRA Cocaine II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semiquantitative and qualitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine at cutoff concentrations of 150 ng/ml and 300 ng/ml. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

6.) Comparison to the Predicate Device

The Roche COBAS INTEGRA ONLINE DAT II Cocaine II 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 Cocaine Metabolite (K951595).

The Roche COBAS INTEGRA ONLINE DAT II Cocaine II assay utilizes a modified KIMS technology relative to the currently marketed Roche COBAS INTEGRA Cocaine Metabolite assay. Differences between this application and the cleared assay include:

- use of a benzoylecgonine monoclonal antibody (mouse) attached to microparticles in solution,
- a soluble drug-polymer conjugate,
- addition of a cutoff concentration of 150 ng/ml, and
- use of new calibrators and unassayed controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 5 2002

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

Re: k023296
Trade/Device Name: Roche Diagnostics ONLINE DAT II Cocaine II
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: October 1, 2002
Received: October 2, 2002

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). Other general information on your responsibilities under the Act may be obtained 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): K023296

Device Name: Roche Diagnostics ONLINE DAT II Cocaine II

Indications for Use: The cassette COBAS INTEGRA Cocaine II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semiquantitative and qualitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine at cutoff concentrations of 150 ng/ml and 300 ng/ml. Semiquantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

(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)
Division of Clinical Laboratory Devices
510(k) Number K023296