April 30, 2026

Hangzhou AllTest Biotech Co., Ltd.
Jenny Xia
Director
LSI International, Inc.
504 E Diamond Ave.
Suite H
Gaithersburg, Maryland 20877

Re: K260342
Trade/Device Name: AllTest Strep A Rapid Test
Regulation Number: 21 CFR 866.3740
Regulation Name: Streptococcus spp. serological reagents
Regulatory Class: Class I
Product Code: GTY
Dated: February 2, 2026
Received: February 2, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology 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)*
K260342

Device Name
AllTest Strep A Rapid Test

Indications for Use *(Describe)*
The AllTest Strep A Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) antigens in throat swab specimens from patients with signs and symptoms of pharyngitis to aid in the diagnosis of Group A Streptococcus infection.
All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

K260342

1. Date: April 21, 2026

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

3. Contact person: Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

4. Device Name: AllTest Strep A Rapid Test
Class: **Class I**

Product Code	**CFR #**	**Panel**
GTY	866.3740 streptococcus spp serological reagents	Microbiology

5. Predicate Devices:
K133343
Wondfo® One Step Strep A Swab Test

6. Intended Use/Indications for Use
The AllTest Strep A Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) antigens in throat swab specimens from patients with signs and symptoms of pharyngitis to aid in the diagnosis of Group A Streptococcus infection.
All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A Streptococcus and should not be used as the sole basis for treatment.

7. Device Description
The AllTest Strep A Rapid Test a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a

procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

8. Substantial Equivalence Information

A summary comparison of features of the AllTest Strep A Rapid Test and the predicate device is provided in Table 1.

Similarities		
Item	**Device**	**Predicate (K133343)**
Intended Use	For the qualitative detection of Strep A antigen from throat swab specimens	Same
Specimen	Throat swab	Same
Assay technical	Immunochromatographic	Same
Test Antibody	Rabbit anti Strep A	Same
Indication for Use	Prescription Use	Same
Differences		
Item	**Device**	**Predicate (K133343)**
Test format	Cassette	Strip
Clinical Sensitivity	95.0% (95% CI: 89.6%-97.7%)	95 %: 95% CI (88-98%)
Clinical Specificity	99.0% (95% CI: 97.5%-99.6%)	98%: 95% CI (96-99%)
Results Reading Time	5 minutes	10 minutes
Analytical sensitivity	1.0×10^4 CFU/swab (2.0×10^5 CFU/mL)	1.5×10^5 CFU/mL
Control Antibodies	Rabbit anti Strep A	Goat polyclonal anti-Strep A

9. Test Principle

Group A *Streptococcus* reacts with the anti-Strep A antibody conjugated to the gold particle. The complex is then bound by the anti-Strep A capture antibody and a visible color test line appears, indicating a positive result. To serve as an onboard procedural control, a control line observed at the control site prior to running the assay will turn red, indicating that the test has been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision/Reproducibility

A test panel consists of a true negative sample (diluent only), a low negative sample ($1.0\text{x}10^5$ CFU/mL), a moderate positive sample (6.0×10^5 CFU /mL) and a LoD sample (2.0×10^5 CFU/mL) were tested. Three lots of the device are used. The study is performed at two runs per day in 5 different days at three different sites. Six professional operators who don't know the sample number code participated in the study (two operators at each site). Each operator tests two runs per day at each concentration with three lots of AllTest Strep A Rapid Test. A total of 30 determinations by each operator at each concentration are made. The obtained results are shown in the following table.

Results / Samples	Positive Agreement % (Positive/Total tested)			Overall Positive Detection
	Site A	Site B	Site C	
True negative sample (Diluent only)	0%(0/60)	0%(0/60)	0%(0/60)	0%(0/180)
Moderate positive sample, 6.0×10^5 CFU/mL	100%(60/60)	100%(60/60)	100%(60/60)	100%(180/180)
LoD sample, 2.0×10^5 CFU/mL	96.7%(58/60)	95.0%(57/60)	95.0%(57/60)	95.6%(172/180)
Low negative sample, 1.0×10^5 CFU/mL	51.7%(31/60)	46.7%(28/60)	48.3%(29/60)	48.9%(88/180)

It's concluded that there are no significant differences of the test results obtained between different users, different sites and different lots in different days. The obtained results are reproducible in good precision.

