K140215

Co-Innovation Biotech Co.,Ltd.

JUN 16 2014

Section 5 - 510(k) Summary

Date of Summary Preparation: 5/19/2014

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
Address: No.13, Yanyuan Road, Tianhe District, Guangzhou, P.R. China
Contact Person: Hong Feng
Contact Email Address: fenghongfda@126.com
Telephone: + 86 -20-62867285
Fax: + 86 -20-62867285

2. Correspondent's Identifications

Correspondent's Name: Co-Innovation Biotech Co.,Ltd.
Address: No.13, Yanyuan Road, Tianhe District, Guangzhou, P.R. China
Contact Person: Hong Feng
Contact Email Address: fenghongfda@126.com
Telephone: + 86 -20-62867285
Fax: + 86 -20-62867285

3. Name of the Device

Recommended classification regulation:

21 CFR 862.3150 Barbiturate test system
21 CFR 862.3170 Benzodiazepine test system
21 CFR 862.3610 Methamphetamine test system
21 CFR 862.3620 Methadone test system
21 CFR 862.3650 Opiate test system
Unclassified,Enzyme immunoassay,phencyclidine

Device class: Class II
Panel: Toxicology (91)
Product code: DIS,JXM,DJC,DJR,DJG,LCM
Common Name:

Barbiturates (BAR) Test System
Benzodiazepines (BZO) Test System
Methylenedioxymethamphetamine (MDMA) Test System
Methadone (MTD) Test System
Oxycodone (OXY) Test System
Phencyclidine (PCP) 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 Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone,Oxycodone, Phencyclidine 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
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Methylenedioxymethampheta mine (MDMA)	3,4-Methylenedioxymetha mphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 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 (Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone,Oxycodone,Phencyclidine)	Same (but the number of drugs detected different)
Intended Users	Prescription Use	Over the Counter (OTC) Use and Prescription Use
Specimen	Urine	Same
Cutoff	Barbiturates:300 ng/mL Benzodiazepines:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methadone:300 ng/mL Oxycodone:100 ng/mL Phencyclidine:25 ng/mL	Same
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 and storage temperature condition . These differences do not affect the performance characteristics of the subject devices.

8. Performance Data:

Accuracy

Single drug Test:

80 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
BAR	+	0	0	0	6	34	80

	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	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
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

80 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
BAR	÷	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	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
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone

PCP	25	Positive	23	Phencyclidine

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:

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
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	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
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

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
BAR	+	0	0	0	6	34	80
	–	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	–	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	–	32	3	5	1	0	
MTD	+	0	0	1	5	35	80

	–	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	–	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	–	35	0	4	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
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

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

June 16, 2014

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

Re: K140215
Trade/Device Name: One Step Single/Multi-drug Test Cup;
One Step Single/Multi-drug Test Dipcard
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: II
Product Code: DIS, JXM, DJC, DJR, DJG, LCM
Dated: January 28, 2014
Received: January 28, 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
k140215

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

Indications for Use *(Describe)*

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
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 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.

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)*

Denise Johnson-lyles -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."