

JUL 16 2002

K021512

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 46250-0457
(317) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: May 8, 2002

2) Device name Proprietary name: COBAS INTEGRA ONLINE DAT II Methadone II

Common name: Methadone Test System

Classification name: Enzyme immunoassay, methadone

3) Predicate device We claim substantial equivalence to the currently marketed Roche COBAS INTEGRA Methadone assay (K951595).

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510(k) Summary, Continued

**4) Device
Description**

The cassette COBAS INTEGRA Methadone II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semi-quantitative and qualitative detection of methadone in human urine at a cutoff concentration of 300 ng/ml.

Principal of procedure

The COBAS INTEGRA ONLINE DAT II Methadone 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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510(k) Summary, Continued

5.) Intended Use

The cassette COBAS INTEGRA Methadone II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semi-quantitative and qualitative detection of methadone in human urine at a cutoff of 300 ng/ml.

6.) Comparison to the Predicate Device

The Roche COBAS INTEGRA ONLINE DAT II Methadone 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 Methadone (K951595).

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

- use of a methadone monoclonal antibody attached to microparticles in solution,
 - a soluble drug-polymer conjugate, and
 - use of new calibrators and unassayed controls.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 16 2002

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

Re: k021512
Trade/Device Name: Roche Diagnostics COBAS INTEGRA DAT II Methadone II
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: May 8, 2002
Received: May 9, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 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):

K021512

Device Name:

Roche Diagnostics COBAS INTEGRA ONLINE DAT II Methadone II

Indications
for Use:

The cassette COBAS INTEGRA Methadone II contains an in vitro diagnostic reagent system intended for use on COBAS INTEGRA systems for the semiquantitative and qualitative detection of methadone in human urine at a cutoff concentration of 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
(Per 21 CFR 801.109)

(Optional format 1-2-96)

OR Over-the-Counter Use

Jean Coogan
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K021512