July 15, 2025

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

Re: K251053
Trade/Device Name: Shinetell Plus™ Digital Early Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: June 3, 2025
Received: June 3, 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,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.07.15 10:23:07 -04'00'

Joseph Kotarek
Branch Chief, Toxicology Branch
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)*
K251053

Device Name
Shinetell PlusTM Digital Early Pregnancy Test

Indications for Use *(Describe)*
Shinetell PlusTM Digital Early Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

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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510(k) SUMMARY
K251053

1. Date: June 29, 2025

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

2. Contact person:
Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Fax: 301-916-6213
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3. Device Name: Shinetell Plus™ Digital Early Pregnancy Test

Classification: Class II
Product Code: LCX
CFR: 21 CFR 862.1155

4. Predicate Devices: Wondfo One Step HCG Urine Pregnancy Test Midstream, Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, K150022

5. Intended Use

Shinetell Plus™ Digital Early Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

6. Device Description

Shinetell Plus™ Digital Early Pregnancy Test is used for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, and is designed to be tested in dip or midstream mode. The test device consists of a single test strip assembled in a plastic housing, with an absorbent tip. The device is in a ready-to- use format.

Shinetell Plus™ Digital Early Pregnancy Test uses lateral flow immunoassay and light reflection for the detection of the HCG in urine specimens. The test would detect the light intensity by using the LED as the light source. After that, the result can be displayed on the display screen.

7. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device
Intended use	A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.	Same
Specimen	Urine	Urine
Assay technical	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	10 mIU/mL	10 mIU/mL
Results	Qualitative	Qualitative
Target user	Over the counter use	Over the counter use
Differences		
Item	Device	Predicate
Readout	Digital/LCD screen	Visual Testing Line
Time to result	3 minutes	5 minutes
Format	Midstream	Strip, cassette, midstream

8. Test Principle

Human chorionic gonadotropin (HCG) is a glycoprotein produced by the placenta during pregnancy. Shinetell Plus™ Digital Early Pregnancy Test uses lateral flow immunoassay and light reflection for the detection of the HCG in urine specimens. After the appropriate urine sample is added to the absorbent tip, the clock symbol will appear and blink on the Display Screen after urine is applied, indicating the test is working. The HCG in urine specimen will react with the anti-β-HCG antibody-colloidal gold conjugate and form a compound. As the liquid flows to the Test area of the test strip, the compound will be captured by the anti-α-HCG antibody immobilized on the Test area, then a colored line will be formed on the Test area.

The test would detect the light intensity by using the LED as the light source. The

background of the LED lighted zone will be darker due to the color of colloidal gold conjugate, and the intensity of the reflected light received by the photodiode decreases significantly. By detecting the signal parameter of the reflected light intensity, which is decreasing significantly, the test can determine that the sample is added properly. The LED light will irradiate the test strip and then be reflected to the photodiode and the photodiode can respond to the different light intensity value by testing the intensity of reflected light.
In approximately 3 minutes, the result will be shown on the display screen. If test value is over the preset threshold, the test result is positive and "Pregnant" is displayed on the screen. Otherwise, the result is negative and "Not Pregnant" is displayed on the screen.
If the sample is added improperly, the background color of the LED lighted zone does not decrease significantly. By detecting the signal parameter of the reflected light intensity, which isn't decreasing significantly, the test can determine that the sample is added improperly, and the test will be invalid and "?" is displayed on the screen

9. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility/Sensitivity
Negative female urine was spiked with hCG standard (Traceable to the 5th WHO) to hCG concentrations of 0, 3, 5, 7.5, 8, 10, 25 and 50 mIU/mL. Each sample was tested by both dip and midstream methods in 10 replicates per day for 5 days for each device lot. Total of three device lots were tested. Tests were performed by three different operators for each sample concentration.
The results are summarized in the table below:
Midstream Testing

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100	0
3	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
7.5	35	15	35	15	36	14	106	44	70.7	29.3
8	25	25	24	26	24	26	73	77	48.7	51.3
10	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100
50	0	50	0	50	0	50	0	150	0	100

Dip Testing

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100	0
3	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
7.5	35	15	36	14	36	14	107	43	71.3	28.7
8	24	26	24	26	24	26	72	78	48	52
10	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100
50	0	50	0	50	0	50	0	150	0	100

Shinetell Plus™ Digital Early Pregnancy Test exhibited reproducible results. Based on the above results, the sensitivity of Shinetell Plus™ Digital Early Pregnancy Test is demonstrated to be 10 mIU/mL.

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

c. Hook effect test:

Negative urine samples were spiked with varying hCG concentrations (6,250 mIU/mL, 12,500 mIU/mL, 25,000 mIU/mL, 50,000 mIU/mL, 100,000 mIU/mL, 200,000 mIU/mL and 500,000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

d. Traceability, Stability, Expected values (controls, calibrators, or methods): Traceability:

Shinetell Plus™ Digital Early Pregnancy Test is calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:

Products in sealed foil pouch are stable for 24 months at 35.6-86°F, based on the real time stability study.

e. Specificity and cross reactivity

To evaluate specificity, 300 urine samples were collected from healthy, non-pregnant female in pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old) groups. 100 people for each age group. Both dip and midstream testing are evaluated. No false positive results were observed for any of the age groups.

