MAY 3 0 2006

K060645

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) 521-7688

Contact Person: Dimitris Demirtzoglou

Date Prepared: March 9, 2006

2) Device name

Proprietary name: Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators

Common name: Calibrators, Drug Mixture

Classification name: Clinical Toxicology Calibrator

3) Predicate devices

We claim substantial equivalence to the currently marketed Roche calibrators:

Preciset DAT Plus I calibrators, cleared in 510(k) K031775 and
Preciset DAT Plus II and Cfas DAT Qualitative Plus cleared in 510(k) K033306.

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4) Device Description

Roche Preciset DAT Plus I calibrators contain a mixture of 10 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine and propoxyphene. The calibrator set contains up to six levels for each drug contained in bottles 1-6. Bottle 1 is negative (drug free) human urine, followed by bottles 2-6 containing increasing amounts of each drug in a multi-analyte mixture. Drug or drug metabolite and their respective levels included are as follows:

Amphetamines: 0, 250, 500, 1000, 3000, 5000 (ng/mL)
Barbiturates: 0, 100, 200, 400 (ng/mL) [no 5^{th} and 6^{th} level]
Benzodiazepines: 0, 150, 300, 600, 1000, 3000 (ng/mL)
Cannabinoids: 0, 20, 50, 100, 200, 300 (ng/mL)
Cocaine: 0, 75, 150, 300, 1000, 5000 (ng/mL)
Methadone: 0, 150, 300, 600, 2000 (ng/mL) [no 6^{th} level]
Methaqualone: 0, 150, 300, 600 (ng/mL) [no 5^{th} and 6^{th} level]
Opiates: 0, 600, 1000, 2000, 4000, 8000 (ng/mL)
PCP: 0, 12.5, 25.0, 50.0 (ng/mL) [no 5^{th} and 6^{th} level]
Propoxyphene: 0, 150, 300, 600 (ng/mL) [no 5^{th} and 6^{th} level]

Roche Preciset DAT Plus II calibrators contain a mixture of 4 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, benzodiazepines, cannabinoids, and opiates. The calibrator set contains up to six levels for each drug contained in bottles 1-6. Bottle 1 is negative (drug free) human urine, followed by bottles 2-6 containing increasing amounts of each drug in a multi-analyte mixture. Drug or drug metabolite and their respective levels included are as follows:

Amphetamines: 0, 150, 300, 600, 1000, 2000 (ng/mL)
Benzodiazepines: 0, 50, 100, 200, 400, 1000 (ng/mL)
Cannabinoids: 0, 10, 20, 40, 100 (ng/mL) [no 6^{th} level]
Opiates: 0, 150, 300, 600, 1000, 2000 (ng/mL)

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4) Device Description (continued)

Roche Cfas DAT Qualitative Plus calibrator contains a mixture of 10 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains a single level for each drug in a drug mixture. Drugs or drug metabolites and their respective levels included are as follows:

Amphetamines: 500 ng/ml
Barbiturates: 200 ng/ml
Benzodiazepines: 300 ng/ml
Cannabinoids: 50 ng/ml
Cocaine: 150 ng/ml
Methadone: 300 ng/ml
Methaqualone: 50 ng/ml
Opiates: 2000 ng/ml
Phencyclidine: 25 ng/ml
Propoxyphene: 300 ng/ml

5.) Intended Use

The Preciset DAT Plus I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

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6.) Comparison to the Predicate Device

The Roche Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus multianalyte calibrators are substantially equivalent to other products cleared for commercial distribution intended for similar use. Most notably, they are substantially equivalent to the currently marketed Roche Preciset DAT Plus I calibrators, cleared in 510(k) K031775 and Preciset DAT Plus II and Cfas DAT Qualitative Plus cleared in 510(k) K033306.

The Preciset DAT Plus I calibrators contain a mixture of 10 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservative. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine and propoxyphene. The calibrator set contains up to six levels for each drug.

The Preciset DAT Plus II calibrators contain a mixture of 4 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservative. Drugs included are amphetamines, benzodiazepines, cannabinoids, and opiates. The calibrator set contains up to six levels for each drug.

The Cfas DAT Qualitative Plus calibrators contain a mixture of 10 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservative. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator contains only a single level of each drug.

The predicate device, Preciset DAT Plus I calibrators contain a mixture of 9 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservatives and stabilizers. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids cocaine, methadone, opiates, phencyclidine, and propoxyphene. The calibrator set contains up to six levels for each drug.

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510(k) Summary, Continued

6.) Comparison to the Predicate Device (continued)

The predicate device, Preciset DAT Plus II calibrators contain a mixture of 2 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservative. Drugs included are benzodiazepines and opiates. The calibrator set contains up to six levels for each drug.

The predicate device, Cfas DAT Qualitative Plus calibrators contain a mixture of 7 different drugs, prepared by the quantitative addition of drug or drug metabolite to drug-free human urine with added preservative. Drugs included are barbiturates, benzodiazepines, cocaine, methadone, opiates, phencyclidine, and propoxyphene. The calibrator contains only a single level of each drug.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Dimitris Demirtzoglou
Regulatory Affairs Consultant
Roche Diagnostics Corp.
9115 Hague Road
Indianapolis, IN 46250-0457

MAY 30 2006

Re: k060645
Trade/Device Name: Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators
Regulation Number: 21 CFR§862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DKB
Dated: March 9, 2006
Received: March 10, 2006

Dear Mr. Demirtzoglou:

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,

Alberto Gutierrez, Ph.D.
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): K060645

Device Name: **Preciset DAT Plus I, Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators**

Indications For Use:

The Preciset DAT Plus I calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Preciset DAT Plus II calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

The Cfas DAT Qualitative Plus calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

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

510(k) K060645