October 31, 2025

Hangzhou Alltest Biotech Co., Ltd
℅ Jenny Xia
Director
LSI International Inc
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877

Re: K252607
Trade/Device Name: AllTest Urinary Tract Infection Test
Regulation Number: 21 CFR 862.1510
Regulation Name: Nitrite (Nonquantitative) Test System
Regulatory Class: Class I (meets the limitations of exemptions in 862.9(c)(9))
Product Code: JMT, LJX

Dear Jenny Xia:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on October 30, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the 510(k) Summary for K252607, as it was inadvertently excluded from our SE letter dated October 30, 2025.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Paula Caposino, OHT7: Office of In Vitro Diagnostics, 301-796-6160, Paula.Caposino@fda.hhs.gov.

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

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Product Code: JMT, LJX
Dated: August 18, 2025
Received: August 18, 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)*
K252607

Device Name
AllTest Urinary Tract Infection Test

Indications for Use *(Describe)*
The AllTest Urinary Tract Infection Test is 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.

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PRAStaff@fda.hhs.gov

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510(k) SUMMARY
K252607

1. Date: October 22, 2025

2. Submitter: Hangzhou AllTest Biotech Co., Ltd.
No. 550 Yinhai Street
Hangzhou, China

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

4. Device Name: AllTest Urinary Tract Infection Test

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: K231045
Healgen URS Test Strip

6. Intended Use:

The AllTest Urinary Tract Infection Test is 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 AllTest Urinary Tract Infection Test is for the qualitative detection of Leukocytes and Nitrite in human 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. Each device is individually packed in a sealed foil pouch.

8. Substantial Equivalence Information

Item	Device	Predicate – K231045
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	1 minute	2 minutes

9. Test Principle

The AllTest Urinary Tract Infection Test 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 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 device. 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	3	27	90%
0.05	14	16	53%
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 was performed at three different 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 AllTest Urinary Tract Infection Test 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. 211 lay users with UTI symptoms were recruited to test her/his own urine sample using the AllTest Urinary Tract Infection Test. Laypersons performed one test with the AllTest Urinary Tract Infection Test 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:

Results by Health Professionals-Alltest / **Layperson Results**	Large (+++)	Moderate (++)	Small (+)	Trace	Negative	Total
Large (+++)	18	1	0	0	0	19
Moderate (++)	1	39	1	0	0	41
Small (+)	0	2	45	1	0	48
Trace	0	0	3	28	0	31
Negative	0	0	0	1	71	72

Total	19	42	49	30	71	211
% Agreement (Exact Match)	94.7%	92.9%	91.8%	93.3%	100.0%	
% Agreement (+/- Color Block)	100	100	100	100	100	

Results by Health Professionals-Alltest / **Layperson Results**	Positive	Negative	Overall
Positive	100	0	100
Negative	0	111	111
Total	100	111	211
% Agreement (Exact Match)	100	100	

Results by Health Professionals (predicate) / **Layperson Results**	Large (+++)	Moderate (++)	Small (+)	Trace	Negative	Total
Large (+++)	17	2	0	0	0	19
Moderate (++)	1	40	0	0	0	41
Small (+)	0	3	43	2	0	48
Trace	0	0	3	28	0	31
Negative	0	0	0	2	70	72
Total	18	45	46	32	70	211
% Agreement (Exact Match)	94.4%	88.9%	93.4%	87.5%	100.0%	
% Agreement (+/- Color Block)	100	100	100	100	100	

Results by Health Professionals (predicate) / **Layperson Results**	Positive	Negative	Overall
Positive	100	0	100
Negative	1	110	111
Total	101	110	211
% Agreement (Exact Match)	99	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 AllTest Urinary Tract Infection Test is substantially equivalent to the predicate.