b. Linearity

Not applicable

c. Stability

Stable at 2-30℃ for 24 months based on real time stability determination at both 2ºC and 30ºC.

d. LoD

The limit of detection (LoD) for the AllTest Strep A Rapid Test was established using limiting dilutions of *Streptococcus pyogenes* and tested by spiking with clinical matrix. A concentrated stock (6.0×10^9 CFU/mL) of inactivated *S. pyogenes* ATCC 12365 was serially diluted in saline solution. 50 µL of each contrived dilution sample was pipetted onto negative throat swab clinical matrix for testing. Each dilution was tested by seven operators with three lots of AllTest Strep A Rapid Test, for a total of 21 results for each dilution. The test results are shown in the following table.

Table: Determining Limit of Detection (LoD) for AllTest Strep A Rapid Test in clinicalmatrix

Dilutions	Concentration	Positive/Tested	% Detection
1/10000	6.0×10^5CFU/mL	21/21	100%
1/30000	2.0×10^5CFU/mL	20/21	95.2%
1/60000	1.0×10^5CFU/mL	10/21	47.6%
1/120000	5.0×10^4CFU/mL	3/21	14.3%
1/300000	2.0×10^4CFU/mL	0/21	0%

The LoD was determined to be 2.0×10^5 CFU/mL when 50 µL of sample was pipetted onto a negative clinical matrix (equivalent to 1.0×10^4 CFU per swab).

The LoD for the AllTest Strep A Rapid Test was also examined by using limiting dilutions of different strains of *S. pyogenes* in saline and pipetting 50 µL of each dilution onto a swab with the clinical matrix. All data showed inclusivity for the six different strains with the following summary data.

Strains	Detection Conc.(CFU/mL)	Positive/Tested	% Detection

ATCC# 14289	$2.0x10^4$	9/9	100%
ATCC# 19615	$1.0x10^3$	9/9	100%
ATCC# 49399	$1.0x10^4$	9/9	100%
ATCC# 12344	$5.0x10^3$	9/9	100%
ATCC# 700294	$2.0x10^4$	9/9	100%
Zeptometrix 0801512	$5.0x10^5$	9/9	100%

e. Interference

The potentially interfering substances of blood, mucus, saliva, and medications used to relieve a sore throat, such as over-the-counter cough drops, lozenges, cough syrups, throat sprays, mouth wash etc. were tested with AllTest Strep A Rapid Test. Each potentially interfering substance was diluted and split into two aliquots. One aliquot was spiked with *S. pyogenes* to a final concentration of 4.0×10^5 CFU/ml. The second aliquot contained no bacteria. These aliquot samples were tested by three batches of AllTest Strep A Rapid Test. Three laboratory assistants with relevant experience performed the test. The obtained results are shown in the following table.

Interfering Substance	**Concentration Tested**	***S. pyogenes* Positive specimen（2×LOD）**			***S. pyogenes* Negative Specimen**		
		Lot1	**Lot2**	**Lot3**	**Lot1**	**Lot2**	**Lot3**
Blood (human)	20% (vol/vol)	+	+	+	-	-	-
Mucin	1mg/mL	+	+	+	-	-	-
OTC Mouthwashes							
Listerine Antiseptic Cool Mint	20%(vol/vol)	+	+	+	-	-	-
Crest Pro-Health Clean Mint	20%(vol/vol)	+	+	+	-	-	-
Crest Pro Health Multi Protection Clean Mint	20%(vol/vol)	+	+	+	-	-	-
Colgate Total Pro-Shield Spearmint	20%(vol/vol)	+	+	+	-	-	-
OTC Lozenges							
Sucrets Sore Throat & Cough Lozenges, Honey Lemon,	5mg/mL	+	+	+	-	-	-
Sucrets Sore Throat Lozenges Cherry	5mg/mL	+	+	+	-	-	-
Halls Mentho-Lyptus Drops Cherry	5mg/mL	+	+	+	-	-	-
Halls Cough Suppressant Cherry Triple Soothing Action	5mg/mL	+	+	+	-	-	-
Cepacol Extra Strength Sore Throat & Cough Drop Lozenges, Cherry	5mg/mL	+	+	+	-	-	-
OTC Throat Sprays							
Mucinex Sore Throat + Pain	20%(vol/vol)	+	+	+	-	-	-

