K031775

510(k) Summary

AUG 0 6 2003

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: June 9, 2003

2) Device name

Proprietary name: Preciset DAT Plus I Calibrators

Common name: Calibrators, Drug Mixture

Classification name: Clinical Toxicology Calibrator

3) Predicate devices

We claim substantial equivalence to the currently marketed Roche calibrators:

Abuscreen OnLine Preciset DAT I Calibrators, cleared in 510(k) K951595 (formerly Abuscreen OnLine Calibration Pack).

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510(k) Summary, Continued

4) Device Description

Roche 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. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, 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 Drugs or drug metabolites and their respective levels included are as follows:

Amphetamines: 0, 250, 500, 1000, 3000, 5000 ng/ml
Barbiturates: 0, 100, 200, 400 ng/ml
Benzodiazepines: 0, 150, 300, 600 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
Opiates: 0, 600, 1000, 2000, 4000, 8000 ng/ml
Phencyclidine: 0, 12.5, 25.0, 50.0 ng/ml
Propoxyphene: 0, 150, 300, 600 ng/ml

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510(k) Summary, Continued

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.

6.) Comparison to the Predicate Device

The Roche Preciset DAT Plus I 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 Abuscreen OnLine Preciset DAT I multianalyte calibrators, manufactured for Roche Diagnostics and cleared in 510(k) submission K951595 by Roche Diagnostics.

The 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 preservative. Drugs included are amphetamines, barbiturates, benzodiazepines, cannabinoids, cocaine, methadone, opiates, phencyclidine, and propoxyphene. The calibrator set contains up to six levels for each drug.

The predicate device, Abuscreen OnLine Preciset DAT I calibrators also 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, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains four levels for each drug.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

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Re: k031775
Trade/Device Name: Roche Preciset DAT Plus I Calibrators
Regulation Number: 21 CFR § 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: II
Product Code: DKB
Dated: June 9, 2003
Received: June 10, 2003

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). 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/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

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Indications for Use Statement

510(k) Number (if known): K031775

Device Name: Roche Preciset DAT Plus I 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)

Division Sign-Off For: Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

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