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

GENPRIME, INC
MAUREEN GARNER
PRESIDENT
1983 HAZELWOOD ROAD
TOMS RIVER NJ 08753

December 8, 2014

Re: K140665
Trade/Device Name: Snap-Top Split Key Cup for use with the GenPrime Drugs of Abuse Reader System
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: II
Product Code: DIS, JXM, DIO
Dated: December 2, 2014
Received: December 3, 2014

Dear Ms. Maureen Garner:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Katherine Serrano -S

For: 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 below.

510(k) Number *(if known)*
K140665

Device Name
Snap-Top Split Key Cup for use with the GenPrime Drugs of Abuse Reader System

Indications for Use *(Describe)*
The Snap-Top Split Key Cup for use with the GenPrime Drugs of Abuse (DOA) Reader System is for in vitro diagnostic use and is intended for prescription use in laboratories, point-of-care and workplaces by trained users. The test is not intended for over-the-counter use. The test cannot be read visually and must be used with the GenPrime DOA Reader. The Snap-Top Split Key Cup qualitatively detects drug classes in human urine at the cutoff concentrations shown below:

Test/ Calibrated to /Cutoff
Amphetamines/ d-Amphetamine/ 500 ng/mL
Barbiturates/ Secobarbital/ 300 ng/mL
Benzodiazepines/ Oxazapam/ 300 ng/mL
Cocaine/ Benzoylecgonine/ 150 ng/mL
Methamphetamine/ d-Methamphetamine/ 500 ng/mL
Methadone/ Methadone/ 300 ng/mL
Morphine/ Morphine/ 300 ng/mL
Morphine 2000/ Morphine/ 2000 ng/mL
Oxycodone/ Oxycodone/ 100 ng/mL
Phencyclidine/ Phencyclidine/ 25 ng/mL
Marijuana/ Delta-9-THC-COOH/ 50 ng/mL

Configurations of the Snap-Top Split Key Cup may consist of any combination of the above listed drug analytes. The Snap-Top Split Key Cup provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

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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II. 510(k) Summary

1. APPLICANT'S INFORMATION:

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2. SUBMITTER'S INFORMATION

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3. DATE PREPARED: December 5, 2014

4. DEVICE INFORMATION

DEVICE NAME: Snap-Top Split Key Cup for use with the GenPrime Drugs of Abuse Reader System

Classification Panel: Clinical Toxicology (91)

Classification Names: Regulatory information applicable to the test system is provided below:

CFR Section	Product Code
862.3150, Barbiturate Test System	DIS
862.3170, Benzodiazepine Test System	JXM
862.3250, Cocaine and cocaine metabolite Test System	DIO

DEVICE CLASSIFICATION: Class II

5. PREDICATE DEVICE: PROFILE®-V MEDTOXScan® Drugs of Abuse Test System, (K080635)

6. DEVICE DESCRIPTION:

The GenPrime Drugs of Abuse (DOA) Reader System consists of a small, portable high resolution flatbed scanner, customized GenPrime DOA Reader Software, and lateral flow tests that are intended for use in the system. The scanner has a custom Scanner Lid with an opening for the test device, and a Scanner Stand, which places the scanner bed at the appropriate angle for running and reading the test devices. The System is intended for use with the Snap-Top Split Key Cup, which is a rapid, single use, disposable immunochromatographic test for the qualitative detection of drugs of abuse in human urine (K130082). This description is limited to the Snap-Top Split Key Cup (SK Cup), with 3 additional drugs being added, giving 11 total drugs.

The Snap-Top SK cup contains up to five (5) test strips embedded in a urine sample cup, containing a total of up to 11 drug test lines (between one and four drug test lines per test strip). Different drug configurations may be used. Each test strip has an internal control line to confirm validity of the test results.

The Snap-Top SK Cup Drugs of Abuse Test devices are run in the GenPrime DOA Reader System according to their specific instructions for use. At the conclusion of the test (5 minutes) an image is captured and the software algorithm determines whether the colored test lines for each analyte are above or below the threshold associated with a negative or positive result. The software also confirms the validity of the results by verifying the presence of control lines. The results are recorded and logged into a database along with an image of the test, patient and operator information and the time of image capture. The results can be viewed, printed, or sent to a recipient via email or other electronic method. The GenPrime DOA Reader is for *in vitro* diagnostic use and is intended for use in laboratories, point-of-care sites and workplaces by trained users. The test is not intended for over-the-counter use. The GenPrime DOA Reader System test devices cannot be read visually.

