August 13, 2024

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

Re: K241978
Trade/Device Name: Shinetell™ Digital Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: July 4, 2024
Received: July 5, 2024

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.

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 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241978

Device Name

ShinetellTM Digital Pregnancy Test

Indications for Use *(Describe)*

ShinetellTM Digital Pregnancy Test is a pregnancy test. It is used for the qualitative detection of hCG in human urine as an aid in early detection of pregnancy. For in vitro diagnostic use, for over the counter use.

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
K241978

1. Date: July 1, 2024

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 20877
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4. Device Name: Shinetell™ Digital Pregnancy Test
Classification: Class II
Product Code: LCX
CFR: 862.1155

5. Predicate Devices: MissLan™ Digital Pregnancy Rapid Test (K222305)

6. Intended Use

Shinetell™ Digital Pregnancy Test is a pregnancy test. It is used for the qualitative detection of hCG in human urine as an aid in early detection of pregnancy. For in vitro diagnostic use, for over the counter use.

7. Device Description

Shinetell™ Digital 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™ Digital 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.

8. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device

Intended use	Early detection of pregnancy	Early detection of pregnancy
Specimen	Urine	Urine
Assay technical	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	25 mIU/mL	25 mIU/mL
Results	Qualitative	Qualitative
Target user	Over the counter use	Over the counter use
Sample application	Midstream and dip methods	Midstream and dip methods
Readout	Digital/LCD screen	Digital/LCD screen
Differences		
Item	Device	Predicate
Appearance	152.4 x 24 x 16.5 mm	155.5 x 21.5 x 14.5 mm
Display Results	"Pregnant" or "Not Pregnant"	"+" or "-"

9. Test Principle

Human chorionic gonadotropin (HCG) is a glycoprotein produced by the placenta during pregnancy. Shinetell™ Digital 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 midstream 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 midstream can determine that the sample is adding 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 adding 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 midstream can determine that the sample is adding improperly, and the test will be invalid and "?" is displayed on the screen.

10. 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, 12.5, 15, 18.75, 22.5, 25, 50, 100 and 200 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)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot 1		Lot 2		Lot 3					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
12.5	50	0	50	0	50	0	150	0	100%	0%
15	22	28	24	26	23	27	69	81	46%	54%
18.75	13	37	12	38	12	38	37	113	25%	75%
22.5	5	45	5	45	5	45	15	135	10%	90%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%
100	0	50	0	50	0	50	0	150	0%	100%
200	0	50	0	50	0	50	0	150	0%	100%

Dip Testing

hCG Concentration (mIU/mL)	Operator 1		Operator 2		Operator 3		Total result		% Negative	% Positive
	Lot 1		Lot 2		Lot 3					
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
12.5	50	0	50	0	50	0	150	0	100%	0%
15	23	27	25	25	25	25	73	77	49%	51%
18.75	12	38	13	37	12	38	37	113	25%	75%
22.5	5	45	6	44	5	45	16	134	11%	89%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%
100	0	50	0	50	0	50	0	150	0%	100%

200	0	50	0	50	0	50	0	150	0%	100%

Overall Testing

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	100	0	100	0	100	0	300	0	100%	0%
12.5	100	0	100	0	100	0	300	0	100%	0%
15	45	55	49	51	48	52	142	158	47%	53%
18.75	25	75	25	75	24	76	74	226	25%	75%
22.5	10	90	11	89	10	90	31	269	10%	90%
25	0	100	0	100	0	100	0	300	0%	100%
50	0	100	0	100	0	100	0	300	0%	100%
100	0	100	0	100	0	100	0	300	0%	100%
200	0	100	0	100	0	100	0	300	0%	100%

Shinetell™ Digital Pregnancy Test exhibited reproducible results.
Based on the above results, the sensitivity of Shinetell™ Digital Pregnancy Test is demonstrated to be 25 mIU/mL.

b. Linearity/assay reportable range:
Linearity is not applicable since this is a qualitative test. The test device was evaluated for high dose or hook effect.

