August 12, 2021

W.H.P.M., Inc.
℅ Joe Shia
Manager
LSI Consulting
504E Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K210327
Trade/Device Name: First Sign Multi-Drug Test Dip Card
First Sign Multi-Drug Test Cup
First Sign Multi-Drug Screen Test Dip Card
First Sign Multi-Drug Screen Test Cup
Regulation Number: 21 CFR 862.3700
Regulation Name: Propoxyphene Test System
Regulatory Class: Class II
Product Code: QBF, NGG, NFY, NFT, NFW, NFV, NGL, PTG, LCM, PTH, QAW
Dated: February 2, 2021
Received: February 4, 2021

Dear Joe Shia:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k210327

Device Name

First Sign Multi-Drug Test Dip Card
First Sign Multi-Drug Test Cup

Indications for Use *(Describe)*

First Sign Multi-Drug Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Test Dip Card can consist of any combination of the above listed drug analytes.
The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

First Sign Multi-Drug Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL

2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Test Cup can consist of any combination of the above listed drug analytes. The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k210327

Device Name

First Sign Multi-Drug Screen Test Dip Card
First Sign Multi-Drug Screen Test Cup

Indications for Use *(Describe)*

First Sign Multi-Drug Screen Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen Test Dip Card can consist of any combination of the above listed drug analytes.
The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only. It is for prescription use.

First Sign Multi-Drug Screen Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL

Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only. It is for prescription use.

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)

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PRAStaff@fda.hhs.gov

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510(k) SUMMARY
k210327

1. Date: August 10, 2021

2. Submitter: W.H.P.M., Inc.
5358 Irwindale Ave.
Irwindale, CA 91706

3. Contact person: Joe Shia
LSI International Inc
504E Diamond Ave., Suite J
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com.

4. Device Name: First Sign Multi-Drug Test Dip Card
First Sign Multi-Drug Test Cup
First Sign Multi-Drug Screen Test Dip Card
First Sign Multi-Drug Screen Test Cup

Classification:

Product Code	**Classification**	**Regulation Section**	**Panel**
NFT Amphetamine	II	862.3100, Amphetamine Test System	Toxicology
NGL Buprenorphine	II	862.3650, Opiate Test System	Toxicology
PTH Secobarbital	II	862.3150, Barbiturate Test System	Toxicology
NFV Oxazepam	II	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine	II	862.3250, Cocaine Test System	Toxicology
PTG 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	II	862.3620, Methadone Test System	Toxicology
NGG Methamphetamine	II	862.3610, Methamphetamine Test System	Toxicology
NGG Methylenedioxymethamphetamine	II	862.3610, Methamphetamine Test System	Toxicology
NGL Morphine	II	862.3650, Opiate Test System	Toxicology
PTG Methadone	II	862.3620, Methadone Test System	Toxicology
NGL Oxycodone	II	862.3650, Opiate Test System	Toxicology
LCM Phencyclidine		Unclassified	Toxicology
QBF Propoxyphene	II	862.3700 Propoxyphene test system.	Toxicology

QAW Nortriptyline	II	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids	II	862.3870, Cannabinoids Test System	Toxicology

5. Predicate Devices: K182701

   Wondfo T-Cup® Multi-Drug Urine Test Cup

6. Intended Use

   First Sign Multi-Drug Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

   Configuration of the First Sign Multi-Drug Test Dip Card can consist of any combination of the above listed drug analytes.

   The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

   For in vitro diagnostic use only.

   First Sign Multi-Drug Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital,

Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
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Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
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Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

First Sign Multi-Drug Screen Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
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Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL

Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only. It is for prescription use.

First Sign Multi-Drug Screen Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
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Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL

Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, Propoxyphene and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only. It is for prescription use.

