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

October 16, 2014

HEALGEN SCIENTIFIC LLC
C/O JOE SHIA
LSI INTERNATIONAL INC.
504 EAST DIAMOND AVE., SUITE F
GAITHERSBURG MD 20877

Re: K142280
Trade/Device Name: Healgen Oxazepam Test (Strip, Cassette, Cup, Dip Card);
Healgen Morphine Test (Strip, Cassette, Cup, Dip Card)
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: II
Product Code: JXM, DJG
Dated: August 12, 2014
Received: August 15, 2014

Dear Mr. 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. 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,

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

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)*
k142280

Device Name
Healgen Oxazepam Test (Strip, Cassette, Cup, Dip Card)
Healgen Morphine Test (Strip, Cassette, Cup, Dip Card)

Indications for Use *(Describe)*
Healgen Oxazepam Test is an immunochromatographic assay for the qualitative determination of Oxazepam (a drug in the benzodiazepine class) in human urine at a Cut-Off concentration of 300 ng/m L. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug Oxazepam is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for oxazepam in urine. 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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen Morphine Test is an immunochromatographic assay for the qualitative determination of morphine (a drug in the opiate class) in human urine at a Cut-Off concentration of 2000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

1. Date: October 6, 2014

2. Submitter: HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX77401

3. Contact person: Jianqiu Fang
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4. Device Name: Healgen Oxazepam Test (Strip, Cassette, Cup, Dip Card)
Healgen Morphine Test (Strip, Cassette, Cup, Dip Card)
Classification:

Product Code	**CFR #**	**Panel**
JXM	21 CFR, 862.3170 Benzodiazepine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology

5. Predicate Devices:
K052115
First Check Multi Drug Cup 12

6. Intended Use
Healgen Oxazepam Test is an immunochromatographic assay for the qualitative determination of Oxazepam (a drug in the benzodiazepine class) in human urine at a Cut-Off concentration of 300 ng/m L. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

The test may yield preliminary positive results even when prescription drug Oxazepam is ingested, at prescribed doses; it is not intended to distinguish between prescription use or abuse of this drug. There is no uniformly recognized cutoff concentration level for oxazepam in urine. 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 is the preferred confirmatory method. Clinical consideration and

professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

Healgen Morphine Test is an immunochromatographic assay for the qualitative determination of morphine (a drug in the opiate class) in human urine at a Cut-Off concentration of 2000 ng/mL. The test is available in a Strip format, a Cassette format, a Dip Card format and a Cup format.

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 is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. It is intended for over-the-counter and for prescription use.

7. Device Description

Healgen Oxazepam Test and Healgen Morphine Test are immunochromatographic assays for Oxazepam and Morphine. Each assay test is a lateral flow system for the qualitative detection of Oxazepam and Morphine (target analyte) in human urine. The products are in vitro diagnostic devices, which come in the form of: Strips, Cassettes, DipCards, or Cups. Each product contains a Test Device (in one of the four formats), and a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the Healgen Oxazepam Test and Healgen Morphine Test and the predicate device is provided in Table 1 & Table 2.

Table 1: Features Comparison of Healgen Oxazepam Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Oxazepam	Benzodiazepine Drug Class
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL	Same

Item	Device	Predicate - K052115
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

Table 2: Features Comparison of Healgen Morphine Test and the Predicate Device

Item	Device	Predicate - K052115
Intended Use	For the qualitative determination of drugs of abuse in human urine.	Same
Drug Analyte	Morphine	Opiate Drug Class
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	2000 ng/mL	Same
Intended Population	For over-the-counter and prescription uses.	For over-the-counter use.
Configurations	Strip, Cassette, Cup, Dip Card	Cup

9. Test Principle

   Healgen Oxazepam Test and Healgen Morphine Test are rapid tests for the qualitative detection of Oxazepam and Morphine in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (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 cut-off 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.

