510(k) SUMMARY

AUG 20 2009

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K082977

Submitter:

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FDA Establishment Registration Number: 3002752660

Date:

October 2, 2008

Contact Person:

Jane Zhang

Product Name:

Bionexia OptiCup

Common Name:

Single-drug lateral flow immunochromatographic test for the simultaneous and qualitative detection of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline in urine

Regulation Name:

Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline test systems

Product Code:

Marijuana	LDJ
Cocaine	DIO
Phencyclidine Hydrochloride	LCM
Morphine	DNK
Methamphetamine	DKZ
Methadone	DJR
Amphetamine	DJC
Barbiturates	DIS
Benzodiazepines	JXM
Nortriptyline	LFG

Classification Number:

Marijuana	21 CFR § 862.3870
Cocaine	21 CFR § 862.3250
Phencyclidine Hydrochloride	21 CFR § 862.3100
Morphine	21 CFR § 862.3640
Methamphetamine	21 CFR § 862.3610
Methadone	21 CFR § 862.3620
Amphetamine	21 CFR § 862.3100
Barbiturates	21 CFR § 862.3150
Benzodiazepines	21 CFR § 862.3170
Nortriptyline	21 CFR § 862.3910

Device Classification:

The Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline test systems have been classified as Class II devices with moderate complexity.

The Bionexia OptiCup is similar to other FDA-cleared devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline in human urine.

Intended Use:

The Bionexia OptiCup is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of elevated levels of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline in human urine at or above the following concentrations:

Marijuana	50 ng/mL
Cocaine	300 ng/mL
Phencyclidine	25 ng/mL
Morphine	2,000 ng/mL
Methamphetamine	1,000 ng/mL
Methadone	300 ng/mL
Amphetamine	1,000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepines	300 ng/mL
Nortriptyline	1,000 ng/mL

The Bionexia OptiCup is used to obtain visual qualitative test results and is intended for healthcare professionals only. It is not intended for over the counter sale to non-professionals.

Configurations of the Bionexia OptiCup can consist of any combination of the above listed drug analytes.

This device provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical test result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography Mass Spectrometry (LC/MS) is the preferred confirmatory method. Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Description:

Bionexia OptiCup is derived from a previously FDA-cleared device, ADT's ACCUSTEP Single and Multi-Strip Cassette/Dipstick DOA Screen Panels (K061005).

The unmodified test is made of various number of single drug-of-abuse (DOA) test strips (from 1 to 10 strips) placed in an open faced housing. These test strips are fixed in position with an adhesive label covering over the absorbent end of the test card with dipping end protruding. When running the test, the dipping end of the test panel is dipped into urine sample and test results read at 5 minutes.

The test strips used in Bionexia OptiCup are made in the exact same manner as the strips used in the cleared ACCUSTEP Single and Multi-Strip Dipstick DOA Screen Panels from one to ten single test strips placed in an open-faced housing inside a plastic cup. In Bionexia OptiCup, these test strips are assembled and fixed in position with an adhesive label covering over the absorbent end of the test card with dipping end protruding. The dipstick assembly is then sealed, (integrated) into a plastic urine cup, which also serves as a urine collection and specimen delivering device to run the test in one integrated device.

Bionexia OptiCup is a user-friendly modification of the unmodified device. To use an unmodified device, user has to collect urine sample in a container, tear open the dipstick device pouch, take off the device cover, dip the device into urine sample and hold it for 5-10 seconds, cover the dipstick device cover, lay device flat and wait for 5 minutes to read the preliminary qualitative test results. To use a modified device, user can open the cup pouch and take out the integrated OptiCup, simultaneously collect, dispense urine for dipping, run the test and obtain preliminary qualitative test results in 5 minutes. The leftover urine specimen in the cup, which is not adulterated or tampered with in any way, can be sent in to a toxicology lab for confirmation especially when a presumptive positive test result is obtained. This modified device allows user to administrate multiple drug test from urine specimen collection, testing, and result confirmation with one single device.

Bionexia OptiCup presents an ideal and convenient format for various testing environments such as hospitals, clinics, workplace pre-employment screening, justice system or court-ordered compliance monitoring and random drug testing. This integrated Cup is designed to accompany available line of drugs of abuse tests from ADT. Customers can choose any combination of the cleared drug of abuse tests and integrated into this cup.

The Bionexia OptiCup is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of elevated levels of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline in human urine at or above the following concentrations:

Marijuana	50 ng/mL
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Morphine	2,000 ng/mL
Methamphetamine	1,000 ng/mL
Methadone	300 ng/mL
Amphetamine	1,000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepines	300 ng/mL
Nortriptyline	1,000 ng/mL

These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing Marijuana,

Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Unmodified Applied DNA Technologies (ADT) Test Device:

The Bionexia OptiCup is derived from a previously FDA cleared device: K061005. This legally marketed but unmodified device and 510(k) number under which it was previously cleared is listed below in Table 1.

Table 1: Unmodified ADT device with K number and Product Codes

Previously Cleared ADT Drug of Abuse Test	510(k) Number	Product Code
ACCUSTEP Single and Multi-Strip DOA Cassette and Dipstick Screen Panels	K061005	LDJ, DIO, LCM, LFG, DKZ, DJR, DKZ, DIS, JXM, DJG

Modified ADT Test Device:

The Bionexia OptiCup is a modified form of a previously FDA-cleared device, K061005. The difference between the modified devices and the unmodified device is that the former has the test strips assembled in a cup format, while the unmodified device has test strips assembled in a dipstick format.

With a cup format, this device can provide many "user friendly" features for the urine-based drug tests. User will be able to collect urine sample, administrate drug test, obtain preliminary test result and send split unadulterated urine sample for confirmation, all with one single drug testing device, the Bionexia OptiCup.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

MK Bio, Inc.
c/o Ms. Jane Zhang
Director of QA/RA
10239 Flanders Court
San Diego, CA 92121

AUG 20 2009

Re: k082977
Trade Name: Bionexia OptiCup
Regulation Number: 21 CFR §862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Codes: DIO, DIS, DJC, DJR, DNK, DKZ, JXM, LCM, LDJ, LFG
Dated: July 16, 2009
Received: July 21, 2009

Dear Ms. Zhang:

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.
Acting 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: K082977

Device Name: Bionexia OptiCup

Indications for Use: The Bionexia OptiCup is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of elevated levels of Marijuana, Cocaine, Phencyclidine, Morphine, Methamphetamine, Methadone, Amphetamine, Barbiturates, Benzodiazepines and Nortriptyline in human urine at or above the following concentrations:

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Barbiturates	300 ng/mL
Benzodiazepines	300 ng/mL
Nortriptyline	1,000 ng/mL

The test strips with an integrated cup is intended for healthcare professionals only. It is not intended for over the counter sale to non-professionals.

(Please do not write below this point)

Concurrence of CDRH, Office of *In Vitro* Device Evaluation and Safety

Prescription Use X

(Per 21 CFR 801.109)

Over-the-counter Use Prescription Use _____

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K082977