MAR - 6 2014

10. 510(K) SUMMARY

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 k132812

Submitter: UCP Biosciences, Inc
1445 Koll Circle, Ste 111
San Jose, CA 95014
Tel: 408-392-0064
Fax: 408-392-0163

Date: February 25, 2014

Contact Person: Dr. Nancy Chen

Trade Name: UCP Multi-Drug Test Key Cups

Common Name:
Amphetamine Test System
Methamphetamine Test System
Cocaine Test System
Barbiturate Test System
Benzodiazepine Test System
Buprenorphine Test System
Methamphetamine Test System (MDMA)
Opiates Test System
Methadone Test System
Opiates Test System (Oxycodone)
Unclassified Test System (Enzyme Immunoassay Phencyclidine)
Cannabinoid Test System
Propoxyphene Test System
Tricyclic Antidepressant Test System

Product Code: DKZ, DIO, DIS, JXM, DJC, DJR, DJG, LCM, LDJ, LFG, JXN

Regulation Section:

CFR 21 § 862.3100
CFR 21 § 862.3150
CFR 21 § 862.3170
CFR 21 § 862.3250
CFR 21 § 862.3610
CFR 21 § 862.3620

CFR 21 § 862.3650
CFR 21 § 862.3870
CFR 21 § 862.3910
CFR 21 § 862.3700
Unclassified, Enzyme immunoassay, Phencyclidine

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

UCP Home™ Drug Screening Test Cups (k130463)

Product Description:

UCP Multi-Drug Test Key Cups are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiapines, Buprenorphine, Cocaines, Marijuana, Methamphetamine, MDMA, Methadone, Opiates, Opiates 300, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Indications For Use:

UCP Multi-Drug Test Key Cups:

The UCP Multi-Drug Test Key Cups are rapid tests for preliminary detection of the following drugs in human urine:

Test	Calibrated to	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 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
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL

Phencyclidine	Phencyclidine	25 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The test configuration comes with a 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 with information concerning the presence or absence of the above stated drugs in a urine sample. The second step is to send preliminary positive samples for confirmation testing by GCMS.

The test is not intended to distinguish between prescription use or abuse of the following drugs: Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants .

There are no uniformly recognized cutoff concentration levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propxyphene, Tricyclic Antidepressant in urine.

Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated.

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

Comparison to Predicate Devices:

When compared to the predicates, UCP Multi-Drug Test Key Cups can qualitatively detect Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, MDMA, Morphine, Opaites 2000, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressant in human urine. Both devices utilize the same cutoff concentrations. Both devices 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. Both devices are intended for prescription use and for OTC consumers use. UCP Multi-Drug Test Key Cups are required a key to activate the tests, whereas the tests in the predicates can be automatically activated while urine specimen is applied into the test cup without requiring a key.

Safety and Effectiveness Data:

Accuracy Studies:

The study design and protocol in the comparison study of using a series of patient specimens is the same as that described in k072062, k091588, k110515, k122419, k130463, k131811. The performance of the candidate devices was compared to the

predicate devices in k130463 by using the clinical samples. Total 80 clinical urine samples per one drug test were included in the comparison study. The clinical samples were obtained from the reference laboratories, all clinical urine samples including drug negative urine samples and drug positive urine samples were tested by the reference method GC/MS, except TCA. The TCA positive urine samples were tested by HPLC method. For each drug test, at least 10% clinical samples contain drug concentrations between 50% below the cutoff level and the cutoff level, and at least 10 % clinical urine samples contain drug concentrations between the cutoff level and 50% above the cutoff level. The testing results have demonstrated that 100% agreements between the candidate device and the predicate device, over 97.5% agreement between the candidate devices and the reference method GC/MS in the comparison study by using clinical urine specimens

Consumer Studies

The study design and protocol in the consumer study of UCP Multi-Drug Test Key Cups is the same as that described in k091588, k110515, k122419, k130463, k131811 was conducted among 115 lay persons in three geographic regions. Fifty seven females and fifty eight males from ages between 18 and 77 years have participated the study. Fifty seven participants had high school education or less, fifty eight 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 97% or above agreement rate with GC/MS results and indicate the lay users can perform UCP Multi-Drug Tests 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 Multi-Drug Test Key Cups including the precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study have been also established. The results have demonstrated that UCP Multi-Drug Test Key Cups performs satisfactorily when used according to the package inserts.

Conclusion:

The performance data in this submission supports UCP Multi-Drug Test Key Cups are substantially equivalent to the predicate devices UCP Home™ Drug Screening Test Cups (k130463).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 6, 2014

UCP BIOSCIENCES, INC.
NANCY CHEN
1445 KOLL CIRCLE, STE. 111
SAN JOSE CA 95112

Re: K132812
Trade/Device Name: UCP Multi-Drug Test Key Cups
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DIO, DIS, JXM, DJC, DJR, DJG, LCM, LDJ, LFG, JXN
Dated: February 18, 2014
Received: February 19, 2014

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132812

Device Name
UCP Multi-Drug Test Key Cups

Indications for Use *(Describe)*
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Avis T. Danishefsky -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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