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, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blind labeled and randomized. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following tables:

Oxazepam

Strip Format

Result / Drug	-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
Lot: 1201001	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201002	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201003	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result / Drug	-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
Lot: 1201004	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201005	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201006	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result / Drug	-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
Lot: 1201007	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201008	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201009	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result / Drug	-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
Lot: 1201010	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201011	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1201012	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine

Strip Format

Result / Drug	-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
Lot: 1112001	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112002	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112003	50-/0+	50-/0+	50-/0+	50-/0+	18-/32+	50+/0-	50+/0-	50+/0-	50+/0-

Cassette Format

Result / Drug	-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
Lot: 1112004	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot:1112005	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112006	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

Result / Drug	-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
Lot: 1112007	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112008	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112009	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

CUP Format

Result / Drug	-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
Lot: 1112010	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112011	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
Lot: 1112012	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable.

c. Stability

The devices are stable at 4-30℃ for 24 months based on the accelerated stability study at 45℃ and real time stability determination at both 4 ℃ and 30℃.

Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

d. Cut-off

A total of 150 samples equally distributed at concentrations of -50% cut-off; -25% cut-off; cut-off; +25% cut-off; +50% cut-off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% cut-off and all negative at and below -25% cut-off for both Oxazepam and Morphine. The following cut-off values for the test devices have been verified.

Test	Calibrator	Cut-off (ng/mL)
Oxazepam Test	Oxazepam	300
Morphine Test	Morphine	2000

e. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentration at 25% below and 25% above cut-off levels. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for different formats.

Oxazepam

4-Acetamidophenol	Doxylamine	Oxolinic acid
Acetophenetidin	Ecaonine dydrochloride	Pentobarbital
N-Acetvprocainamide	Ecqonine methylester	Perphenazine
Acetvsalicvlic acid	(-)-Y-Ephedrine	Phencyclidine
Aminopvrine	Fenoprofen	Phenelzine
Amityptvline	Furosemide	Phenobarbital
Amorbarbital	Gentisic acid	Phentermine
Amoxicillin	Hemoglobin	L-Phenylephrine
Ampicillin	Hydrocortisone	Phenylethylamine
l-Ascorbic Acid	O-Hydroxyhippuric acid	Phenylpropanotamine
D.L-Amphetamine	p-Hydroxy-methamphetamine	Prednisone
Apormorphine	3-Hydroxytyramine	D.L-Propanolol

Aspartame	Ibuprofen	D-Propoxyphene
Atropine	Imipramine	D-Pseudoephedrine
Benzillic acid	Iproniazid	Quinine
Benzoic acid	(±)Isoproterenol	Ranitidine
Benzoylecaonine	Isoxsuprine	Salicylic acid
Benzphetamine	Ketamine	Secobarbital
Bilirubin	Ketoprofen	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	Labetalol	Sertraline
Caffeine	Loperamide	Sulfamethazine
Cannabidiol	Maprotiline	Sulindac
Chloralhvdrate	Meperidine	Tetrahydrocortisone,3 Acetate
Chloramphenicol	Meprobamate	Tetrahydrocortisone,(β-D glucuronide)
Chlorothiazide	Methadone	Tetrahydrozoline
(±)Chlorpheniramine	Methoxyphenamine	Thiamine
Chlorpromazine	(+) 3,4-Methylenedioxy-amphetamine	Thioridazine
Chlorquine	(+)3,4-Methylenedioxy-methamphetamine	D.L-Tyrosine
Cholesterol	Nalidixic acid	Tolbutamide
Clomipramine	Nalorphine	Triamterene
Clonidine	Naloxone	Trifluoperazine
Cocaine hydrochloride	Naltrexone	Trimethoprim
Cortisone	Naproxen	Triyptamine
(-)cotinine	Niacinamide	D.L-Tryptophan
Creatinine	Nifedipine	Tyramine
Dextromethlorphan	Norethindrone	Uric acid
Diclolrfenac	D-Norpropoxyphene	Verapamil
Diflunisal	Noscapine	Zomepirac
Diaoxin	D.L-Octopamine	
Diphenhydramine	Oxalic acid	