Relief							
Chloraseptic Max	20%(vol/vol)	+	+	+	-	-	-
OTC Cough Syrups							
Tylenol Cough and Sore Throat	10%(vol/vol)	+	+	+	-	-	-
Basic Care Tussin DM, Cough Suppressant & Expectorant	10%(vol/vol)	+	+	+	-	-	-
Robitussin (Guaifenesin Syrup)	10%(vol/vol)	+	+	+	-	-	-
Robitussin Nighttime Cough	10%(vol/vol)	+	+	+	-	-	-
Children's Dimetapp Cold & Flu	10%(vol/vol)	+	+	+	-	-	-
Children's Dimetapp Cold & Cough	10%(vol/vol)	+	+	+	-	-	-
Active Ingredients							
Acetaminophen (Tylenol)	5mg/mL	+	+	+	-	-	-
Brompheniramine Maleate	5mg/mL	+	+	+	-	-	-
Chlorpheniramine Maleate	5mg/mL	+	+	+	-	-	-
Dextromethorphan HBr	5mg/mL	+	+	+	-	-	-
Diphenhydramine HCI	5mg/mL	+	+	+	-	-	-
Doxylamine Succinate	5mg/mL	+	+	+	-	-	-
Guaifenesin(Guaiacol Glyceryl)	5mg/mL	+	+	+	-	-	-
Ibuprofen (Advil)	5mg/mL	+	+	+	-	-	-
Phenylephrine HCI	5mg/mL	+	+	+	-	-	-

Neither false positive nor false negative results are shown in the AllTest Strep A Rapid Test at the concentrations listed.

f. Analytical Specificity

Analytical specificity (cross-reactivity) of AllTest Strep A Rapid Test was carried out for organisms likely to be found in the respiratory tract. It was tested by three lots of AllTest Strep A Rapid Test. Three professional users performed the test. The obtained results are summarized in the following table.

Organisms	**Concentration Tested**	**Test results**		
		Lot1	**Lot2**	**Lot3**
Adenovirus 3	$1.05\times10^{6}TCID_{50}$/ml	-	-	-
Adenovirus 7	$8.89\times10^{5}TCID_{50}$/ml	-	-	-
Adenovirus Type I	$1.15\times10^{7}TCID_{50}$/ml	-	-	-
Adenovirus Type II	$1.6\times10^{8}TCID_{50}$/ml	-	-	-
Arcanobacterium haemolyticum	1×10^{9}CFU/ml	-	-	-
Bordetella pertussis	1×10^{9}CFU/ml	-	-	-

Candida albicans	1×10^9CFU/ml	-	-	-
Corynebacterium diphtheria	1×10^9CFU/ml	-	-	-
Cytomegalovirus	$5.01\times10^5TCID_{50}$/ml	-	-	-
Enterococcus faecalis	1×10^9CFU/ml	-	-	-
Enterococcus faecium	1×10^9CFU/ml	-	-	-
Enterovirus (VR-28 Human Coxsackievirus)	3.4×10^8TCID50/mL	-	-	-
Epstein Barr Virus	2.23×10^7copies/ml	-	-	-
Escherichia coli	1×10^9CFU/ml	-	-	-
Fusobacterium necrophorum	1×10^9CFU/ml	-	-	-
Haemophilus influenzae	6.97×10^8CFU/ml	-	-	-
Haemophilus parahaemolyticus	1×10^9CFU/ml	-	-	-
Haemophilus parainfluenzae	3.97×10^7CFU/ml	-	-	-
HSV Type 1 MacIntyre strain	3.16×10^6TCID50/mL	-	-	-
Human coronavirus OC43	1.05×10^6TCID50/mL	-	-	-
Human metapneumovirus (HMPV-27 A2)	$3.55\times10^5TCID_{50}$/ml	-	-	-
Human parainfluenza Type 1	$1.02\times10^8TCID_{50}$/ml	-	-	-
Human parainfluenza Type 2	$1.6\times10^6TCID_{50}$/ml	-	-	-
Human parainfluenza Type 3	$1.6\times10^8TCID_{50}$/ml	-	-	-
Human rhinovirus 26	6.1×10^6TCID50/mL	-	-	-
Klebsiella pneumoniae	1×10^9CFU/ml	-	-	-
Lactobacillus sp. (Lactobacillus casei)	1×10^9CFU/ml	-	-	-
Legionella pneumophila	1×10^9bacteria/ml	-	-	-
Measles Virus	$8.9\times10^5TCID_{50}$/ml	-	-	-
Moraxella (Branhamella) catarrhalis	1×10^9CFU/ml	-	-	-
Moraxella lacunata	1×10^9CFU/ml	-	-	-
Mumps virus	$2.8\times10^6TCID_{50}$/ml	-	-	-
Mycobacterium tuberculosis	1×10^9bacteria/ml	-	-	-
Mycobacterium tuberculosis (avirulent strain)	1.3×10^9CFU/ml	-	-	-
Neisseria gonorrhoeae	1×10^9CFU/ml	-	-	-
Neisseria lactamica	1×10^9CFU/ml	-	-	-
Neisseria meningitides	1×10^9CFU/ml	-	-	-
Neisseria mucosa	1×10^9CFU/ml	-	-	-
Neisseria sicca	1×10^9CFU/ml	-	-	-
Neisseria subflava	1×10^9CFU/ml	-	-	-
Proteus vulgaris	1×10^9CFU/ml	-	-	-
Pseudomonas aeruginosa	1×10^9CFU/ml	-	-	-
Respiratory syncytial virus Type A	1.6×10^8PFU/ml	-	-	-
Respiratory syncytial virus Type B	$8.9\times10^5TCID_{50}$/ml	-	-	-

