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 k091612

FEB 2 4 2010

Submitter:

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San Jose, CA 95014
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Date:

May 28, 2009

Contact Person:

Dr. Nancy Chen

Trade Name:

UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests

Common Name:

Buprenorphine Test System
Amphetamine Test System
Methamphetamine Test System
Cocaine Test System

Product Code:

DJG, DKZ, LAF, DIO

Regulation Section:

CFR 21 § 862.3650
CFR 21 § 862.3100
CFR 21 § 862.3610
CFR 21 § 862.3250

Panel: Toxicology (91)

Device Classification: II

Substantially Equivalent Devices:

ACON BUP One Step Buprenorphine Test Strip
ACON BUP One Step Buprenorphine Test Device

ACON AMP-300 One Step Amphetamine Test Strip
ACON AMP-300 One Step Amphetamine Test Device

ACON mAMP-500 One Step Methamphetamine Test Strip
ACON mAMP-500 One Step Methamphetamine Test Device

ACON COC-150 One Step Cocaine Test Strip
ACON COC-150 One Step Cocaine Test Device

Product Description:

UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Buprenorphine, Amphetamine, Methamphetamine, Cocaine and their metabolites at the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Intended Use:

UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests are rapid, qualitative, competitive binding immunoassays and intended for qualitatively the detection of Buprenorphine, Amphetamine, Methamphetamine, Cocaine and their metabolites in human urine at the following cut-off concentrations:

Buprenorphine	10 ng/mL
Amphetamine	300 ng/mL
Methamphetamine	500 ng/mL
Cocaine	150 ng/mL

The tests provide only preliminary test results, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/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 drugs levels.

For professional use only
For In Vitro Diagnostics only

Comparison to Predicate Devices:

When compared to the predicates, UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests provide the qualitative determination of the same drugs in the same matrix, and utilizes the same cutoff concentrations. Both tests 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.

Safety and Effectiveness Data:

Accuracy

A clinical comparison study 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 at the point of care sites. The study was compared the test results between UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Test with GC/MS or LC/MS analysis and the predicate devices. UCP Drug Screening Buprenorphine, AMP 300, mAMP 500 and COC 150 Test demonstrated performance of $\geq$ 97% for all drugs when performance was compared to a legally marketed device and GC/MS or LC/MS.

Other Information about Performance Characteristics:

The performance characteristics of UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests were evaluated by precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study. The study results indicate that UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests performs satisfactorily when used according to the package inserts.

Conclusion:

UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests are substantially equivalent to ACON BUP One Step Buprenorphine Test, ACON AMP-300 One Step Amphtamine Test, ACON mAMP-500 One Step Methamphtamine Test, ACON COC-150 One Step Cocaine Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

FEB 24 2010

Re: k091612
Trade Name: UCP Rapid Drug Screening BUP, AMP 300, mAMP 500 and Cocaine 150 Tests
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Codes: DKZ, DJG, LAF, DIO
Dated: January 25, 2010
Received: January 27, 2010

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.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k091612

Device Name: UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests,

Indications For Use:

The UCP Drug Screening Buprenorphine, Amphetamine 300, Methamphetamine 500, Cocaine 150 Tests are rapid, qualitative, competitive binding immunoassays for the detection the following drug in human urine:

Test	Calibrator	Cut-off
Buprenorphine	Buprenorphine	10 ng/mL
Amphetamine	D-Amphetamine	300 ng/mL
Methamphetamine	D-Methamphetamine	500 ng/mL
Cocaine	Benzoylecgonine	150 ng/mL

The tests contain three formats: 1) Test Card/Strip; 2) Test Device, 3) Test Cup. The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for in vitro diagnostics use.

The tests only provide a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration 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 drug levels.

Prescription Ues x AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091612