All analytes on the Snap-Top SK Cup for use with the GenPrime DOA Reader System were previously cleared (K130082) except for the drug tests for benzodiazepines, cocaine and barbiturates.

The GenPrime DOA Reader System detects drug classes at the following cutoff concentrations for the Snap-Top SK Cup device:

Test	Drug (Calibrator)	Cutoff
AMP	Amphetamine (d-Amphetamine)	500 ng/mL
BAR	Barbiturates (Secobarbital)	300 ng/mL
BZO	Benzodiazepines (Oxazapam)	300 ng/mL
COC	Cocaine (Benzoylecgonine)	150 ng/mL
MTD	Methadone (Methadone)	300 ng/mL
MET	Methamphetamine (d-Methamphetamine)	500 ng/mL
MOP 300	Morphine	300 ng/mL
MOP 2000	Morphine	2000 ng/mL
OXY	Oxycodone (Oxycodone)	100 ng/mL
PCP	Phencyclidine (Phencyclidine)	25 ng/mL
THC	Marijuana (Delta-9-THC-COOH)	50 ng/mL

Configurations of the Snap-Top SK Cup may consist of any combination of the above listed drug analytes. Refer to specific product labeling for the combination of drug tests included in that test device.

7. INDICATIONS FOR USE:

The Snap-Top Split Key Cup for use with the GenPrime Drugs of Abuse (DOA) Reader System is for *in vitro* diagnostic use and is intended for prescription use in laboratories, point-of-care and workplaces by trained users. The test is not intended for over-the-counter use. The test cannot be read visually and must be used with the GenPrime DOA Reader. The Snap-Top Split Key Cup qualitatively detects drug classes in human urine at the cutoff concentrations shown below:

Test	Calibrated to	Cutoff
Amphetamines	d-Amphetamine	500 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazapam	300 ng/mL
Cocaine	Benzoylecgonine	150 ng/mL
Methamphetamine	d-Methamphetamine	500 ng/mL
Methadone	Methadone	300 ng/mL
Morphine	Morphine	300 ng/mL
Morphine 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL

Configurations of the Snap-Top Split Key Cup may consist of any combination of the above listed drug analytes.

The Snap-Top Split Key Cup provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography / mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Special conditions for use statement(s):

The device is for *in vitro* diagnostic prescription use.

The GenPrime DOA Reader System test devices cannot be read visually.

The GenPrime DOA Reader System only provides a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The test is not intended for over-the-counter use.

Special instrument requirements:

- The GenPrime DOA Reader is required.
- The GenPrime DOA Reader Software must be loaded onto a PC, laptop computer or Windows compatible device meeting the following minimum requirements:

GenPrime DOA Reader Software System Requirements
Operating System • MS Windows® XP with Service Pack 3, MS Windows® Vista, MS Windows® 7 or MS Windows® 8
Hardware • Minimum Processor: Intel® Pentium® 4 1.5 GHz or equivalent • Minimum RAM: 1 GB • Free hard disc space: minimum of 50 MB at Installation, needs additional disc space while operating; an additional 850 MB necessary for installation of MS .NET Framework 4.0 • Mouse for optimal interaction with user interface (e.g. IntelliMouse® / Microsoft®) • Standard keyboard with cursor keys, Num-Pad and Insert-, Delete-, Page up/down keys. Recommended with cable. • Minimum: 1 USB 2.0-compatible port
External Software • PDF-Compatible viewing application, i.e. Adobe Reader

