June 16, 2023

Healgen Scientific LLC
% Joe Shia
Director
LSI International Inc.
504 East Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K231045
Trade/Device Name: Healgen URS Test Strips
Regulation Number: 21 CFR 862.1510
Regulation Name: Nitrite (Non-Quantitative) Test System
Regulatory Class: Class I (meets the limitations of exemptions in 862.9(c)(9))
Product Code: JMT, LJX
Dated: April 7, 2023
Received: April 12, 2023

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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k231045

Device Name
Healgen URS Test Strips

Indications for Use *(Describe)*
The Healgen URS Test Strips are for the qualitative detection of Leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home 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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510(k) SUMMARY
K231045

1. Date: June 15, 2023

2. Submitter: Healgen Scientific LLC
5213 Maple Street
Bellaire, TX77401

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite I
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4. Device Name: Healgen URS Test Strips

Classification: Class I
(meets the limitations of exemptions in 862.9(c)(9))

Product Code	CFR #	Panel
LJX	21 CFR § 864.7675, Leukocyte Peroxidase Test System	Hematology
JMT	21 CFR § 862.1510, Nitrite Test System	Chemistry

5. Predicate Devices: K100024
Teco Diagnostics UTI Test Strips

6. Intended Use:

The Healgen URS Test Strips are for the qualitative detection of Leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home use only.

7. Device Description:

Healgen URS Test Strips are in vitro diagnostic test devices for qualitative detection of leukocyte and nitrite in urine.

The device is composed of two color pads aligned on a strip. One pad is employed for testing leukocyte and the other for nitrite by visually reading the color change of the pad and comparing with the corresponding blocks on a color chart.

8. Substantial Equivalence Information

Item	Device	Predicate – K100024
Indication(s) for use	For the detection of nitrite and leukocytes in urine.	Same
Nitrite test methodology	By conversion of nitrate to nitrite using the action of p-arsanilic acid to form a diazonium compound in an acid medium. This compound then couples with 1, 2, 3, 4-tetrahydrobenzo(*h*) quinoline to produce a pink color.	Same
Leukocyte test methodology	By hydrolysis of an indoxyl ester derivative through the action of leukocyte esterase. The liberated indoxyl ester reacts with a diazonium salt to produce a colored compound (pink to purple).	Same
Specimen Type	Human urine	Same
Testing parameters	Nitrite and leukocytes	Same
Conditions for Use	Over-the-Counter	Same
Test Read Time	2 minutes for both nitrite and leukocytes	2 minutes for leukocytes 1 minute for nitrite

9. Test Principle

The Healgen URS Test Strips measure the color developed in 2 reaction zones (leukocytes and nitrite pads) on the test strips following application of a urine sample. The developed colors are then compared to calibration colors located on the Healgen color chart card and the result for each pad is determined based on the minimum color distance between the developed colors and calibration colors.

The leukocytes test is using the hydrolysis of an indoxyl ester derivative through the action of leukocyte esterase. The liberated indoxyl ester reacts with a diazonium salt to produce a colored compound (pink to purple).

The Nitrite test uses the conversion of nitrate to nitrite by the action of p-arsanilic acid to form a diazonium compound in an acid medium. This compound then couples with 1, 2, 3, 4-tetrahydrobenzo (*h*) quinoline to produce a pink color.

10. Performance Characteristics

1. Assay Cut-off
   A sensitivity study was performed to evaluate the lower limits of detection for each analyte on the URS Test Strips. Urine samples were spiked to known concentrations of each analyte. These samples were then diluted to the lowest positive concentrations that are indicated on the color chart. Each sample was tested duplicates with three device lots by five different operators.

Leukocyte Concentration (cells/µL)	Negative	Positive	Limit of Detection
30	0	30	100%
15	0	30	100%
10	16	14	47%
5	28	2	7%
3	30	0	0

Nitrite Concentration (mg/dL)	Negative	Positive	Limit of Detection
0.1	0	30	100%
0.08	0	30	100%
0.06	5	25	83%
0.05	15	15	50%
0.04	30	0	0

   LOD values of 15 cells/µL and 0.05 mg/dL are verified for Leukocyte and nitrite respectively.

