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

May 13, 2015

HEALGEN SCIENTIFIC LLC
C/O JOE SHIA
BUSINESS DIRECTOR
504 EAST DIAMOND AVE. SUITE I
GAITHERSBURG MD 20877

Re: K150356
Trade/Device Name: Healgen Multi-Drug Urine Test Cup,
Healgen Multi-Drug Urine Test Dip Card
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: II
Product Code: JXM, DJG, DIO, LDJ, LAF, DKZ
Dated: April 14, 2015
Received: April 17, 2015

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

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)*
k150356

Device Name
Healgen Multi-Drug Urine Test Cup
Healgen Multi-Drug Urine Test Dip Card

Indications for Use *(Describe)*
Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine and Oxycodone in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine(AMP)	1000 ng/mL
Oxazepam (OXA)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Morphine (MOR)	2000 ng/mL
Oxycodone (OXY)	100 ng/mL

Configuration of the Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs oxazepam 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.

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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510(k) SUMMARY

1. Date: May 8, 2015

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

3. Contact person: Jianqiu Fang
HEALGEN SCIENTIFIC LLC
5213 Maple St
Bellaire, TX77401
Telephone: 713-733-8088
Fax: 713-733-8088
Email: bryan@healgen.com

4. Device Name: Healgen Multi-Drug Urine Test Cup
Healgen Multi-Drug Urine Test Dip Card

Classification: Class II

Product Code	Regulation Section	Panel
DKZ Amphetamine	21 CFR § 862.3100, Amphetamine Test System	Toxicology
LDJ Cannabinoids	21 CFR § 862.3870, Cannabinoids Test System	Toxicology
DIO Cocaine	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology
LAF Methamphetamine	21 CFR § 862.3610, Methamphetamine Test System	Toxicology
DJG Morphine	21 CFR § 862.3650, Opiate Test System	Toxicology
JXM Oxazepam	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology
DJG Oxycodone	21 CFR § 862.3650, Opiate Test System	Toxicology

5. Description of the device:
Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test DipCard are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine and Oxycodone, in human urine samples. Healgen Multi-Drug devices detect each of analytes on different strips.
A positive urine sample will not generate a colored-line for the specific drug tested in the designated region. A negative urine specimen or a urine sample containing Amphetamine, Oxazepam, Cocaine,

Cannabinoids, Methamphetamine, Morphine, and Oxycodone at the concentration below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a test control, a color line will always appear at the control region.

6. Predicate Devices:
   K142280; Healgen Oxazepam and Morphine Tests (Strip, Cassette, Dip Card, Cup)
   K143187; Healgen Amphetamine and Oxycodone Tests (Strip, Cassette, Dip Card, Cup)
   K141647; Healgen Cocaine and Morphine Tests (Strip, Cassette, Dip Card, Cup)
   K140546; Healgen Marijuana and Methamphetamine Tests (Strip, Cassette, Dip Card, Cup)

7. Intended Use / Indications for Use
   Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine and Oxycodone in human urine at the cutoff concentrations of:

Drug(Identifier)	**Cut-off level**
Amphetamine(AMP)	1000 ng/mL
Oxazepam (OXA)	300 ng/mL
Cocaine (COC)	300 ng/mL
Cannabinoids (THC)	50 ng/mL
Methamphetamine (MET)	1000 ng/mL
Morphine (MOR)	2000 ng/mL
Oxycodone (OXY)	100 ng/mL

   Configuration of the Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.

   The test may yield positive results for the prescription drugs oxazepam 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.

8. Substantial Equivalence Information
   Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card are a modified product format derived from the previously FDA-cleared Healgen single DOA Tests. A summary comparison of

features of the Healgen Multi-Drug Urine Test Cup and Healgen Multi-Drug Urine Test Dip Card and the predicate devices is provided in the following Table

Item	New Devices	Predicate devices (K142280, K143187, K141647, K140546)
Indication(s) for use	For the qualitative determination of Amphetamine (AMP), Oxazepam (OXA), Cocaine (COC), Cannabinoids (THC), Methamphetamine (MET), Morphine (MOR), Oxycodone(OXY) in human urine. The configurations of the New Devices are available in any combination of the above tests.	For the qualitative determination of Amphetamine, Oxazepam, Cocaine, Cannabinoids, Methamphetamine, Morphine, Oxycodone, in human urine. The configurations of the Predicate devices are only available in single drug test.
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or	Same
Results	Qualitative	Same
Specimen Type	Human urine	Same
Cut Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (OXA):300 ng/ml Cocaine(COC): 300 ng/ml Cannabinoids (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 2000 ng/ml Oxycodone(OXY) : 100 ng/ml	Same
Configurations	Cup, Dip Card	Same
Intended Use	OTC Use & Prescription Use	Same

Healgen Multi-Drug Urine Test Cup is a multi-drug test that offers any combination from 2 to 7 drugs of abuse tests while the predicate devices are single-drug test. And the Healgen Multi-Drug Urine Test Dip Card is the same as the test dip card format of the predicate devices except that the Healgen Multi-Drug Urine Test Dip Card is a multi-drug test that offers any combination from 2 to 7 drugs of abuse tests while the predicate devices are single-drug test.

9. Conclusion

Verification studies were conducted in support of the modification to have a multi-drug test cup and test card test, including interference studies and a lay-user study. Based on the test principle and acceptable performance characteristics, it’s concluded that the Healgen Multi-Drug Urine Test Cup, and Healgen Multi-Drug Urine Test Dip Card are substantially equivalent to the predicates.