



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

July 19, 2013

UCP Biosciences, Inc  
C/O Nancy Chen  
1445 Koll Circle, Ste. 111  
SAN JOSE CA 95112

Re: K131811

Trade/Device Name: UCP Compact Drug Test Cards  
UPC 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: June 21, 2013

Received: June 24, 2013

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 Part 801); 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 regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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, Ph.D.**

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

### Indications for Use Form

510(k) Number (if known): k131811

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

Indications for Use:

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

<b>Test</b>	<b>Calibrator</b>	<b>Cut-off</b>
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 ng/mL
Cocaine	Benzoylcegonine	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 mg/mL
Tricyclic Antidepressants	Nortriptyline	1000 ng/mL

Prescription Use   x  

And/Or

Over the Counter Use   x  

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

**Katherine Serrano -S**

Division Sign-Off  
Office of In Vitro Devices and Radiologic Health

510(k) k131811

**Indications for Use Form**

510(k) Number (if known): k131811

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

Indications for Use:

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 health care professional users.

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.

Prescription Use

And/Or

Over the Counter Use

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

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

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