8. DISCUSSION OF TECHNOLOGICAL CHARACTERISTICS:

Similarities and differences to predicate device

Both the candidate and the predicate test systems are used to detect the presence of drugs of abuse and their metabolites in human urine. In both systems, a urine sample is added to the test device and allowed to react for a specified period of time, after which an instrument is used to read the test device and interpret and display the test result. Both the candidate and predicate test device are rapid single use disposable devices that use immunochromatographic lateral flow technology. Both the candidate and predicate test utilize gold-conjugated reagents to generate reddish-purple test and control lines, which are read by the instrument. Both devices are competitive assays where concentration of drug is inversely related to the signal detected by the instrument. The candidate device measures line intensities using image analysis algorithms and then performs the analysis and outputs the results via a Windows compatible computer. The predicate device uses a CIS (contact imaging sensor) to measure line intensity and performs the analysis and outputs results using an embedded operating system and display. The candidate device requires that the operator manually time test development (5 minutes) and then operate the instrument, while the predicate instrument internally times test strip development (10 minutes) and then scans the test cassette.

Overall performance and characteristics of the Snap-Top SK Cup GenPrime DOA Reader System and the predicate device, the MEDTOXScan® are summarized in Table 1 below:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Determines qualitative positive or negative result from drugs of abuse immunoassay screens using an instrument reader.	Same
Single-Use Test Device	Produces colored lines on device.	Same
Assay Type	Competitive assay where concentration of drug is inversely related to the visible signal detected by the instrument.	Same
System Procedure	Sample is added to a single use test device, which is then read by instrument. Instrument is designed to read multiple single use test devices, one at a time.	Same
Measurement Method	Scans the single-use test device to detect a signal.	Same
Differences		
Item	**Device**	**Predicate**
Test Device Format	Reads multiple formats of single-use test devices in different cup formats.	Reads a single-use test cassette.
Test Time and Timing Method	Operator manually times test development for 5 minutes and then operates the instrument.	Instrument internally times test strip development for 10 minutes and then scans the test cassette.
Detection Method	Measures density of visible lines against background on single-use test device.	Measures reflectance of visible lines on single use test cassette.
Output	Outputs "presumptive positive", "negative", and "invalid" test results on a graphic user interface displayed on a computer screen and automatically stores results along with test information. Operator has ability to print and/or export results.	Outputs "positive," "negative," and "invalid" test results on paper printout or LCD screen; stores and uploads results.
Cutoff values	BAR cutoff is 300ng BZO cutoff is 300ng MTD cutoff is 300ng MOP cutoff is 300ng	BAR cutoff is 200ng BZO cutoff is 150ng MTD cutoff is 200ng MOP cutoff is 100ng
Power Requirements	AC power only	AC or battery power
Additional Requirements	Windows®-based computer and cable accessories	None.

Table 1. Similarities and Differences between the GenPrime DOA Reader System and predicate system.

The manufacturer believes that the technological characteristics of the Snap-Top SK Cup are substantially similar to those of the predicate device.

9. DISCUSSION OF NON-CLINICAL TESTS PERFORMED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Laboratory performance studies were conducted to determine the substantial equivalence of the Snap-Top SK Cup to the predicate system. Testing was only conducted for BAR, BZO and COC since the other analytes of the device have been previously cleared under K130082. These studies are as follows:

Sensitivity/Precision/Distribution of Random Error

The precision studies were performed in the hands of the intended users at three sites representative of laboratory, workplace, and POC settings. The studies were performed with an intended use operator at each site. The operators performed the tests following the instructions for use, which are included with the GenPrime DOA Reader.

Precision studies were performed with the target analytes at 0%, 25%, 50%, 75%, 125%, 150%, 175%, and 200% of the cutoff. Urine test solutions were created with human urine

and calibrator drugs. GC/MS and/or LC/MS/MS were performed to confirm the concentration of calibrator drug in each test solution. The identity of the samples was masked from the operator, and they were tested in random order. Each urine specimen was labeled with a unique alpha-numeric sample ID prior to delivery to the POC sites.