Morphine

4-Acetamidophenol	Ecgonine methylester	Oxolinic acid
Acetophenetidin	(-) -Y -Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G

Aminopyrine	Estrone-3-sulfate	Pentazocine
Amitryptyline	Ethyl-p-aminobenzoate	Pentobarbital
Amobarbital	Fenoprofen	Perphenazine
Amoxicillin	Furosemide	Phencyclidine
Ampicillin	Gentisic acid	Phenelzine
Ascorbic acid	Hemoglobin	Phenobarbital
D,L-Amphetamine	Hydralazine	Phentermine
Apomorphine	Hydrochlorothiazide	L-Phenylephrine
Aspartame	Hydrocortisone	β-Phenylethylamine
Atropine	O-Hydroxyhippuric acid	Phenylpropanolamine
Benzilic acid	p-Hydroxy methamphetamine	Prednisone
Benzoic acid	3-Hydroxytyramine	D,L-Propanolol
Benzoylecgonine	Ibuprofen	D-Propoxyphene
Benzphetamine	Imipramine	D-Pseudoephedrine
Bilirubin (±)	Iproniazid	Quinidine
Brompheniramine	Isoproterenol	Quinine
Caffeine	Isoxsuprine	Ranitidine
Cannabidiol	Ketamine	Salicylic acid
Chloralhydrate	Ketoprofen	Secobarbital
Chloramphenicol	Labetalol	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Loperamide	Sulfamethazine
Chlorothiazide	Maprotiline	Sulindac
(±) Chlorpheniramine	Meperidine	Temazepam
Chlorpromazine	Meprobamate	Tetracycline
Chlorquine	Methadone	Tetrahydrocortisone, 3 Acetate
Cholesterol	Methoxyphenamine	Tetrahydrocortisone3 (β-D glucuronide)
Clomipramine	(+) 3,4-Methylenedioxy-amphetamine	Tetrahydrozoline
Clonidine	(+)3,4-Methylenedioxy-methamphetamine	Thiamine
Cocaine hydrochloride	Nalidixic acid	Thioridazine
Cortisone	Nalorphine	D, L-Tyrosine
(-) Cotinine	Naloxone	Tolbutamide
Creatinine	Naltrexone	Triamterene
Deoxycorticosterone	Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Trimethoprim
Diazepam	Nifedipine	Trimipramine
Diclofenac	Norethindrone	Tryptamine

Diflunisal	D-Norpropoxyphene	D, L-Tryptophan
Digoxin	Noscapine	Tyramine
Diphenhydramine	D,L-Octopamine	Uric acid
Doxylamine	Oxalic acid	Verapamil
Ecgonine hydrochloride	Oxazepam	Zomepirac

f. Specificity

To test the specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device for all formats. The obtained lowest detectable concentration was used to calculate the cross-reactivity. There were no differences observed for different formats.

Oxazepam **(Cut-off=300 ng/mL)**	**Result** Positive at 300 ng/mL	**% Cross-Reactivity** 100%
Alprazolam	Positive at 200 ng/mL	150%
Bromazepam	Positive at 1560 ng/mL	19%
Chlordiazepoxide HCL	Positive at 1560 ng/mL	19%
Clobazam	Positive at 100 ng/mL	300%
Clonazepam	Positive at 780 ng/mL	38%
Clorazepate Dipotassium	Positive at 200 ng/mL	150%
Delorazepam	Positive at 1560 ng/mL	19%
Desalkylflurazepam	Positive at 400 ng/mL	75%
Diazepam	Positive at 200 ng/mL	150%
Estazolam	Positive at 2500 ng/mL	12%
Flunitrazepam	Positive at 400 ng/mL	75%
a-Hydroxyalprazolam	Positive at 1260 ng/mL	24%
(±) Lorazepam	Positive at 1560 ng/mL	19%
RS-Lorazepam glucuronide	Positive at 160 ng/mL	188%
Midazolam	Positive at 12500 ng/mL	2.4%
Nitrazepam	Positive at 100 ng/mL	300%
Norchlordiazepoxide	Positive at 200 ng/mL	150%
Nordiazepam	Positive at 400 ng/mL	75%
Temazepam	Positive at 100 ng/mL	300%
Triazolam	Positive at 2500 ng/mL	12%

