K131110

Co-Innovation Biotech Co.,Ltd.

JAN 15 2014

Section 5 - 510(k) Summary

Date of Summary Preparation: 12/30/2013

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
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2. Correspondent's Identifications

Correspondent's Name: Co-Innovation Biotech Co.,Ltd.
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3. Name of the Device

Recommended classification regulation:

21 CFR 862.3100
21 CFR 862.3610
21 CFR 862.3250
21 CFR 862.3870
21 CFR 862.3640

Device class: Class II
Panel: Toxicology (91)
Product code: DKZ,DJC,DIO,LDJ,DKN
Common Name:

Amphetamine Test System
Methamphetamine Test System
Cocaine Test System
Cannabinoid Test System
Morphine Test System

Proprietary names:

One Step Single/Multi-drug Test Cup
One Step Single/Multi-drug Test Dipcard

4. The Predicate Devices

K091588 UCP Home™ Drug Screening Test Cards
UCP Home™ Drug Screening Test Cup

5. Device Description

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Cocaines, Marijuana, Methamphetamine,Morphine and their metabolites at or above the cut-off levels as indicated. The tests can be performed without the use of an instrument.

6. Intended Use of Device

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 2000 (MOP)	Morphine	2000 ng/mL

The tests contain two formats:1) Test Cup, 2) Test Dipcard, 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. They are intended for prescription use in clinical laboratories only and not for point-of-care use.

This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/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.

7. Comparison to Predicate Devices:

A summary comparison of features of the One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard and the predicate devices is provided in the following Table:

Item	Device	Predicate (K091588)
Indication for use	Qualitative detection of drugs-of-abuse in urine (Cocaine ,Morphine,Methamphetamine,Amphetamine,Marijuana)	Same (but the number of drugs detected different)
Intended Users	Prescription Use	Over the Counter (OTC) Use and Prescription Use
Specimen	Urine	Same
Cutoff	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Amphetamine:1000 ng/mL Morphine:2000 ng/mL Marijuana:50 ng/mL	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Amphetamine:1000 ng/mL Morphine:300 ng/mL Marijuana:50 ng/mL
Read time	5 minutes	Same
Storage	4 ~ 30 ℃	2 ~ 30 ℃
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Dipcard and Cup	Card and Cup

Remark:

1、 The subject devices have all features of the predicate device except the number of drugs detected, the cutoff of Morphine and storage temperature condition different. These differences do not affect the performance characteristics of the subject devices.

8. Performance Data:

Accuracy

Single drug Test:

165-186 clinical urine specimens for each drug were analyzed by GC/MS and by one lot of the corresponding One Step Single drug Test Cup. Samples were divided by concentration into five categories:drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	1	10	29	176
	-	117	7	11	1	0	
COC	+	0	0	1	9	31	186
	-	133	0	12	0	0	
THC	+	0	0	1	12	31	165
	-	107	4	9	1	0	

MET	+	0	0	1	17	44	165
	-	85	4	13	1	0	
MOP	+	0	0	2	19	57	165
	-	67	5	15	0	0	

Analysis of Discordant Results with One Step Single drug Test Cup

One Step Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylecgonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor-Δ9–THC-9-COOH
THC	50	Negative	59	11-nor-Δ9–THC-9-COOH

165-186 clinical urine specimens for each drug were analyzed by GC/MS and by one lot of the corresponding One Step Single drug Test Dipcard. Samples were divided by concentration into five categories: drug free,less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	1	10	29	176
	-	117	7	11	1	0	
COC	+	0	0	1	9	31	186
	-	133	0	12	0	0	
THC	+	0	0	1	12	31	165
	-	107	4	9	1	0	
MET	+	0	0	1	17	44	165
	-	85	4	13	1	0	
MOP	+	0	0	2	19	57	165
	-	67	5	15	0	0	

Analysis of Discordant Results with One Step Single drug Test Dipcard

One Step Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylecgonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor-Δ9–THC-9-COOH
THC	50	Negative	59	11-nor-Δ9–THC-9-COOH

Multi-drug Test:

80 clinical urine specimens for each drug were analyzed by GC/MS and by one lot of the corresponding One Step Multi-drug Test Cup. Samples were divided by concentration into five categories:drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Co-Innovation Biotech Co.,Ltd.

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	1	10	29	80
	-	25	3	11	1	0	
COC	+	0	0	1	9	31	80
	-	27	0	12	0	0	
THC	+	0	0	1	12	27	80
	-	26	4	9	1	0	
MET	+	0	0	1	12	27	80
	-	24	2	13	1	0	
MOP	+	0	0	2	11	29	80
	-	21	2	15	0	0	

Analysis of Discordant Results with One Step Multi-drug Test Cup

One Step Multi-drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylecgonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor-Δ9-THC-9-COOH
THC	50	Negative	59	11-nor-Δ9-THC-9-COOH

80 clinical urine specimens for each drug were analyzed by GC/MS and by one lot of the corresponding One Step Multi-drug Test Dipcard. Samples were divided by concentration into five categories: drug free,less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	1	10	29	80
	-	25	3	11	1	0	
COC	+	0	0	1	9	31	80
	-	27	0	12	0	0	
THC	+	0	0	1	12	27	80
	-	26	4	9	1	0	
MET	+	0	0	1	12	27	80
	-	24	2	13	1	0	
MOP	+	0	0	2	11	29	80
	-	21	2	15	0	0	

Analysis of Discordant Results with One Step Multi-drug Test Dipcard

One Step Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylecgonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor-Δ9-THC-9-COOH
THC	50	Negative	59	11-nor-Δ9-THC-9-COOH

Other Information About Performance Characteristics:

The performance characteristics of One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard were evaluated by precision study, sensitivity study, specificity and cross reactivity study, interference study and stability study. The study results indicate that One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard perform satisfactorily when used according to the package inserts.

10. Conclusion:

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are substantially equivalent to UCP Home™ Drug Screening Test Cards and UCP Home™ Drug Screening Test Cup.

--- End of this section ---

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

January 15, 2014

CO-INNOVATION BIOTECH CO., LTD.
HONG FENG, PRODUCT MANAGER
NO. 13 YANYUAN ROAD. TIANHE DISTRICT
GUANGZHOU, GUANGDONG 510507
CH

Re: K131110
Trade/Device Name: One Step Single/Multi-drug Test Cup;
One Step Single Single/Multi-drug Test Dipcard
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DJC, DKN, LDJ, DIO
Dated: January 2, 2014
Received: January 2, 2014

Dear Hong Feng:

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 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 -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)*
K131180

Device Name
One-Step Single/Multi-drug Test Cup; One-Step single/multi-drug Test Card

Indications for Use *(Describe)*

One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays designed to qualitatively detect the presence of drugs and drug metabolites in human urine at or above the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 2000 (MOP)	Morphine	2000 ng/mL

The tests contain two formats: 1) Test Cup, 2) Test Dipcard. 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. They are intended for prescription use in clinical laboratories only and not for point-of-care use.

These tests provide only a preliminary analytical test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the One Step Multi-drug Test Cup Insert or One Step Single/Multi-drug Test Dipcard Insert, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

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)*

Avis T. Danishefsky -S