Performance of the Snap-Top SK Cup was evaluated for each drug analyte by testing each drug at the stated concentration using a minimum of 10 tests per operator. Each of the operators used a different GenPrime DOA Reader. Results for this study are summarized in Table 2 below:

Table 2. Sensitivity/Precision/Distribution of Random Error

BAR (300 ng/mL)					
% of Cutoff	**ng/mL**	**N**	**# NEG**	**# POS**	**Precision**
NEG	0	45	45	0	100%
25%	75	45	45	0	100%
50%	150	46	46	0	100%
75%	225	45	39	6	86.7%
125%	375	45	0	45	100%
150%	450	45	0	45	100%
175%	525	45	0	45	100%
200%	600	46	0	46	100%
BZO (300 ng/mL)					
% of Cutoff	**ng/mL**	**N**	**# NEG**	**# POS**	**Precision**
NEG	0	45	45	0	100%
25%	75	50	50	0	100%
50%	150	50	48	2	96.0%
75%	225	50	29	21	58.0%
125%	375	50	2	48	96.0%
150%	450	49	0	49	100%
175%	525	49	0	49	100%
200%	600	49	0	49	100%
COC (150 ng/mL)					
% of Cutoff	**ng/mL**	**N**	**# NEG**	**# POS**	**Precision**
NEG	0	45	45	0	100%
25%	37.5	45	45	0	100%
50%	75	46	46	0	100%
75%	112.5	45	28	17	62.2%
125%	187.5	45	1	44	97.8%
150%	225	46	0	46	100%
175%	262.5	46	0	46	100%
200%	300	47	0	47	100%

Table 2. Sensitivity/Precision/Distribution of Random Error, continued

All Drugs (95% CI)				
% of Cutoff	**N**	**# NEG**	**# POS**	**Precision**
NEG	135	135	0	100% (97.2-100)
25%	140	140	0	100% (97.3-100)
50%	142	140	2	98.6% (95.0-99.6)
75%	140	96	44	68.6% (60.5-75.7)
125%	140	3	137	97.9% (93.9-99.3)
150%	140	0	140	100% (97.3-100)
175%	140	0	140	100% (97.3-100)
200%	142	0	142	100% (97.4-100)

Related Compounds and Cross Reactants

Analytical specificity studies were performed to determine whether drugs and drug metabolites within the same class of drugs or with similar molecular structures cross-react in the test system. Results are expressed as the minimum concentration required to produce a positive result in the indicated assay.

Reference standards for the various metabolites and compounds were prepared at 100 µg/mL in pooled negative human urine samples. Compounds that tested positive were serially diluted until a negative result was observed. Results shown are expressed as the minimum concentration producing a positive result in the indicated assay. A list of these compounds and their level of cross reactivity is shown in Table 3 below.

Table 3. Snap-Top Split Key Cup Related Compounds and Cross-Reactants

Related Compound or Cross-Reactant	Result	% Cross Reactive
Barbiturate (BAR) (Secobarbital) (300 ng/mL)		
Butabarbital	Positive at 75 ng/mL	400%
Aprobarbital	Positive at 200 ng/mL	150%
Barbital	Positive at 250 ng/mL	120%
Butethal	Positive at 250 ng/mL	120%
Phenobarbital	Positive at 250 ng/mL	120%
Pentobarbital	Positive at 300 ng/mL	100%
Alphenal	Positive at 600 ng/mL	50%
Cyclopentobarbital	Positive at 600 ng/mL	50%
Amobarbital	Positive at 850 ng/mL	35%
Allobarbital	Positive at 1000 ng/mL	30%
Butalbital	Positive at 5000 ng/mL	6%
Mephobarbital	Positive at 50000 ng/mL	1%
Barbituric Acid	Negative at 100000 ng/mL	N/A
Glutethimide	Negative at 100000 ng/mL	N/A
Hexobarbital	Negative at 100000 ng/mL	N/A
Phenytoin (diphenylhydantoin)	Negative at 100000 ng/mL	N/A
Thiopental	Negative at 100000 ng/mL	N/A
Benzodiazepine (BZO) (Oxazepam) 300 ng/mL		
Temazepam glucuronide	Positive at 50 ng/mL	600%
Clobazam	Positive at 98 ng/mL	306%
N-Desmethylflunitrazepam	Positive at 100 ng/mL	300%
Nitrazepam	Positive at 100 ng/mL	300%
Oxazepam glucuronide	Positive at 100 ng/mL	300%
Temazepam	Positive at 125 ng/mL	240%
RS-Lorazepam glucuronide	Positive at 150 ng/mL	200%
Diazepam	Positive at 195 ng/mL	154%
Flunitrazepam	Positive at 195 ng/mL	154%
Clorazepate	Positive at 200 ng/mL	150%
Alprazolam	Positive at 250 ng/mL	120%
Desalkylflurazepam	Positive at 390 ng/mL	77%
Nordiazepam	Positive at 390 ng/mL	77%
Clonazepam	Positive at 400 ng/mL	75%
Bromazepam	Positive at 1000 ng/mL	30%
Estazolam	Positive at 1250 ng/mL	24%
Alprazolam-OH (α-Hydroxyalprazolam)	Positive at 1262 ng/mL	24%
Lorazepam (d,l)	Positive at 1500 ng/mL	20%
Triazolam	Positive at 2500 ng/mL	12%
Chlordiazepoxide	Positive at 3125 ng/mL	10%
Norchlordiazepoxide (N-Desmethylchlordiazepoxide)	Positive at 6250 ng/mL	5%
Midazolam	Positive at 12500 ng/mL	2%
Triazolam, 1-hydroxy	Positive at 50000 ng/mL	N/A