Hook effect test:
Negative female 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) and were tested with 3 lots of the candidate device. 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.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Traceability:
Shinetell™ Digital Pregnancy Test is calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:
Shinetell™ Digital Pregnancy Test is stable for 24 months at 2°C to 30°C based on real time stability study.

d. Specificity and cross reactivity
To evaluate specificity, 300 female urine samples were collected from healthy,

non-pregnant females in pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old), and post-menopausal (>55 years old) groups. A total of 100 samples from each age group were collected and these samples were tested by lay persons using both dip and midstream methods. No false positive results were observed for any of the age groups.

To evaluate cross-reactivity, negative and positive female urine samples (0, 5 and 25 mIU/mL hCG) were spiked with potential cross reactants (500 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 female urine samples (0 and 5 mIU/mL hCG) and positive female urine samples (25 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™ Digital Pregnancy Test is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

e. Interfering substance

To evaluate potential interferers with Shinetell™ Digital Pregnancy Test, urine samples containing 0, 5 and 25 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**
Glucose	2000 mg/dL
Albumin	2000 mg/dL
Bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Uric acid	23.5 mg/dL
Acetaminophen	20 mg/dL
Amoxicillin	20 mg/dL
Aspirin	80 mg/dL
Gentisic acid	20 mg/dL
Salicylic Acid	20 mg/dL
Ascorbic acid	20 mg/dL
Folic acid	0.03 mg/dL
Vitamin B1	80 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Ibuprofen	40 mg/dL
Pregnanediol	1.5 mg/dL
β-hydroxybutyrate	2000 mg/dL

EDTA	80 mg/dL
Ethanol	1%
Ketone	20 mg/dL
Thiophene	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL

To evaluate the effect of urine pH on the results of Shinetell™ Digital Pregnancy Test, urine samples containing 0, 5 and 25 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™ Digital Pregnancy Test.

To evaluate the effect of urine density on the results of Shinetell™ Digital Pregnancy Test, urine samples containing 0, 5 and 25 mIU/mL hCG were tested at density values of 1.000, 1.004, 1.009, 1.015, 1.021, 1.026, 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™ Digital 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 subjects were suspected to be pregnant and they are all in the early stage of less than 5 weeks. All samples were tested with candidate and predicate devices at three POC sites (3 different professionals using the candidate device and 1 professional using the predicate device at each site).

Summary midstream testing results

Midstream method		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	52	0	52
	Negative	0	48	48
	Total	52	48	100

Summary dip testing results

Dip method		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	41	0	41
	Negative	0	59	59
	Total	41	59	100

The conformity between Shinetell™ Digital Pregnancy Test (midstream method / dip method) and the predicate device is 100%.

C. Lay person study

First study:

200 women's individual pregnancy status was self-tested. 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

Midstream method		Professional		
		Positive	Negative	Total
Layperson	Positive	47	0	47
	Negative	0	53	53
	Total	47	53	100

Dip method		Professional		
		Positive	Negative	Total
Layperson	Positive	46	0	46
	Negative	0	54	54
	Total	46	54	100

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

Second study:

Negative urine sample pools were spiked with 5 mIU/mL hCG and 25 mIU/mL hCG. All aliquots were blind labeled by the person who prepared the samples and didn't take part in the sample testing. Both laypersons and professionals use dip method to test the above samples. 100 laypersons tested the 5 mIU/mL hCG aliquots and 100 laypersons tested the 25 mIU/mL hCG aliquots. Each testing site had a study administrator to observe or monitor the studies by laypersons without providing assistance to the participants.

Summary

hCG Concentration (mIU/mL)	Lay person result		Professional result		The percentage of correct results (%)
	No. of Positive	No. of Negative	No. of Positive	No. of Negative	
5	0	100	0	100	100%
25	100	0	100	0	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.

11. Conclusion

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