To evaluate cross-reactivity, negative and positive urine samples (0, 5 and 10 mIU/mL hCG) were spiked with potential cross reactants (1000 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). No cross-reactivity was observed at tested concentration.

To evaluate the effect of the hCG β-core fragment, Negative urine samples (0 and 5 mIU/mL hCG) and positive urine samples (10 and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment (hCGβcf) at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000pmol/L and 500,000pmol/L. The performance of Shinetell Plus™ Digital Early Pregnancy Test i s not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

f. Interfering substance

To evaluate potential interferers with Shinetell Plus™ Digital Early Pregnancy Test, urine samples containing 0, 5 and 10 mIU/mL hCG were spiked with the interfering substance to obtain the certain desired test concentration. No interference effect was observed at the tested concentration shown in table below:

Substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Albumin	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6ug/dL
Ethanol	1.0%
Bilirubin	2mg/dL
Pregnanediol	1500μg/dL
Thiophene	20 mg/dL
Ketone	20 mg/dL

To evaluate the effect of urine pH on the results of Shinetell Plus™ Digital Early Pregnancy Test, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that urine pH ranges between 4 and 9 does not affect the performance of Shinetell Plus™ Digital Early Pregnancy Test.

To evaluate the effect of urine density on the results of Shinetell Plus™ Digital Early Pregnancy Test, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.011, 1.015, 1.019, 1.024, 1.029 and 1.035. The results indicated that urine with a relative density of 1.000 to 1.035 does not affect the performance of Shinetell Plus™ Digital Early Pregnancy Test.

B. Method comparison study

Method comparison with predicate device

The performance of the new device was compared to the predicate test. Urine samples were collected from 200 women presenting to test for pregnancy. All of these women were suspected to be pregnant in the early stage of less than 5 weeks. All samples were tested with candidate and predicate devices at three POC sites.

Dip Testing

Pregnancy Test (Shinetell Plus™)	Predicate Test (Wondfo test)		Total
	Positive (+)	Negative (-)	
Positive (+)	49	0	49
Negative (-)	0	51	51
Total	49	51	100

Midstream Testing

Pregnancy Test (Shinetell Plus™)	Predicate Test (Wondfo test)		Total
	Positive (+)	Negative (-)	
Positive (+)	48	0	48
Negative (-)	0	52	52
Total	48	52	100

The conformity between Shinetell Plus™ Digital Early Pregnancy Test and the predicate device is 100%.

C. Lay person study

200 women's individual pregnancy status was self-tested using either in-stream method or dip method. Individuals with varying educational and occupational

backgrounds from three sites were chosen for the study. Each subject tested her own urine sample using the device according to the package insert and provided a sample for professional testing.

Summary

In-Stream Method		**Professional Result**		**Total**
		Positive	**Negative**	
Lay user Result	**Positive**	48	0	48
	Negative	0	52	52
Total		48	52	100

Dip Method		**Professional Result**		**Total**
		Positive	**Negative**	
Lay user Result	**Positive**	49	0	49
	Negative	0	51	51
Total		49	51	100

From the above tables, the lay person results showed 100% positive and 100% negative conformity with the professional results.

Spiked urine samples were also tested by lay person. Urine samples were prepared at 5mIU/ml, 7.5mIU/ml, 8mIU/ml and 10mIU/ml hCG concentrations by spiking hCG into negative pooled urine specimens. Each sample was aliquoted into individual containers and blind-labeled. These samples were tested by 200 lay persons.

Lay person vs Professional

hCG Concentrations	Lay person results		Professional results		Percent Agreement
	No. of Negative	No. of Positive	No. of Negative	No. of Positive	
5 mIU/ml	100	0	100	0	100%
7.5 mIU/ml	71	29	69	31	98%
8 mIU/ml	50	50	52	48	98%
10 mIU/ml	0	100	0	100	100%

Each lay person was given a questionnaire to assess the readability of the labeling. The results of the questionnaire reflected that the consumers found the test easy to use and that they did not have trouble understanding the labeling and interpreting

the results.

D. Early Pregnancy Test Study

In this study, total 650 urine samples from 65 characterized cycle segments of conceptive cycles were collected from 65 pregnant women. All samples were masked and randomized. Each sample was tested both in-stream and dip methods using three lots of the device. The new device detected 67.7% positive hCG five days before the Expected Menstrual Period (EMP), and 100% positive hCG on the day of EMP. No differences were observed between different test methods. The following table is the summary of the data.

Day relative to Expected Menstrual Period(EMP)	Number of Positive	Number of Negative	Number of Total	% Positive
EMP-8	3	62	65	4.6%
EMP-7	8	57	65	12.3%
EMP-6	23	42	65	35.3%
EMP-5	44	21	65	67.7%
EMP-4	56	9	65	86.2%
EMP-3	62	3	65	95.4%
EMP-2	64	1	65	98.5%
EMP-1	65	0	65	100.0%
EMP	65	0	65	100.0%
EMP+1	65	0	65	100.0%

10. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the device, it's concluded that Shinetell Plus™ Digital Early Pregnancy Test is substantially equivalent to the predicate.