Related Compound or Cross-Reactant	Result	% Cross Reactive
Sertraline	Negative at 100000 ng/mL	N/A
7-Aminoclonazepam	Negative at 100000 ng/mL	N/A
7-Aminoflunitrazepam	Negative at 100000 ng/mL	N/A
Flurazepam	Negative at 100000 ng/mL	N/A
Cocaine (COC) (Benzoylecgonine) 150 ng/mL		
Cocaine	Positive at 2000 ng/mL	8%
Cocaethylene	Positive at 9325 ng/mL	2%
Ecgonine	Positive at 30000 ng/mL	1%
Ecgonine Methyl Ester	Negative at 100000 ng/mL	N/A

Interference Data

Endogenous Compounds

The Snap-Top Split Key Cup was tested for interference with 15 endogenous compounds. The compounds were dissolved in appropriate solvents at a concentration of at least 1.0 mg/mL. Each compound was further diluted to 100 µg/mL in contrived specimens containing 50% of each assay cut-off and 150% of each assay cut-off. None of the compounds listed below showed interference at 100 µg/mL.

1-Thyroxine (d)
Creatinine
Epinephrine
Acetaldehyde
Acetone
Albumin, Human
Bilirubin
Cholesterol
Glucose, Standard
Hemoglobin, Human
Sodium Chloride
Uric Acid
B-Estradiol
Estriol
Tetrahydrocortisone-3-acetate

pH and Specific Gravity

The Snap-Top SK Cup was assayed with pH values of 3.0, 4.0, 7.0 and 9.0 ± 0.1. Each sample was assayed in triplicate. The pH samples were fortified with drug concentrations at 50% (negative) and 150% (positive) of cutoff. All four pH samples gave negative results in the 50% of cutoff level for each drug, and all gave positive results at the 150% of cutoff level for each drug.

The Snap-Top SK Cup was assayed in triplicate with samples with specific gravity values of 1.003, 1.015 and 1.030 ± 0.001. The specific gravity samples were fortified with drug concentrations as described above for pH to give strong negative and strong positive results. All three specific gravity samples gave negative results when fortified to the maximum strong negative level for each drug, and all gave positive results when fortified to the minimum strong positive level for each drug.

Prescription Drugs

A study was conducted to determine the cross-reactivity of the device with compounds spiked into either weak-positive or weak-negative urine containing Barbiturates, Benzodiazepines, and Cocaine. The following compounds demonstrated no cross-reactivity when tested with the Snap Top Split Key Cup at a concentration of 25 µg/mL (unless otherwise noted).