Morphine **(Cut-off=2000 ng/mL)**	**Result** Positive at 2000 ng/mL	**% Cross-Reactivity** 100%
O6-Acetylmorphine	Positive at 2500 ng/mL	80%
Codeine	Positive at 1000 ng/mL	200%
EthylMorphine	Positive at 250 ng/mL	800%
Heroin	Positive at 5000 ng/mL	40%
Hydromorphone	Positive at 2500 ng/mL	80%
Hydrocodone	Positive at 5000 ng/mL	40%
Oxycodone	Positive at 75000 ng/mL	3%
Thebaine	Positive at 13,000 ng/mL	15%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 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 batches of each device for all formats. 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 for different formats.

2. Comparison Studies

The method comparison studies for the Oxazepam Test, and the Morphine Test were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Oxazepam

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Oxazepam Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	549	306	Negative
Viewer A	523	303	Negative
Viewer B	549	306	Negative
Viewer B	523	303	Negative
Viewer B	579	312	Negative
Viewer C	549	306	Negative
Viewer C	523	303	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer B	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Viewer C	Positive	0	0	0	13	24
	Negative	10	15	15	3	0

Discordant Results of Oxazepam Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	549	306	Negative
Viewer A	523	303	Negative
Viewer A	579	312	Negative
Viewer B	549	306	Negative
Viewer B	523	303	Negative
Viewer B	579	312	Negative
Viewer C	549	306	Negative
Viewer C	523	303	Negative
Viewer C	579	312	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer B	Positive	0	0	0	14	24
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of Oxazepam Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	549	306	Negative
Viewer A	523	303	Negative
Viewer B	523	303	Negative
Viewer B	579	312	Negative
Viewer C	549	306	Negative
Viewer C	523	303	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Viewer B	Positive	0	0	0	12	24
	Negative	10	15	15	4	0
Viewer C	Positive	0	0	0	14	24
	Negative	10	15	15	2	0

Discordant Results of OxazepamDip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	505	315	Negative
Viewer A	549	306	Negative

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	523	303	Negative
Viewer A	579	312	Negative
Viewer B	505	315	Negative
Viewer B	549	306	Negative
Viewer B	523	303	Negative
Viewer B	579	312	Negative
Viewer C	549	306	Negative
Viewer C	523	303	Negative

Morphine

Strip format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer C	Positive	0	0	0	15	23
	Negative	10	16	14	2	0

Discordant Results of Morphine Strip

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer A	468	2036	Negative
Viewer A	466	2019	Negative
Viewer A	453	2066	Negative
Viewer A	449	2005	Negative
Viewer B	468	2036	Negative
Viewer B	466	2019	Negative
Viewer B	453	2066	Negative
Viewer B	449	2005	Negative
Viewer C	466	2019	Negative

Viewer	Sample Number	GC/MS Result	Strip Format Viewer Results
Viewer C	449	2005	Negative

Cassette format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Viewer B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results of Morphine Cassette

Viewer	Sample Number	GC/MS Result	Cassette Format Viewer Results
Viewer A	468	2036	Negative
Viewer A	466	2019	Negative
Viewer A	449	2005	Negative
Viewer B	405	2053	Negative
Viewer B	468	2036	Negative
Viewer B	466	2019	Negative
Viewer B	449	2005	Negative
Viewer C	405	2053	Negative
Viewer C	468	2036	Negative
Viewer C	466	2019	Negative
Viewer C	449	2005	Negative

