510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222305

B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

C Proprietary and Established Names

MissLan™ Digital Pregnancy Rapid Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - Human Chorionic Gonadotropin (hCG) Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Human Chorionic Gonadotropin (hCG)

C Type of Test:

Qualitative chromatographic immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MissLan™ Digital Pregnancy Rapid Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in 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.

C Special Conditions for Use Statement(s):

OTC - Over the Counter

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

The MissLan™ Digital Pregnancy Rapid Test is a lateral flow immunoassay with a digital display for detection of hCG. The test is packaged as a single test or as two tests, assembled in a plastic housing with an absorbent tip and includes a package insert with instructions. The device can be used in both dip and midstream modes. The result is displayed digitally by using a light source to detect a colored test. It is for over-the-counter use.

B Principle of Operation:

The MissLan™ Digital Pregnancy Rapid Test is a lateral flow immunoassay. To use the test, the user either 1) dips the absorbent tip into the urine for 10 seconds or 2) uses the midstream technique to place the absorbent tip into the stream of urine for 10 seconds. The user then places the test on a flat surface. As the liquid flows to the test area of the test strip, hCG in the urine specimen reacts with the anti-βhCG antibody-colloidal gold conjugate to form a compound. The compound is captured by the anti-αhCG antibody immobilized on the test area. A colored test line will develop if the hCG concentration is above the threshold, indicating a positive result. If there is no hCG in the urine, no colored line develops in the test zone, indicating a negative result. A colored line will develop in the control zone if sufficient sample volume has been applied to the test strip.

The MissLan™ Digital Pregnancy Rapid Test utilizes a light emitting diode (LED) as a light source and light reflection to determine the presence or absence of the colored test and control lines. After adding the sample, the hourglass symbol will flash until two beeps are heard, indicating sufficient sample collection time. Within 5 minutes two beep sounds will be heard, the

hourglass symbol will disappear, and the result will be shown on the display screen. If the test result is positive, a "+" symbol is displayed on the screen. If the result is negative, a "-" symbol is displayed on the screen. If the test result is invalid, a book symbol is displayed on the screen.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Preview® Digital Pregnancy Test

B Predicate 510(k) Number(s):

K173229

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222305	K173229
Device Trade Name	MissLan™ Digital Pregnancy Rapid Test	Preview® Digital Pregnancy Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of hCG to aid in the early detection of pregnancy	Same
Test Principle	Chromatographic immunoassay	Same
Sample Matrix	Urine	Same
hCG Sensitivity	25 mIU/mL	Same
Sample Application	Midstream and dip methods	Same
General Device Characteristic Differences		
Traceability	Traceable to the 5th World Health Organization (WHO) International Standard	Traceable to the 4th World Health Organization (WHO) International Standard
Time to Result	5 minutes	Between 3 to 5 minutes

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A pooled negative female human urine sample was spiked with hCG to provide nine urine samples with hCG concentrations of 0, 12.5, 15, 18.75, 22.5, 25, 50, 100 and 200 mIU/mL. Each sample was tested using 3 lots of the MissLan™ Digital Pregnancy Rapid Test. The tests were performed in replicates of 10, over the course of 5 non-consecutive days by 3 different operators using both the dip and midstream method. Each operator conducted testing using one lot. A total of 150 tests per concentration were performed per sampling method. The device cutoff is 25 mIU/mL hCG.

Overall midstream method precision results

hCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
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	24	26	24	26	71	79	47	53
18.75	12	38	11	39	11	39	34	116	23	77
22.5	5	45	5	45	6	44	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 dip method precision results

hCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
0	50	0	50	0	50	0	150	0	100	0
12.5	50	0	50	0	50	0	150	0	100	0
15	24	26	24	26	25	25	73	77	49	51
18.75	12	38	11	39	12	38	35	115	23	77
22.5	4	46	5	45	5	45	14	136	9	91
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

2. Linearity:

Not applicable. This is a qualitative device.

3. Analytical Specificity/Interference:

Cross-reactivity:
The candidate device was tested for potential cross-reactivity from luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH). Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels of 0 mIU/mL, 5 mIU/mL and 25 mIU/mL that were then spiked with each cross reactants at the following concentrations: 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH. Samples were tested in replicates of 3 with 3 lots of the candidate device. The results demonstrated no cross reactivity at the LH, FSH and TSH concentrations tested in either negative or positive urine samples.

