February 28, 2023

Guangzhou Decheng Biotechnology Co., Ltd.
% Joe Shia, Director
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K230038
Trade/Device Name: MissLan® Pregnancy Rapid Test (Strip), MissLan® Pregnancy Rapid Test (Midstream)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: January 5, 2023
Received: January 6, 2023

Dear Joe Shia:

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Caposino -S
Digitally signed by Paula Caposino -S
Date: 2023.02.28 17:36:04 -05'00'

Paula Caposino, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230038

Device Name
MissLan® Pregnancy Rapid Test (Strip)
MissLan® Pregnancy Rapid Test (Midstream)

Indications for Use *(Describe)*
MissLan® Pregnancy Rapid Test (Strip) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment. Only for use outside the body. For over the counter use.

MissLan® Pregnancy Rapid Test (Midstream) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment. Only for use outside the body. 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.

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

K230038

1. Date: February 26, 2023

2. Submitter: Guangzhou Decheng Biotechnology Co., Ltd.
Building 2, No.68, Nanxiang 1st Road, Science City, Huangpu District, Guangzhou, Guangdong, 510000, China

3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4. Device Name: MissLan® Pregnancy Rapid Test (Strip)
MissLan® Pregnancy Rapid Test (Midstream)
Classification: Class II
Product Code: LCX
CFR: 862.1155

5. Predicate Devices: One Step HCG Urine Pregnancy Test (K043443)

6. Intended Use

MissLan® Pregnancy Rapid Test (Strip) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment. Only for use outside the body. For over the counter use.

MissLan® Pregnancy Rapid Test (Midstream) is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment. Only for use outside the body. For over the counter use.

7. Device Description

MissLan® Pregnancy Rapid Test will be sold in Midstream and Strip format. The Midstream format consists of a single test strip assembled in a plastic housing, with an absorbent tip, and is designed to be tested in dip or midstream mode. The Strip format is a single test strip. The Midstream format contains one Test Midstream sealed in a desiccated aluminum pouch and Instructions for Use. The Strip format contains one Test strip sealed in a desiccated aluminum pouch, Urine Collection Cup and Instructions for Use. The device is in a ready-to-use format and does not require assembly before use.

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
Read time	3-5 minutes	3-5 minutes
Differences		
Item	Device	Predicate
Device format	Midstream, Strip	Midstream, Strip, Cassette
Target user	Over the counter use	For over-the-counter and professional use

9. Test Principle

MissLan® Pregnancy Rapid Test uses lateral flow immunoassay for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. If hCG is present in the sample, it will reach the Test Zone ("T") of the membrane and form a colored line. When the test is performed properly, a colored line will always appear in the Control Zone ("C"). The test result is shown in the result window and read visually between 3 and 5 minutes of urine application. Two distinct colored lines, one in the Test Zone and another in the Control Zone indicate a positive test result (pregnant). Absence of a colored line in the Test Zone and only a colored line in the Control Zone indicates a negative test result (not pregnant). Absence of a colored line in the Control Zone even in the presence of a colored line in the Test Zone indicates an invalid test result.

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 in 10 replicates per day for 5 days for each device lot. Total of three device lots for each format were tested. Tests were performed by three different operators for each sample concentration.
The results are summarized in the table below:

Midstream format (in-stream method)

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	25	25	26	24	23	27	74	76	49.3%	50.7%
18.75	12	38	13	37	12	38	37	113	24.7%	75.3%
22.5	5	45	4	46	4	46	13	137	8.7%	91.3%
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%

Midstream format (dip method)

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	25	25	27	23	24	26	76	74	50.7%	49.3%
18.75	12	38	13	37	13	37	38	112	25.3%	74.7%
22.5	5	45	5	45	4	46	14	136	9.3%	90.7%
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%

Strip format

hCG Concentration	Operator 1	Operator 2	Operator 3	Total result	% Negative	% Positive

(mIU/mL)	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	25	25	24	26	24	26	73	77	48.7%	51.3%
18.75	11	39	12	38	13	37	36	114	24.0%	76.0%
22.5	5	45	4	46	5	45	14	136	9.3%	90.7%
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%

MissLan® Pregnancy Rapid Test exhibited reproducibility of results.
Based on the above results, the sensitivity of MissLan® Pregnancy Rapid 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 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.

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

Stability:
A 32-month real time stability test is planned to verify the shelf-life stability of the device. Three batches for each format in sealed foil pouch are currently stable for 30 months at 2°C and 30°C, and the real time stability study is still on going.

d. Specificity and cross reactivity
To evaluate specificity, 450 urine samples were collected from normal, non-pregnant female in pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old) groups. 150 people for each age group. In each age group, 50 participants were tested with test strip, 50 participants were tested with test midstream using dip method, and 50 participants

tested with test midstream using in-stream method. No false positive results were observed for any of the age groups.

To evaluate cross-reactivity, negative and positive 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 urine samples (0 and 5 mIU/mL hCG) and positive 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 MissLan® Pregnancy Rapid Test is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

e. Interfering substance

To evaluate potential interferers with MissLan® Pregnancy Rapid 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 MissLan® Pregnancy Rapid 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 MissLan® Pregnancy Rapid Test.

To evaluate the effect of urine density on the results of MissLan® Pregnancy Rapid Test, urine samples containing 0, 5 and 25 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that urine with a relative density of 1.000 to 1.035 does not affect the performance of MissLan® Pregnancy Rapid 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. Approximately half of the 200 women were suspected to be pregnant and most of them are 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). The same samples were tested on both format by different operators.

The results are summarized in the table below.

Candidate device		Predicate device		
		Positive	Negative	Total
Strip Device	Positive	101	0	101
	Negative	0	99	99
	Total	101	99	200

Candidate device		Predicate device		
		Positive	Negative	Total
Midstream Device In-stream method	Positive	52	0	52
	Negative	0	48	48

	Total	52	48	100

Candidate device		Predicate device		
		Positive	Negative	Total
Midstream Device Dip method	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

The conformity between MissLan® Pregnancy Rapid Test 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.

The results are summarized in the table below.

Strip Device

Strip format		Professional		
		Positive	Negative	Total
Layperson	Positive	52	0	52
	Negative	0	48	48
	Total	52	48	100

Midstream Device

Midstream format (in-stream method)		Professional		
		Positive	Negative	Total
Layperson	Positive	26	0	26
	Negative	0	24	24
	Total	26	24	50

Midstream format (dip method)		Professional		
		Positive	Negative	Total
Layperson	Positive	23	0	23
	Negative	0	27	27
	Total	23	27	50

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

Second study:

200 women's individual pregnancy status was self-tested. 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. 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		The percentage of correct results (%)
	No. of Positive	No. of Negative	
5	0	100	100%
25	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, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that MissLan® Pregnancy Rapid Test (Strip) and MissLan® Pregnancy Rapid Test (Midstream) are substantially equivalent to the predicate.