510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K251040

B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

C Proprietary and Established Names

MissLan® Early Detection Digital Pregnancy Test; MissLan® Early Result Digital Pregnancy 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

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® Early Detection Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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® Early Result Digital Pregnancy Test is used for qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine. This test is intended for use as an aid in early detection of pregnancy, in some cases as early as six (6) days before the day of the missed period, i.e. as early as five (5) days before the day of the expected period. 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:

Not applicable.

IV Device/System Characteristics:

A Device Description:

MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test are digital tests that consist of a single test strip assembled in plastic housing with an absorbent tip. They tests are powered by battery and the testing results are displayed on an LCD screen. The MissLan® Early Detection Digital Pregnancy Test displays test results with graphic symbols: “+” (pregnant), “-” (not pregnant) and “*(image of an open book)*” (invalid); the MissLan® Early Result Digital Pregnancy Test displays test results with text, including "Pregnant", "Not Pregnant" and “Error”. The tests can be used in midstream or dip mode and are provided in ready-to use formats in a sealed pouch with instructions for use

B Principle of Operation:

MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test use a lateral flow immunoassay and light reflection for in vitro qualitative detection of human chorionic gonadotropin (hCG) in human urine, with sensitivity of 10 mIU/mL. Testing is conducted by immersing the absorbent tip in urine or urinating on the absorbent tip until the user hears two beeps (roughly 10 seconds). If hCG is present in the urine sample, it will react with the anti-β-HCG antibody-colloidal gold conjugate and form a compound. As the liquid flows to the test line of the test, the compound will be captured by the

anti-α-HCG antibody immobilized on the test line, then a colored line will form. The device will detect the light intensity by using the LED as the light source. After that, the result is shown on the display screen within 5 minutes, accompanied by two beeps.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test Midstream

B Predicate 510(k) Number(s):
K150022

C Comparison with Predicate(s):

Device & Predicate Device(s):	K251040	K150022
Device Trade Name	MissLan® Early Detection Digital Pregnancy Test; MissLan® Early Result Digital Pregnancy Test	Wondfo One Step HCG Urine Pregnancy Test (Strip, Cassette, Midstream)
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of human chorionic gonadotropin (hCG) in human urine as an aid in early detection of pregnancy	Same
Sample Matrix	Urine	Same
Claimed Analytical Sensitivity	10 mIU/mL	Same
Methodology	Immunochromatographic Assay	Same
General Device Characteristic Differences		
Intended Use Environment	Over-the-counter use	Prescription Use and Over-the-counter use
Device Format	Midstream (and Dip)	Strip, Cassette, Midstream
Powered	Battery-powered	No battery
Traceability	World Health Organization (WHO) 5th International Standard	World Health Organization (WHO) 4th International Standard
Results Display Format	Digitally displayed; Graphic Symbols: "+", "-" or "book" (invalid) Text: "Pregnant", "Not Pregnant", or "Error"	Non-digital, analog display, visual lines; 2 lines = Pregnant 1 line = Not Pregnant No line = Invalid

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A pooled urine sample from non-pregnant females (negative) was spiked with hCG to provide nine urine samples with hCG concentrations of 0, 2.5, 5, 6, 7, 8, 10, 15, and 25 mIU/mL. Each sample was tested using 3 lots of the MissLan® Early Detection Digital Pregnancy Test and 3 lots of the MissLan® Early Result Digital Pregnancy Test. Testing was performed using both the midstream sampling method and dip sampling method. The tests were performed in replicates of 10, over the course of 5 days by 3 different operators for each sample concentration. A total of 150 tests per concentration were performed per tested sampling method. The device cut-off is 10 mIU/mL hCG.

Summary of MissLan® Early Detection Digital Pregnancy Test testing in midstream mode

hCG concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
0	50	0	50	0	50	0	150	0	100	0
2.5	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
6	39	11	39	11	38	12	116	34	77	23
7	23	27	24	26	22	28	70	80	46	54
8	14	36	15	35	14	36	45	105	29	71
10	0	50	0	50	0	50	0	150	0	100
15	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100

Summary of MissLan® Early Detection Digital Pregnancy Test testing in dip mode

hCG concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
0	50	0	50	0	50	0	150	0	100	0
2.5	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
6	39	11	39	11	39	11	117	33	78	22
7	22	28	22	28	22	28	66	84	44	56
8	13	37	14	36	14	36	42	108	27	73
10	0	50	0	50	0	50	0	150	0	100
15	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100

Summary of MissLan® Early Result Digital Pregnancy Test testing in midstream mode

hCG concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
0	50	0	50	0	50	0	150	0	100	0
2.5	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
6	37	13	38	12	38	12	113	37	75	25
7	23	27	25	25	23	27	76	74	47	53
8	13	37	14	36	13	37	40	110	27	73
10	0	50	0	50	0	50	0	150	0	100
15	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100