2. Precision/Reproducibility
   The precision study on the URS Test Strips was performed at three clinical sites with two operators at each site. The evaluation included three replicate assays over five days. A total of forty-five assays results on each of eight levels of control were obtained. All sample concentrations were masked.

Three lots of the device were used with each level of control. The obtained results are listed in the following tables.

Leukocyte Results:

Control	Expected Range	N	% Agreement with Expected Results
Negative	Negative	45	100
Trace	15	45	100
Small	70	45	100
Moderate	125	45	100
Large	500	45	100

Nitrite Results:

Control Sample	Expected Value	N	% Agreement with Expected Results
0.1 mg/dL	Positive	45	100%
0.3 mg/dL	Positive	45	100%

Leukocyte and Nitrite Results:

Control Sample		Expected Value	N	% Agreement with Expected Results
Leukocyte	Small	70	45	100%
Nitrite	0.1 mg/dL	Positive	45	100%

3. Analytical specificity

Potentially interfering substances were added to negative urine or urine with different leukocyte and nitrite concentrations. These samples were tested with three lots of the Healgen URS Test Strips by three different operators. The following substances showed no interference with the tests at the specified concentrations. High glucose levels (≥1000 mg/dL) and high ascorbic acid (≥150 mg/dL) may decrease leukocyte readings. High ascorbic acid (≥150 mg/dL) may cause a false negative nitrite reading.

Substances	Testing Concentration (mg/dL)
Albumin	1000
Ammonium Chloride	400
Ascorbic Acid	100
Bilirubin	10
Ciprofloxacin	1

Creatinine	600
Fructose	18
Galactose	15
Glucose	500
Glycine	900
Hemoglobin	100
Lactose	29
Oxalic Acid	1
Phenazopyridine	30
Phenolpthalein	4
Potassium Chloride	1200
Riboflavin	50
Sodium Nitrate	10
Sodium Nitrite*	10
Sodium Phosphate	1000
Sulfamethoxazole	40
Theophylline	4
Urea	4000

* This interference is tested for Leukocyte results only.

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 5 to 9 were tested at different leukocyte and nitrite concentrations. The test results show that pH >8.0 may cause false positive leukocyte readings, and specific gravity ≥1.035 may cause false negative leukocyte readings. There is no effect of both pH and specific gravity on nitrite testing.

4. Stability

   The devices are stable at 2-30℃ for 24 months based on real-time stability studies.

5. Method Comparison and Lay-user Studies

   Three sites were selected to perform the lay-user studies. 150 lay users with UTI symptoms were recruited to test her/his own urine sample using the Healgen URS Test Strips. Laypersons performed one test with the Healgen URS Test Strips according to the product insert and then collected a sample of their urine for comparison testing by healthcare professionals.

   The results obtained by the lay users compared to the results obtained by the healthcare professionals are summarized below:

Predicate Results by Health Professionals / Layperson Results	Large (3+)	Moderate (2+)	Small (1+)	Trace	Negative	Total
Large (3+)	10	0	0	0	0	10
Moderate (2+)	1	23	0	0	0	24
Small (1+)	0	2	26	1	0	29
Trace	0	0	3	23	1	27
Negative	0	0	0	2	58	60
Total	11	25	29	26	59	150
% Agreement (Exact Match)	90.9	92	89.7	88.5	98.3	
% Agreement (+/- Color Block)	100	100	100	100	100	

Predicate Results by Health Professionals / Layperson Results	Positive	Negative	Overall
Positive	32	0	32
Negative	0	118	118
Total	32	118	150
% Agreement (Exact Match)	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 the package insert and the score revealed a reading grade level of less than 7.

6. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and performance characteristics of the device including LOD, precision, interference, method comparison and lay-user studies of the devices, it's concluded that Healgen URS Test Strips is substantially equivalent to the predicate.