



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

UCP Biosciences, Inc.
c/o Dr. Nancy Chen
1445 Koll Circle, Suite 111
San Jose, CA 95112

SEP 20 2007

Re: k072062
Trade/Device Name: UCP Multiple Drug Screen Test Cups
Regulation Number: 21 CFR 862.3910
Regulation Name: Tricyclic Antidepressant Drugs Test System.
Regulatory Class: Class II
Product Code: LFG, JXN, DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM
Dated: August 23, 2007
Received: August 24, 2007

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.

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.

Director

Division of Chemistry and Toxicology

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k072062

Device Name: UCP Multiple Drug Screen Test Cups

Indication For Use:

The UCP Multiple Drug Screen Test Cups are rapid, qualitative, competitive binding immunoassays for the detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, MDMA, Morphine, Opiate 2000, Oxycodone, Phencyclidine, Tricyclic Antidepressants, Propoxyphene and their metabolites in human urine at the following cutoff levels:

<u>Test</u>	<u>Calibrator</u>	<u>Cut-off</u>
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 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
Opiate 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL

The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). The test configuration comes with any combination of multiple drug screen tests. 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 X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use ____
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K072062