Interference:
A urine pool from non-pregnant females was used to prepare samples with hCG levels of 5 mIU/mL and 25 mIU/mL that were then spiked with potentially interfering exogenous and endogenous substances (test samples). Samples were tested in 3 replicates on 3 lots by 3 operators on the candidate device. The results demonstrated no interference from substances at the concentrations shown in the table below.

Potentially interfering substances tested

Substance tested	Highest concentration tested that demonstrated no interference (mg/dL)
Acetaminophen	20
Salicylic acid	20
Albumin	2000
Amoxicillin	20
Ampicillin	20
Ascorbic acid	20
Aspirin	80
Atropine	20
β-hydroxybutyrate	2000
Benzoylecgonine	10
Bilirubin	40
Caffeine	20
EDTA	80
Ethanol	1% v/v
Folic acid	0.03
Gentisic acid	20
Glucose	2000
Hemoglobin	1000
Ibuprofen	40
Ketone	20

Substance tested	Highest concentration tested that demonstrated no interference (mg/dL)
Phenylpropanolamine	20
Pregnanediol	1.5
Tetracycline	20
Thiophene	20
Cannabinol	10
Ephedrine	20
phenothiazine	20
Uric acid	23.5
Vitamin B1	80

Effect of hCG β-core fragment:
Negative female urine samples (0 and 5 mIU/mL hCG) and positive urine samples (25 mIU/mL and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L and 500,000 pmol/L. The results demonstrated that the candidate device is not affected by concentrations of hCG beta-core fragment up to 500,000 pmol/L.

Effect of urine pH:
To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL, 5 mIU/mL, and 25 mIU/mL hCG were adjusted to pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and tested using the candidate device. The results demonstrated that changes in pH ranging from 4.0 to 9.0 do not interfere with either positive or negative results from the device.

Effect of urine specific gravity
To evaluate potential interference from changes in specific gravity, urine samples containing 0 mIU/mL, 5 mIU/mL, and 25 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.020, 1.030 and 1.035. The results demonstrated that changes in specific gravity ranging from 1.000 to 1.035 do not interfere with either positive or negative results from the device.

High dose hook effect study:
Negative pooled female urine samples spiked with varying hCG concentrations (6,250, 12,500, 25,000, 50,000, 100,000, 200,000, and 500,000 mIU/mL) were tested on 3 lots of the candidate device. No hook effect was observed at concentrations up to 500,000 mIU/mL hCG.

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The MissLan™ Digital Pregnancy Rapid Test is traceable to the 5th World Health Organization (WHO) International Standard for hCG, NIBSC code 07/364.

6. Detection Limit:

The detection limit was determined in the precision study (see Section VII.A.1. above).

7. Assay Cut-Off:

The device's cut-off is 25 mIU/mL. See Precision/Reproducibility (Section VII.A.1.) section above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A total of 200 urine samples were collected from women with ages ranging from 18 to 45 years, who presented to 3 clinics for pregnancy testing. Approximately half of the 200 women were suspected to be pregnant and most of them were in the early stages of pregnancy (less than 5 weeks). The samples were masked and randomized prior to testing by professionals using the candidate device (in dip mode and midstream mode) and the predicate device (Preview® Digital Pregnancy Test; in dip mode and midstream mode). One hundred (100) samples were tested per sampling mode across 3 lots. A summary of the results is presented in the table below:

Midstream method

Midstream method		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	55	0	55
	Negative	0	45	45
	Total	55	45	100

Dip method

Dip method		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	47	0	47
	Negative	0	53	53
	Total	47	53	100

The data show that the agreement of the MissLan™ Digital Pregnancy Rapid Test with the predicate device was 100%.

2. Matrix Comparison:

Not Applicable. The device is intended for urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:

   Not Applicable

2. Clinical Specificity:

   Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

a. Lay User Study:

A lay user study was conducted at 3 sites with 200 volunteers with diverse educational and occupational background who were between the ages of 18 and 45. This included 100 lay users using the dip method and 100 lay users using the midstream method. The lay users tested their own urine sample and provided a sample for professional testing. Ease of use of the candidate device was assessed through a questionnaire that was completed at the end of the study. The questionnaire results indicated that lay users found the test easy to use, the results clear and easy to read and the instructions for use easy to understand. The data show that the agreement between lay user results and professional results was 100%.

Lay user study results:

Midstream method		Professional user		
		Positive	Negative	Total
Lay user	Positive	55	0	55
	Negative	0	45	45
	Total	55	45	100

Dip method		Professional user		
		Positive	Negative	Total
Lay user	Positive	55	0	55
	Negative	0	45	45
	Total	55	45	100

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.