December 23, 2025

Healgen Scientific LLC
% Jenny Xia
Director
LSI International Inc
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877

Re: K251800
Trade/Device Name: Healgen® URS Test Strips
Regulation Number: 21 CFR 864.1510
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: December 4, 2025
Received: December 4, 2025

Dear Jenny Xia:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.
Deputy 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251800

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K251800

1. Date: December 7, 2025

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

3. Contact person: Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20878
Telephone: 301-525-6856
Fax: 301-916-6213
Email: jxia@lsi-consulting.org

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	Clinical Chemistry

5. Predicate Devices: K231045
Healgen URS 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:

The Healgen® URS Test Strips are in vitro diagnostic test devices for the qualitative detection of leukocytes and nitrites in urine. The device is composed of two color pads aligned on a strip. One pad is employed for testing leukocytes and the other for nitrites by visually reading the color change of the applicable pad and comparing with the corresponding blocks on a color chart.

8. Substantial Equivalence Information

Item	Device	Predicate – K231045
Indication(s) for 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.	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.
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	Leukocytes and Nitrite	Same
Intended Users	For over-the-counter use	Same
Test Read Time	2 minutes for both leukocytes and nitrite	Same
Detection Method	Visual	Same
Test Format	Dip or Midstream	Midstream

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 Healgen® 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 in duplicate with three device lots by five different operators.

Leukocyte Concentration (cells/μL)	Negative	Positive	Limit of Detection
15	0	30	100%
12	6	24	80%
10	14	16	53%
5	26	4	13%
3	30	0	0

Nitrite Concentration (mg/dL)	Negative	Positive	Limit of Detection
0.08	0	30	100%
0.07	2	28	93%
0.06	7	23	77%
0.05	15	15	50%
0.04	30	0	0

LOD values of 10 cells/μL and 0.05 mg/dL are verified for Leukocyte and nitrite respectively.

2. Precision/Reproducibility

The precision study on the Healgen® URS Test Strips was performed at three testing sites with one operator at each site. The evaluation included three replicate assays over five days. A total of forty-five assays results on each concentration 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

Concentration (cells/μL)	Expected Range	N	% Agreement with Expected Results
0	Neg.	45	100
15	15	45	100
70	70	45	100
125	125	45	100
500	500	45	100

Nitrite

Concentration (mg/dL)	Expected Range	N	% Agreement with Expected Results
0	Neg.	45	100
0.08	Positive	45	100
0.1	Positive	45	100

3. Analytical specificity

Potentially interfering substances were added to negative urine or urine with different analytes 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**
Albumin	1000 mg/dL
Ascorbic Acid	100 mg/dL
Hemoglobin	100 mg/dL

Citric Acid	50 mg/dL
Bilirubin	10 mg/dL
Ciprofloxacin	1 mg/dL
Creatine	8 mg/dL
Acetoacetate Acid	1 mmol/L
Ammonium Chloride	400 mg/dL
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Galactose	80 mg/dL
Glucose	500 mg/dL
Glycine	1000 mg/dL
KCL	1500 mg/dL
NaCl	2800 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	1200 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	10 mg/dL
Sodium Nitrite	10 mg/dL
Sodium Phosphate	1000 mg/dL
Sulfamethoxazole	40 mg/dL
Urobilinogen	3.0 mg/dL
Urea	4000 mg/dL
Riboflavin	50 mg/dL
Theophylline	100 mg/dL
Phenolphthalein	120 mg/dL
Phenazopyridine	30 mg/dL
Glutathione	200mg/dL
Hypochlorite	1mg/dL
Hydrochloric Acid	1mg/dL
Peroxide	0.1mg/dL
Atropine	30mg/dL
Fructose	5000 mg/dL
Lactose	5000 mg/dL
Ketone	200 mg/dL
Mesna	50mg/dL

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.005 to 1.035 specific gravity or urine samples with pH 5 to 8.5 were tested at different leukocyte and nitrite concentrations. The test results show that there is no effect of both pH and specific gravity on leukocyte and nitrite test results.

4. Stability
   The device is stable at 2-30℃ for 24 months based on real-time stability studies.

5. Method Comparison and Lay-user Studies
   A total of 234 clinical samples were obtained from 234 subjects with UTI symptoms. These samples were randomized and tested by seven operators using three lots of the candidate device and one lot of the Healgen 10 Reagent Strips for Urinalysis device (K111999). The obtained results are shown below.

Comparison Results between Candidate Device and Healgen 10 Reagent Strips for Urinalysis (K111999) Device by Health Professionals

Leukocytes

Healgen 10 Reagent Strips for Urinalysis / **Healgen® URS Test Strips**	500 (3+)	125 (2+)	70 (1+)	15（±）	Negative	Total
500 (3+)	13	0	0	0	0	13
125 (2+)	0	43	1	0	0	44
70 (1+)	0	2	55	1	0	58
15(±)	0	0	0	35	1	36
Negative	0	0	0	0	83	83
Total	13	45	56	36	84	234
% Agreement (Exact Match)	100	95.6	98.2	97.2	98.8	
% Agreement (+/- Color Block)	100	100	100	100	100	

Nitrite

Healgen 10 Reagent Strips for Urinalysis / **Healgen® URS Test Strips**	Positive	Negative	Overall
Positive	100	0	100
Negative	0	134	134
Total	100	134	234

% Agreement (Exact Match)	100	100	
% Agreement (+/- Color Block)	100	100	

Lay-user Study

Three sites were selected to perform the lay-user studies. 234 lay users with UTI symptoms were recruited to test their 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:

Comparison Results between Lay-user and Health Professionals Using Healgen® URS Test Strips

Leukocytes

Results by Health Professionals / **Layperson Results**	500 (3+)	125 (2+)	70 (1+)	15（±）	Negative	Total
500 (3+)	13	0	0	0	0	13
125 (2+)	1	44	0	0	0	45
70 (1+)	0	0	55	1	0	56
15(±)	0	0	2	33	1	36
Negative	0	0	0	0	84	84
Total	14	44	57	34	85	234
% Agreement (Exact Match)	92.9	100	96.5	97.1	98.8	
% Agreement (+/- Color Block)	100	100	100	100	100	

Nitrite

Results by Health Professionals / **Layperson Results**	Positive	Negative	Overall
Positive	100	0	100

Negative	0	134	134
Total	100	134	234
% Agreement (Exact Match)	100	100	
% Agreement (+/- Color Block)	100	100	

Comparison Results between Lay-user and Health Professionals Using the Healgen 10 Reagent Strips for Urinalysis Device (K111999)

Leukocytes

Results by Health Professionals / Layperson Results	500 (3+)	125 (2+)	70 (1+)	15(±)	Negative	Total
Large (3+)	13	0	0	0	0	13
Moderate (2+)	1	42	1	0	0	44
Small (1+)	0	2	54	2	0	58
Trace	0	0	2	32	2	36
Negative	0	0	0	0	83	83
Total	14	44	57	34	85	234
% Agreement (Exact Match)	92.9	95.5	94.7	94.1	97.6	
% Agreement (+/- Color Block)	100	100	100	100	100	

Nitrite

Results by Health Professionals / Layperson Results	Positive	Negative	Overall
Positive	100	0	100
Negative	0	134	134
Total	100	134	234
% Agreement (Exact Match)	100	100	
% Agreement (+/- Color Block)	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 8.

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 the Healgen® URS Test Strips are substantially equivalent to the predicate.