Serratia marcescens	1×10^9CFU/ml	-	-	-
Staphylococcus aureus	1×10^9CFU/ml	-	-	-
Staphylococcus epidermidis	1×10^9CFU/ml	-	-	-
Staphylococcus haemolyticus	1×10^9CFU/ml	-	-	-
Staphylococcus marcescens	5.7×10^8CFU/ml	-	-	-
Streptococcus agalactiae (Group B)	1×10^9CFU/ml	-	-	-
Streptococcus anginosus (Group G)	1×10^9CFU/ml	-	-	-
Streptococcus dysgalactiae (Group C)	4.14×10^8CFU/ml	-	-	-
Streptococcus mitis	1×10^9CFU/ml	-	-	-
Streptococcus mutans	1×10^9CFU/ml	-	-	-
Streptococcus oralis	1×10^9CFU/ml	-	-	-
Streptococcus pneumoniae	7.22×10^8CFU/ml	-	-	-
Streptococcus salivarius	1×10^9CFU/ml	-	-	-
Streptococcus sanguis	1×10^9CFU/ml	-	-	-
Streptococcus sp. (bovis II) Group D	3.7×10^9CFU/ml	-	-	-
Streptococcus sp. Strain H60R (Group F)	2.3×10^7CFU/ml	-	-	-
Yersinia enterocolitica	1×10^9CFU/ml	-	-	-

No cross reactivity was found for the above organisms at the concentrations tested.

2. Comparison Studies

   NA

3. Clinical Studies

   A total of 525 subjects with symptoms of Strep A were enrolled in the study. Of the 525 total specimens, 121 were found to be positive (+) by culture and 404 were found to be negative (-) by culture. These test results are summarized in the following tables.

AllTest Strep A Rapid Test	Culture Comparator		
	Positive	Negative	Total
Positive	115	4	119
Negative	6	400	406
Total	121	404	525
Sensitivity	95.0% (95% CI: 89.6%-97.7%)		
Specificity	99.0% (95% CI: 97.5%-99.6%)		

Age	**Sensitivity**	**Sensitivity (95% CI)**	**Specificity**	**Specificity (95% CI)**
0-5	96.6% (56/58)	88.3%-99.0%	98.7% (147/149)	95.2%-99.6%
6-21	92.7% (51/55)	82.7%-97.1%	99.1% (214/216)	96.7%-99.7%
21+	100% (8/8)	67.6%-100%	100% (39/39)	91.0%-100%
Total	95.0% (115/121)	89.6%-97.7%	99.0% (400/404)	97.5%-99.6%

There were no statistical differences in the AllTest Strep A Rapid Test performance between the age groups. The overall clinical sensitivity is 95.0%. The overall clinical specificity is 99.0%.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, LoD, interference, specificity and clinical study of the device, it's concluded that AllTest Strep A Rapid Test is substantially equivalent to the predicate.