K090939

Confidential

JUN 18 2009

510(k) Summary: C.f.a.s. DAT Qualitative Plus Clinical and Control Set DAT Clinical

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.

Submitter Name, Address, Contact

Roche Diagnostics
9115 Hague Rd.
Indianapolis, IN 46250
317-521-3742

Contact Person: Michelle Neff

Date Prepared: April 2, 2009

Proprietary and Established Names

Proprietary names:
C.f.a.s. DAT Qualitative Plus Clinical
Control Set DAT Clinical

Regulatory Information

C.f.a.s. DAT Qualitative Plus Clinical

Product Code	Classification	Regulation Section	Panel
DKB	Class II	862.3200	Toxicology (91)

Control Set DAT Clinical

Product Code	Classification	Regulation Section	Panel
DIF	Class I	862.3280	Toxicology (91)

Predicate Devices

C.f.a.s. DAT Qualitative Plus Clinical

We claim substantial equivalence to the currently marketed Roche calibrators :

- Preciset DAT Plus I Calibrators (K031775)
- Preciset DAT Plus II and Cfas DAT Qualitative Plus Calibrators (K033306)

Control Set DAT Clinical

We claim substantial equivalence to the currently marketed Roche controls :

- Control Set DAT I, Control Set DAT II, Control Set DAT III, (K080183)

Device Description

C.f.a.s. DAT Qualitative Plus Clinical calibrators contain a mixture of 10 different drugs, prepared by quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbituates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. The calibrator set contains a single level for each drug in a drug mixture. Drug concentrations are verified by gas chromatography/mass spectrometry (GC/MS). Drugs or drug metabolites and their respective levels included are as follows:

Amphetamines: 500 ng/mL
Barbituates: 200 ng/mL
Benzodiazepines: 100 ng/mL
Cannabinoids: 50 ng/mL
Cocaine: 300 ng/mL
Methadone: 300 ng/mL
Methaqualone: 300 ng/mL
Opiates: 300 ng/mL
Phencyclidine: 25 ng/mL
Propoxyphene: 300 ng/mL

Control Set DAT Clinical controls contain a mixture of 10 different drugs, prepared by quantitative addition of drug or drug metabolite to drug-free human urine. Drugs included are amphetamines, barbituates, benzodiazepines, cannabinoids, cocaine, methadone, methaqualone, opiates, phencyclidine, and propoxyphene. Drug concentrations are verified by gas chromatography/mass spectrometry (GC/MS). Target concentrations are established at ±25% of the assay cutoff.

Drug	Assay Cutoff (ng/mL)	Target Concentration (ng/mL)	
		PreciNeg	PreciPos
Amphetamines	500	375	625
Barbituates	200	150	250
Benzodiazepines	100	75	125
Cannabinoids	50	37.5	62.5
Cocaine	300	225	375
Methadone	300	225	375
Methaqualone	300	225	375
Opiates	300	225	375
Phencyclidine	25	18.8	31.3
Propoxyphene	300	225	375

Intended Use	The C.f.a.s. DAT Qualitative Plus Clinical calibrator is designed for the qualitative calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers. The Control Set DAT Clinical is for use as an assayed control in the Roche test system for qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.
Comparison to the Predicate Device	The recommended controls to be used with the proposed ONLINE Amphetamines II assay are the Control Set DAT I, Control Set DAT II, Control Set DAT III (K080183).

	New Device	Predicate Device		
Item	**C.f.a.s. DAT Qualitative Plus Clinical**	Preciset DAT Plus I Calibrators	Preciset DAT Plus II	Cfas DAT Qualitative Plus Calibrators
Intended Use	Same	Designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.	Designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.	Designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.
Analytes	Amphetamines Barbituates Benzodiazepines Cannabinoids Cocaine Methadone Methaqualone Opiates Phencyclidine Propoxyphene	Amphetamines Barbituates Benzodiazepines Cannabinoids Cocaine Methadone Opiates Phencyclidine Propoxyphene	Benzodiazepines Opiates	Barbituates Benzodiazepines Cocaine Methadone Opiates Phencyclidine Propoxyphene
Form	Same	Liquid	Liquid	Liquid
Traceability	Same	GC/MS	GC/MS	GC/MS
Matrix	Same	Human urine based	Human urine based	Human urine based
Number of Levels	1	Up to 6	Up to 6	1

	New Device	Predicate Device
Item	**Control Set DAT Clinical**	Control Set DAT I, Control Set DAT II, Control Set DAT III
Intended Use	Same	For use as an assayed control in the Roche test system for the qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.
Analytes	Same	Amphetamines (*d*-methamphetamine) Barbituates (secobarbital) Benzodiazepines (nordiazepam) Cannabinoids (Δ^9 THC-COOH) Cocaine (benzoylecgonine)

		Methadone (*dl*-methadone) Methaqualone (methaqualone) Opiates (*d*-morphine) PCP (phencyclidine) Propoxyphene (propoxyphene)
Form	Same	Liquid
Traceability	Same	GC/MS
Matrix	Same	Human urine based
Number of Levels	1	2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 18 2009

Roche Diagnostics
ATTN: Ms. Michelle L. Neff
9115 Hague Road
Indianapolis, IN 46250

Re: k090939
Trade/Device Name: Roche C.F.A.S. DAT Qualitative Plus
Clinical calibrator and Control Set DAT Clinical
Regulation Number: 21 CFR §862.3280
Regulation Name: Clinical toxicology control material.
Regulatory Class: Class II
Product Code: DKB, DIF
Dated: April 2, 2009
Received: April 3, 2009

Dear Ms. Neff:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090939

Device Name: C.f.a.s. DAT Qualitative Plus Clinical & Control Set DAT Clinical

Indication For Use:

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

The Control Set DAT Clinical is for use as an assayed control in the Roche test system for qualitative and semiquantitative determination of drugs of abuse in human urine on automated clinical chemistry analyzers.

Prescription Use ___x___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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