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UCP Home Drug Screening Test

10. 510(K) SUMMARY

SEP 04 2009

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The Assigned 510(k) number is k091588

Submitter:

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Date:

May 28, 2009

Contact Person:

Dr. Nancy Chen

Trade Name:

UCP Home™ Drug Screening Test Card
UCP Home™ Drug Screening Test Cup

Common Name:

Amphetamine Test System
Methamphetamine Test System
Cocaine Test System
Barbiturate Test System
Benzodiazepine Test System
Methamphetamine Test System (MDMA)
Opiates Test System
Methadone Test System
Opiates Test System (Oxycodone)
Phencyclidine Test (unclassified)
Cannabinoid Test System
Tricyclic Antidepressant Test System

Product Code:

DKZ, LAF, DIO, DIS, JXM, DJC, DMB, DJG, LCM, LDJ, LFG

Regulation Section:

CFR 21 § 862.3650
CFR 21 § 862.3100

UCP Home Drug Screening Test

CFR 21 § 862.3100
CFR 21 § 862.3250
CFR 21 § 862.3150
CFR 21 § 862.3610
CFR 21 § 862.3620
CFR 21 § 862.3250
CFR 21 § 862.3250
CFR 21 § 862.3100
CFR 21 § 862.3870
CFR 21 § 862.3910

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

UCP Rapid Drug Screening Tests
UCP Rapid Drug Screening Tricyclic Antidepressants Tests
UCP Multiple Drug Screen Test Cups

Product Description:

UCP Home Drug Screening Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiapines, Cocaines, Marijuana, Methamphetamine, MDMA, Opiates, Morphine, Oxycodone, Phencyclidine, Tricyclic Antidepressants and their metabolites at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Intended Use:

2. UCP Home™ Drug Screening Tests:

UCP Home™ Drug Screening Tests are rapid, qualitative, competitive binding immunoassays for qualitatively the detection of the following drugs and their metabolites in human urine at the following cut-off concentrations:

Marjuana:	50 ng/mL
Cocaine:	300 ng/mL
Amphetamine:	1000 ng/mL
Methamphetamine:	1000 ng/mL
Opiates:	2000 ng/mL

Morphine:	300 ng/mL
Phencyclidine:	25 ng/mL
Barbiturares:	300 ng/mL
Benzodiazepines:	300 ng/mL
Methadone:	300 ng/mL
Oxycodone:	100 ng/mL
MDMA:	500 ng/mL
Tricyclic Antidepressants:	1000 ng/mL

The tests are intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory test in the second step of the two-step process, is provided in the package labeling.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Oxycodone, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Oxycodone, Tricyclic Antidepressant in urine. The tests provide only preliminary test results, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

For Over-The-Counter (OTC) use
For In Vitro Diagnostics only

Comparison to Predicate Devices:

When compared to the predicates, UCP Home Drug Screening Tests provide the qualitative determination of the same drugs in the same matrix, and utilizes the same cutoff concentrations. Both tests are immunochromatographic, lateral flow assays for the qualitative detection of drugs with visual, qualitative end results. Both tests are intended to provide preliminary analytical test results. The predicates are intended for professional use only, whereas UCP Home Drug Screening Tests are intended for OTC consumers use.

Safety and Effectiveness Data:

Accuracy

UCP Home Drug Screening Test

A clinical comparison study for UCP Home Drug Screening Tests can be found in 510k submissions (k050540, k061457, k072062).

Consumer Studies

The consumer study for UCP Home Drug Screening Test Cards was conducted among 115 lay persons in three geographic regions: Texas, Pennsylvania and California. Fifty eight females and fifty seven males from ages between 18 and 75 years have participated the studies. Fifty eight participants had high school education or less, fifty seven participants had finished college courses. None of the participants had experiences using drug testing products before. A separately consumer study for UCP Home Drug Screening Test Cups was conducted among 110 lay persons in three geographic regions: Texas, Pennsylvania and California. Fifty five females and fifty five males from ages between 18 and 77 years participated the study. Fifty five participants had high school education or less, fifty five participants had finished college courses. None of the participants had experiences using drug testing products before. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). The urine samples with various drug concentrations were prepared by spiking pure drugs or drug metabolites into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS but TCA, TCA concentrations in the urine samples was confirmed by HPLC. The test results performed by the lay users showed 96.7% or above agreement rate with GC/MS results and indicate the lay users can perform UCP Home Drug Screening Test Card or Cup satisfactorily by following the test instruction. The post-study survey was conducted to determine if the lay users can understand the test instruction, the meaning of the test results and how to interpret the test results. Consumers were asked 9 questions including whether the test was easy to run, the results was easy to read, how to interpret the test results, importance of confirmatory test and some medicines and foods may affect the test results. Participant responses support that the lay users can understand how to run the test, interpret the test results, the importance of confirmatory test, and some issues concerning certain prescription medicines and foods may affect the test results.

Other Information about Performance Characteristics:

The performance characteristics of UCP Home Drug Screening Tests including the precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study can be found in 510k submissions (k050540, k061457, k072062)

Conclusion:

UCP Home Drug Screening Test

UCP Home Drug Screening Test Cards and UCP Home Drug Screening Test Cups are substantially equivalent to UCP Rapid Drug Screening Tests, UCP Rapid Drug Screening Tricyclic Antidepressants, UCP Multiple Drug Screen Test Cups.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 04 2009

UCP Biosciences Inc.
c/o Nancy Chen
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San Jose, CA 95112

Re: k091588
Trade Name: UCP Home Drug Screening Test Cards and UCP Home Drug Screening Test Cups
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Codes: DKZ, DIS, JXM, DIO, DJC, DMB, DJG, LCM, LDJ, LFG
Dated: August 13, 2009
Received: August 13, 2009

Dear Ms. Chen:

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).

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 (301) 796-5450. 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 (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Indications for Use

510(k) Number (if known): k091588

Device Name: UCP Home Drug Screening Test Cards and UCP Home Drug Screening Test Cups

Indications For Use:

The UCP Home Drug Screening Test Cards and UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection the following drugs and their metabolites in human urine:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Cocaine	Benzoylecgonine	300 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL
Methadone	Methadone	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
MDMA	MDMA	500 ng/mL
Morphine	Morphine	300 ng/mL
Opiate 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencylidine	25 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The tests contain two formats: 1) Test Card; 2) Test Cup. The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for over-the-counter (OTC) users as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided. The test is also intended for health care professional users.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Oxycodone, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Oxycodone, Tricyclic Antidepressant in urine. The tests only provide 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 for most drugs (HPLC is the preferred confirmatory method for Tri-cyclic Antidepressants). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

Prescription Ues X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Division Sign-Off
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) k091588