DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 21, 2015

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

Re: K151213
Trade/Device Name: UCP Drug Test Mini 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: July 22, 2015
Received: July 23, 2015

Dear Nancy 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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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)*
k151213

Device Name
UCP Drug Test Mini Cups

Indications for Use *(Describe)*
The UCP Drug Test Mini 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
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	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortiptyline	1000 ng/mL

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, 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 prescription use

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressant in urine. The tests provide only preliminary data, 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 results, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

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)*

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

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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 k151213

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

1. **Date the summary was prepare:** July 8, 2015

2. **Submitter's Name:** UCP Biosciences, Inc

3. **Submitter's Address:** 1445 Koll Circle, STE 111, San Jose, CA 95112

4. **Name of the Device:**

   Trade Name: UCP Drug Test Mini 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)
   Amphetamine Test System (Enzyme Immunoassay Phencyclidine)
   Cannabinoid Test System
   Propoxyphene Test System
   Tricyclic Antidepressant Test System

5. Classification

   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

6. Description of the Device:

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

7. Test Principle:

UCP Drug Test Mini Cups is competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of drugs and their metabolites at the designed cutoff levels in human urine.

8. Intended Use:

UCP Drug Test Mini Cups 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:

Test	**Calibrator**	**Cut-off**
Marijuana:	Delta-9-THC-COOH	50 ng/mL
Cocaine:	Benzoylecgonine	300 ng/mL
Amphetamine:	D-Amphetamine	1000 ng/mL
Methamphetamine:	D-Methamphetamine	1000 ng/mL
Opiates:	Morphine	2000 ng/mL
Morphine:	Morphine	300 ng/mL
Phencyclidine:	Phencyclidine	25 ng/mL
Barbiturates:	Secobarbital	300 ng/mL
Benzodiazepines:	Oxazepam	300 ng/mL

Buprenorphine	Buprenorphine	10 ng/mL
Methadone:	Methadone	300 ng/mL
Oxycodone:	Oxycodone	100 ng/mL
MDMA:	MDMA	500 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressants:	Nortriptyline	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 the consumers 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 test also is intended for prescription use.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene Tricyclic Antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. 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

9. Comparison to Predicate Devices:

When compared to the predicates, UCP Drug Test Mini Cups can qualitatively detect Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, MDMA, Morphine, Opaites 2000, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressant and their metabolites 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 health care professionals use and for OTC consumers use. Only modification was made in the modified device is the test cup has a smaller dimension.

10. Performance Characteristics:

The test strips of the candidate device are the same as those cleared with the predicate device. Drug cutoffs of the candidate devices are also identical to the predicate devices. Analytical performance was established in the predicate submission. In addition, verification studies were conducted in support of the modification – a smaller size test

cup, including the precision study, inter lots reproducibility study, sensitivity study, pH and specific gravity study, accuracy study and the lay users study. The results have demonstrated that UCP Drug Test Mini Cups performs satisfactorily when used according to the package inserts.

11. Conclusion:

Based on the test principle and acceptable performance characteristics, it is concluded that the candidate device is substantially equivalent to the predicate in k130463.