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer B	Positive	0	0	0	12	23
	Negative	10	16	14	5	0
Viewer C	Positive	0	0	0	12	23
	Negative	10	16	14	5	0

Discordant Results of Morphine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	405	2053	Negative
Viewer A	468	2036	Negative
Viewer A	466	2019	Negative
Viewer A	449	2005	Negative
Viewer B	405	2053	Negative
Viewer B	468	2036	Negative
Viewer B	466	2019	Negative
Viewer B	449	2005	Negative
Viewer B	429	2067	Negative
Viewer C	405	2053	Negative
Viewer C	468	2036	Negative
Viewer C	466	2019	Negative
Viewer C	449	2005	Negative
Viewer C	429	2067	Negative

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	15	23
	Negative	10	16	14	2	0
Viewer B	Positive	0	0	0	14	23
	Negative	10	16	14	3	0
Viewer C	Positive	0	0	0	13	23
	Negative	10	16	14	4	0

Discordant Results of Morphine Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	466	2019	Negative
Viewer A	449	2005	Negative
Viewer B	468	2036	Negative
Viewer B	466	2019	Negative
Viewer B	449	2005	Negative
Viewer C	405	2053	Negative
Viewer C	468	2036	Negative
Viewer C	466	2019	Negative
Viewer C	449	2005	Negative

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons testing the Oxazepam devices and another set of 140 persons testing the morphine devices. A total of 44 females and 96 males tested the Oxazepam samples, and 41 females and 99 males tested the Morphine samples. They had diverse educational and professional backgrounds and ranged in age from 21 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 GC/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. The results are summarized below.

Comparison between GC/MS and Lay Person Results (Oxazepam Strip)

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxazepam Cassette)

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxazepam DipCard)

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	1	19	95%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

Comparison between GC/MS and Lay Person Results (Oxazepam Cup)

% of Cutoff	Number of samples	Oxazepam Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	75	0	20	100%
-50% Cutoff	20	150	0	20	100%
-25% Cutoff	20	225	2	18	90%
+25% Cutoff	20	375	19	1	95%
+50% Cutoff	20	450	20	0	100%
+75% Cutoff	20	525	20	0	100%

Comparison between GC/MS and Lay Person Results (Morphine Strip)

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	500	0	20	100%
-50% Cutoff	20	1000	0	20	100%
-25% Cutoff	20	1500	2	18	90%
+25% Cutoff	20	2500	19	1	95%
+50% Cutoff	20	3000	20	0	100%
+75% Cutoff	20	3500	20	0	100%

Comparison between GC/MS and Lay Person Results (Morphine Cassette)

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	500	0	20	100%
-50% Cutoff	20	1000	0	20	100%
-25% Cutoff	20	1500	1	19	95%
+25% Cutoff	20	2500	19	1	95%
+50% Cutoff	20	3000	20	0	100%
+75% Cutoff	20	3500	20	0	100%

Comparison between GC/MS and Lay Person Results (Morphine DipCard)

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	500	0	20	100%
-50% Cutoff	20	1000	0	20	100%
-25% Cutoff	20	1500	2	18	90%
+25% Cutoff	20	2500	18	2	90%
+50% Cutoff	20	3000	20	0	100%
+75% Cutoff	20	3500	20	0	100%

Comparison between GC/MS and Lay Person Results (Morphine Cup)

% of Cutoff	Number of samples	MOP Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100%Cutoff	20	0	0	20	100%
-75%Cutoff	20	500	0	20	100%
-50% Cutoff	20	1000	0	20	100%
-25% Cutoff	20	1500	2	18	90%
+25% Cutoff	20	2500	19	1	95%
+50% Cutoff	20	3000	20	0	100%
+75% Cutoff	20	3500	20	0	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 and method comparison of the devices, it's concluded that the Healgen Oxazepam Test, and Healgen Morphine Test are substantially equivalent to the predicate.