7. Device Description

The First Sign Multi-Drug Test Dip Card, First Sign Multi-Drug Test Cup, First Sign Multi-Drug Screen Test Dip Card and First Sign Multi-Drug Screen Test Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Butalbital, Methadone, Buprenorphine, Phencyclidine, Methylenedioxymethamphetamine, Tricyclic Antidepressants, EDDP and Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices. The Dip Card kits contain a Dip Card device, a package insert and a urine cup for sample collection. The Cup kits contain a Cup device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the First Sign Multi-Drug Test Dip Card and First Sign Multi-Drug Test Cup and the predicate devices is provided in following tables.

Table 1: Features Comparison of First Sign Multi-Drug Test Dip Card and the Predicate Devices

Item	Device	Predicate - K182701
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml or 500 ng/mL Oxazepam (BZO):300 ng/ml Cocaine (COC): 300 ng/ml or 150 ng/mL 11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml or 500 ng/mL Morphine (OPI 2000/MOP 300): 2000ng/mL or 300 ng/mL Oxycodone (OXY) : 100 ng/ml Butalbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml	Same

	Buprenorphine (BUP): 10 ng/ml D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP): 300 ng/ml Propoxyphene (PPX): 300 ng/ml	
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Dip Card	Cup

Table 2: Features Comparison of First Sign Multi-Drug Test Cup Tests and the Predicate Devices

Item	Device	Predicate - K182701
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml or 500 ng/mL Oxazepam (BZO):300 ng/ml Cocaine (COC): 300 ng/ml or 150 ng/mL 11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml or 500 ng/mL Morphine (OPI 2000/MOP 300): 2000ng/mL or 300 ng/mL Oxycodone (OXY): 100 ng/ml Butalbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Buprenorphine (BUP): 10 ng/ml D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP): 300 ng/ml Propoxyphene (PPX): 300 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same

Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Cup	Cup

Table 3: Features Comparison of First Sign Multi-Drug Screen Test Dip Card and the Predicate Devices

Item	Device	Predicate - K182701
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml or 500 ng/mL Oxazepam (BZO):300 ng/ml Cocaine (COC): 300 ng/ml or 150 ng/mL 11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml or 500 ng/mL Morphine (OPI 2000/MOP 300): 2000ng/mL or 300 ng/mL Oxycodone (OXY) : 100 ng/ml Butalbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Buprenorphine (BUP): 10 ng/ml D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP): 300 ng/ml Propoxyphene (PPX): 300 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription	For over-the-counter
Configurations	Dip Card	Cup

Table 4: Features Comparison of First Sign Multi-Drug Screen Test Cup Tests and the Predicate Devices

Item	Device	Predicate - K182701
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml or 500 ng/mL Oxazepam (BZO):300 ng/ml Cocaine (COC): 300 ng/ml or 150 ng/mL	Same

	11-Nor-Δ^9-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml or 500 ng/mL Morphine (OPI 2000/MOP 300): 2000ng/mL or 300 ng/mL Oxycodone (OXY): 100 ng/ml Butalbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Buprenorphine (BUP): 10 ng/ml D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP): 300 ng/ml Propoxyphene (PPX): 300 ng/ml	
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription	For over-the-counter
Configurations	Cup	Cup

9. Test Principle

The First Sign Multi-Drug Test Dip Card, First Sign Multi-Drug Test Cup, First Sign Multi-Drug Screen Test Dip Card, and First Sign Multi-Drug Screen Test Cup are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Butalbital, Methadone, Buprenorphine, Phencyclidine, Methylenedioxymethamphetamine, Tricyclic Antidepressants, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine and Propoxyphene in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off , +75% cut

off and +100% cut off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables for Propoxyphene. The data for AMP1000, COC300 and THC were reported in the cleared k142353. The data for BUP, BAR and MOP 300 were reported in the cleared k152551. The data for BZO, MET1000 and MOP 2000 were reported in the cleared k150162. The data for MTD, PCP and OXY were reported in the cleared k151441. The data for EDDP, MDMA and TCA were reported in the cleared k160793. The data for AMP 500, COC150 and MET 500 were reported in the cleared First Sign submission of k171695.

