DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 3, 2016

UCP BIOSCIENCES, INC
NANCY CHEN
OFFICIAL CORRESPONDENT
1445 KOLL CIRCLE, SUITE 111
SAN JOSE CA 95112

Re: K152908
Trade/Device Name: UCP Compact Drug Test Cards, UCP Compact Drug Test 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: March 21, 2016
Received: March 23, 2016

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. 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)*
k152908

Device Name
UCP Compact Drug Test Cards, UCP Compact Drug Test Cups

Indications for Use *(Describe)*
UCP Compact Drug Tests Cards and UCP Compact Drug Tests 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
EDDP:	EDDP	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 configuration comes with single drug screening test or any combinations of multiple drug screening tests. 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 must 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 k152908

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

Date: February 15, 2016

Contact Person: Dr. Nancy Chen

Trade Name: UCP Compact™ DrugTest Cards,
UCP Compact™ Drug Test 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
Methadone Test System (EDDP)
Amphetamine 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

Panel: Toxicology (91)

Device Classification: II

Predicates:

UCP Compact™ Drug Test Cards/UCP Compact™ Drug Test Cups (k131811)
Advin Multi-Drug Screen Test Dip Card and Advin Multi-Drug Test Cup (k122809)

Product Description:

UCP Compact Drug Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiapines, Buprenorphine, Cocaines, EDDP (Methadone metabolite), 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.

Intended Use:

UCP Compact™ Drug Test Cards, UCP Compact™ Drug Test Cups:

UCP Compact™ Drug Tests Cards and UCP Compact™ Drug Tests 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
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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

EDDP:	EDDP	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 configuration comes with single drug screening test or any combinations of multiple drug screening tests. 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 must 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 Compact Drug Tests can qualitatively detect Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, EDDP (Methadone metabolite), 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. UCP Compact Drug Tests can detect up to 16 drugs including new drug EDDP, whereas the predicates can detect up to 15 drugs.

Safety and Effectiveness Data:

Accuracy Studies:

The accuracy study for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, Morphine, Phencyclidine, Barbiturates, Buprenorphine, Benzodiazepines, Methadone, Oxycodone, MDMA, Propoxyphene, Tricyclic Antidepressants drug tests in UCP Compact Drug Tests can be found in the following 510(k) submissions: k061457, k091588, K091612, k110515, k122419, k123863, k130463, k131811, k132812.

The accuracy study for UCP EDDP tests was conducted using 80 clinical urine specimens per each drug including approximately 10% of the specimens containing one type drug at concentrations between -50% cutoff to cutoff ranges, another 10% of the specimens containing one type drug at concentrations between cutoffs to +50% cutoff ranges. The study was compared the test results between UCP EDDP tests with the reference method GC/MS. UCP EDDP tests demonstrated performance of ≥ 98% accuracy when compared to the reference method GC/MS.

Consumer Studies

The study design and protocol in the consumer study of UCP Compact Drug Tests is the same as that described in k091588, K091612, k110515, k122419, k123863, k130463, k131811, k132812 and was conducted among 230 lay persons in three geographic regions. One hundred fifteen females and one hundred fifteen males from ages between 18 and 75 years have participated the study. One hundred fourteen participants had high school education or less, one hundred sixteen 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 Compact 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 Compact Drug Tests including the precision/reproducibility study, sensitivity study, specificity and cross reactivity study, interference study and stability study have been also established. The results have

demonstrated that UCP Compact Drug Tests performs satisfactorily when used according to the package inserts.

Conclusion:

The performance data in this submission supports UCP Compact™ Drug Test Cards and UCP Compact™ Drug Test Cups are substantially equivalent to the predicate devices UCP Compact™ Drug Test Cards and UCP Compact™ Drug Test Cups in k131811, and Advin Multi-Drug Screen Test Dip Card and Advin Multi-Drug Test Cup in k122809.