K043303

MAR 1 1 2005

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
9115 Hague Rd.
Indianapolis, IN 46250
(317) 521-7637

Contact Person: Kerwin Kaufman

Date Prepared: November 29, 2004

2) Device name

Proprietary name: ONLINE DAT Propoxyphene Plus

Common name: Propoxyphene test system

Classification name: Enzyme immunoassay, Propoxyphene

3) Predicate device

We claim substantial equivalence to the currently marketed Abuscreen OnLine Propoxyphene assay (K983700).

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4) Device Description

The Roche ONLINE DAT Propoxyphene Plus assay is an in vitro diagnostic test for the qualitative and semi-quantitative detection of propoxyphene and its metabolites in human urine on automated clinical chemistry analyzers at a cutoff of 300 ng/ml. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program.

Principal of procedure

The ONLINE DAT Propoxyphene Plus assay is based on the kinetic interaction of microparticles in a solution (KIMS technology). Assay measurement is based on measurable changes in light transmission related to the interaction of microparticles in a solution and the sample drug of interest, if present. Propoxyphene drug derivative is conjugated to microparticles in solution, and propoxyphene polyclonal antibody (goat) is solubilized in buffer. 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. 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-conjugated microparticles + free antibody = particle aggregates
(↑ absorbance)

Positive Sample

sample drug + drug-conjugated microparticle = particle aggregation inhibited
drug-conjugated microparticles + free antibody = particle aggregates

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5.) Intended Use

Propoxyphene Plus is an in vitro diagnostic test for the qualitative and semi-quantitative detection of propoxyphene and its metabolites in human urine on automated clinical chemistry analyzers at a cutoff of 300 ng/ml. Semi-quantitative 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 ONLINE DAT Propoxyphene Plus 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 Propoxyphene (K983700).

Both the new and predicate device assays are based on the kinetic interaction of microparticles in a solution (KIMS technology). Differences between this application and the predicate cleared assay include:

- a change in the accelerant / activator contained in the diluent solution used to make the antibody working solution (R1 reagent), and
- use of new (previously cleared) calibrators and unassayed controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 1 2005

Mr. Kerwin Kaufman
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k043303
Trade/Device Name: ONLINE DAT Propoxyphene Plus
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene test system
Regulatory Class: Class II
Product Code: JXN
Dated: February 15, 2005
Received: February 17, 2005

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 (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K043303**

Device Name: ONLINE DAT Propoxyphene Plus

Indications For Use:

Propoxyphene Plus is an in vitro diagnostic test for the qualitative and semi-quantitative detection of propoxyphene and its metabolites in human urine on Roche/Hitachi automated clinical chemistry analyzers at a cutoff of 300 ng/ml. Semi-quantitative test results may be obtained that permit laboratories to assess assay performance as part of a quality control program. Measurements obtained by this device are used in the diagnosis of propoxyphene use or abuse and do not measure a level of toxicity.

Propoxyphene Plus provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

K043303