Propoxyphene

Dip Card

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
	0	**80.7**	**165.5**	**248.1**	**339.9**	**416.8**	**497.2**	**558.1**	**677.3**
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-

Cup

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+100% Cut-off
	0	**80.7**	**165.5**	**248.1**	**339.9**	**416.8**	**497.2**	**558.1**	**677.3**
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

The cut-off value of 300ng/mL is verified for propoxyphene.

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 50°C. Real time stability studies are ongoing.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables. There were no differences observed between the Dip Card and the Cup formats.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Ethanol	Oxolinic acid
N-Acetylprocainamide	Erythromycin	Oxymetazoline

Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline
Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine
Diflunisal	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

e. Specificity

To test specificity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Propoxyphene. The data for AMP1000, COC300 and THC were reported in the cleared k142353. The data for BUP, BAR and MOP 300 were reported in the cleared k152551. The data for BZO, MET1000 and MOP 2000 were reported in the cleared k150162. The data for MTD, PCP and OXY were reported in the cleared k151441. The data for EDDP, MDMA and TCA were reported in the cleared k160793. The data for AMP 500, COC150 and MET 500 were reported in the cleared First Sign submission of k171695. There were no differences observed between the First Sign Multi-Drug Test Dip Card and First Sign Multi-Drug Test Cup.

Propoxyphene (Cut-off=300 ng/mL)	**Result Positive at(ng/ml)**	**% Cross-Reactivity**
d-Propoxyphene	300	100%
Norpropoxyphene	1500	20%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed between the First Sign Multi-Drug Test Dip Card and First Sign Multi-Drug Test Cup.

2. Comparison Studies

Method comparison studies for the First Sign Multi-Drug Test Dip Card and the First Sign Multi-Drug Test Cup were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Propoxyphene. The data for AMP1000, COC300 and THC were reported in the cleared k142353. The data for BUP, BAR and MOP 300 were reported in the cleared k152551. The data for BZO, MET1000 and MOP 2000 were reported in the cleared k150162. The data for MTD, PCP and OXY were reported in the cleared k151441. The data for EDDP, MDMA and TCA were reported in the cleared k160793. The data for AMP 500, COC150 and MET 500 were reported in the cleared First Sign submission of k171695.

Propoxyphene

Dip Card		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	10	15	14	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	15	15	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	20200406-030	268.2	Positive
Viewer B	20200408-001	277.6	Positive
Viewer A	20200407-003	332.0	Negative

Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	19	20
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer B	20200408-032	292.8	Positive
Viewer C	20200408-032	292.8	Positive
Viewer A	20200406-010	327.4	Negative

Lay-user study

A lay user study was performed at three intended user sites with 280 lay persons for each device format. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Typical Results are shown below.

First Sign Multi-Drug Test

Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150):

Assay	Results	Concentration						
		-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP 500	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
BAR 300	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of	100%	100%	100%	100%	95%	100%	100%

	correct results (%)							
BZO 300	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BUP 10	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
COC 150	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
EDDP 300	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MDMA 500	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MET 500	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MOP 300	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20

	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MTD 300	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
OXY 100	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PCP 25	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
PPX 300	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
TCA 1000	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
THC 50	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%

Configuration 2 (AMP 1000, MET 1000, MOP 2000 (OPI), COC 300):

Assay	Results	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP 1000	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
BAR 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
BZO 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
BUP 10	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
COC 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
EDDP 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%

MDMA 500	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MET 1000	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
OPI 2000	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
MTD 300	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
OXY 100	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
PCP 25	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
PPX 300	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20

	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
TCA 1000	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
THC 50	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the First Sign Multi-Drug Test Dip Card, First Sign Multi-Drug Test Cup, First Sign Multi-Drug Screen Test Dip Card and First Sign Multi-Drug Screen Test Cup are substantially equivalent to the predicate.