Table 4. Prescription Drugs

N-Acetylprocainamide	Fenoprofen	Niacinamide	Sulfamethazine
Amoxicillin	Furosemide	Nifedipine	Sulindac
Ampicillin	Hydralazine	Noscapine	Tetracycline
l-Ascorbic Acid	Hydrochlorothiazide	Oxolinic acid	Tetrahydrocortisone 3-acetate
Atropine	Hydrocortisone	Oxymetazoline	Tetrahydrozoline
Chlorothiazide*	o-Hydroxyhippuric acid	Papaverine	Thiamine
Chlorpromazine	Ketamine	Penicillin-G	Thioridazine
Clonidine	Ketoprofen	Perphenazine	Tolbutamide
l-Cotinine	Labetalol	Phenelzine	Triamterene
Cortisone	Loperamide	Prednisone	Trifluoperazine
Diclofenac	Meprobamate	d,l-Propranolol	Trimethoprim
Diflunisal	Methoxyphenamine	Quinine	d,l-Tryptophan
Digoxin	Methylphenidate	Quinidine	Verapamil
Diphenhydramine	Nalidixic acid	Serotonin	Zomepirac
Erythromycin			

*tested at 12.5 µg/mL

Common Drugs

Drug free urine samples were spiked with drug concentrations that were at 50% (negative) and 150% (positive) of cutoff. Concentrations of 100,000 ng/mL of the common drugs were then added to the preparation and assayed by the GenPrime DOA Reader System. If a common compound name is followed by the drug abbreviation (e.g., "BAR"), then it has expected reactivity in the specified drug test (see Related Compounds and Cross Reactants) and was not assayed for interference in that drug test. Samples were evaluated in triplicate by in-house operators. None of the common drugs affected the expected results for the Split Key Cup (Table 4):

Table 5. Common Drugs Evaluated with the GenPrime DOA Reader System Split Key Cup

Acetylsalicylic Acid	Chlorpheniramine	Morphine
Acetaminophen	Cocaine **- COC**	Phenobarbital – **BAR**
Brompheniramine maleate	Dextromethorphan	Phenytoin (Diphenylhydantoin)-**BAR**
Caffeine	Doxylamine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Salicylic Acid

Discussion of Clinical Tests Performed for Determination of Substantial Equivalence

The accuracy of the Snap-Top SK Cup was evaluated at three sites representative of laboratory, workplace, and POC settings with blind coded clinical urine samples that contained varying concentrations of drugs as determined by GC/MS or LC/MS/MS. For each drug, a minimum of 40 unaltered positive and 40 unaltered negative clinical samples were assessed. Negative samples were screened negative by EIA, 10% of which were also confirmed by GC/MS or LC/MS/MS. Results were stratified to give values of 0%, 0-50%, 50-100%, 100-150% and >150% of cutoff. Results summaries are provided below in Table 5, for all sites combined. Discordant results and the drug levels detected by GC/MS or LC/MS/MS are provided in Table 6 below.

Table 5. Summary of method comparison data for the Split Key Cup (all sites combined)

DRUG (cutoff)	GenPrime Test System SK Cup	No Drug	Relative to Cutoff				Agreement with Reference
			Negative (<50%)	Near Cutoff Negative (50-100%)	Near Cutoff Positive (100-150%)	Positive (>150%)	
BAR (300)	Positive	0	0	2	4	36	100%
	Negative	42	3	3	0	0	96.0%
BZO (300)	Positive	0	0	2	4	36	100%
	Negative	36	2	2	0	0	95.2%
COC (150)	Positive	0	0	0	4	36	100%
	Negative	36	0	4	0	0	100%
All Drugs	Positive (95% CI)	0	0	4	12	108	100% (96.9-100)
	Negative (95% CI)	114	5	9	0	0	97.0% (92.5-98.8)

Table 6. Discordant Results for the Split Key Cup

Cutoff Value (ng/mL)	Drug	GenPrime DOA Reader System	GC/MS or LC/MS/MS Value
300	BAR	Presumptive Positive	Phenobarbital at 160 ng/mL (=192 ng/mL BAR equiv)
300	BAR	Presumptive Positive	Butalbital at 4788 ng/mL (=287 ng/mL BAR equiv)
300	BZO	Presumptive Positive	Oxazepam at 271 ng/mL
		Presumptive Positive	Oxazepam at 235 ng/mL

10. CONCLUSION

The Snap-Top SK Cup has the same intended use, similar technological characteristics and equivalent precision, interference, cross-reactivity and clinical accuracy as the predicate device. The data demonstrate that the addition of three new drugs to the test menu do not raise any new issues of safety or effectiveness. GenPrime believes that the Snap-Top SK Cup is substantially equivalent to the predicate device.