K992890

NOV 23 1999

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 August 26, 1999

2) Device name

Proprietary name: Roche COBAS INTEGRA Opiates

Common name: Opiates test system

Classification name: Enzymatic Immunoassay, Opiate

3) Predicate device

We claim substantial equivalence to the currently marketed Roche Abuscreen OnLine II for Opiates (K974840).

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510(k) Summary, Continued

4) Device description

The cassette COBAS INTEGRA Opiates contains an in vitro diagnostic reagent test system intended for use on the COBAS INTEGRA 700 for the semiquantitative and qualitative detection of morphine and its metabolites at cutoff concentrations of 300 and 2000 ng/mL in human urine.

The cassette COBAS INTEGRA Opiates is based on the kinetic interaction of microparticles in a solutions (KIMS) as a measured by changes in light transmission.

In the absence of sample drug, soluble drug-polymer conjugate binds to antibody bound microparticle, causing the formation of particle aggregates.

When a urine sample containing the dug in question is present, this drug competes with the drug conjugate 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 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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510(k) Summary, Continued

5) Intended use

The cassette COBAS INTEGRA Opiates contains an in vitro diagnostic reagent test system intended for use on the COBAS INTEGRA 700 for the semiquantitative and qualitative detection of morphine and its metabolites at cutoff concentrations of 300 and 2000 ng/mL in human urine.

6) Comparison to the predicate device, similarities

The Roche COBAS INTEGRA Opiates 300/2000 and the predicate device use the same reagents, and have similar performance characteristics. Modifications to the Roche COBAS INTEGRA Opiates 300/2000 include the addition of:

- a 300 ng/mL semiquantitative cutoff and
- an application for the Integra family of analyzers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 23 1999

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

Re: K992890
Trade Name: COBAS INTEGRA Opiates 300/2000
Regulatory Class: II
Product Code: DJG
Dated: November 8, 1999
Received: November 9, 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): K992890

Device Name: Roche COBAS INTEGRA Opiates

Indications for Use: The cassette COBAS INTEGRA Opiates contains an in vitro diagnostic reagent test system intended for use on the COBAS INTEGRA 700 for the semiquantitative and qualitative detection of morphine and its metabolites at cutoff concentrations of 300 and 2000 ng/mL in human urine.

(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 Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992890