Summary of MissLan® Early Result Digital Pregnancy Test testing in dip mode

hCG concentration (mIU/mL)	Operator 1 Lot 1		Operator 2 Lot 2		Operator 3 Lot 3		Total number of results		Overall precision	
	-	+	-	+	-	+	-	+	% Negative	% Positive
0	50	0	50	0	50	0	150	0	100	0
2.5	50	0	50	0	50	0	150	0	100	0
5	50	0	50	0	50	0	150	0	100	0
6	38	12	38	12	38	12	114	36	76	24
7	23	27	24	26	23	27	70	80	47	53
8	13	37	13	37	13	37	39	111	26	74
10	0	50	0	50	0	50	0	150	0	100
15	0	50	0	50	0	50	0	150	0	100
25	0	50	0	50	0	50	0	150	0	100

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Interference from endogenous and exogenous compounds:
To evaluate potential interference from certain exogenous and endogenous compounds, negative urine from healthy non-pregnant females containing 0 mIU/mL, 5mIU/mL, and 10 mIU/mL hCG were spiked with potentially interfering substances at the concentrations listed below. Samples were tested using 3 different lots of the MissLan® Early Detection Digital Pregnancy Test and 3 different lots of the MissLan® Early Result Digital Pregnancy Test in triplicate by 3 operators. No interference was observed at the concentrations shown in the table below:

Substance Tested	Highest Concentration tested that demonstrated no interference
Acetaminophen	20 mg/dL
Acetylsalicylic acid	80 mg/dL
Albumin	2000 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Benzoylecgonine	10 mg/dL
Bilirubin	40 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Codeine	0.006 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1%
Folic Acid	0.03 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	1000 mg/dL
Ibuprofen	40 mg/dL
Ketone	20 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic Acid	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Uric Acid	23.5 mg/dL
Vitamin B1	80 mg/dL

Cross-reactivity of similar compounds:
Negative and positive urine samples (0 mIU/mL, 5 mIU/mL and 10 mIU/mL hCG) were spiked with potential cross reactants: 500 mIU/mL luteinizing hormone (hLH), 1000 mIU/mL follicle-stimulating hormone (hFSH), 1 mIU/mL thyroid-stimulating hormone (hTSH). The samples were tested in replicates of 10 by 3 operators, using 3 lots of each device. No cross reactivity was observed at the tested concentrations.

Effects of urine pH:
A study was performed to evaluate the effects of pH on the device. Negative urine (0 mIU/mL and 5 mIU/mL) and positive urine (10 mIU/mL) were adjusted to have pH values of 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0. Samples were tested in replicates of 3, by 3 operators, using 3 lots of each device. The results demonstrated that urine pH levels between the ranges of 4.0 and 9.0 do not affect test performance.

Effects of urine specific gravity:
A study was performed to evaluate the effects of urine specific gravity on the device. Negative urine (0 mIU/mL) and positive urine (10 mIU/mL hCG) samples were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, and 1.035. Samples were tested in replicates of 3, by 3 operators, using 3 lots of each device. The results demonstrated that urine with specific gravity ranging from 1.000 and 1.035 does not affect test performance.

High dose hook effect study:
Negative urine samples were spiked with hCG at concentrations of ranging from 6,250 mIU/mL to 500,000 mIU/mL. Three lots of each device were tested by 3 different operators. The results demonstrated that no hook effect was observed at hCG concentrations up to 500,000 mIU/mL.

Effects of hCG β-core fragment:
Testing was performed to evaluate whether high levels of beta core fragment interfere with the device. Negative urine samples (0 mIU/mL and 5 mIU/mL hCG) and positive urine samples (10 mIU/mL 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, 250,000 pmol/L, and 500,000 pmol/L. All samples were tested in replicates of 10 using 3 lots of both devices. The results show that the devices were not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

4. Assay Reportable Range:

   Not applicable.

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

   MissLan® Early Detection Digital Pregnancy Test and MissLan® Early Result Digital Pregnancy Test are calibrated against reference material traceable to the WHO International Standard 5th edition, NIBSC code 07/364.

6. Detection Limit:

   A detection limit study was performed using negative female urine samples spiked with hCG traceable to the WHO 5th IS for hCG to obtain concentrations of 0, 2.5, 5, 6, 7.5, 8, 10, 15, 25 mIU /ml hCG. The samples were measured in 10 replicates, two runs a day, using 3 lots for each device. Both dip and midstream sampling modes were evaluated. The tests were performed by six operators who each tested a single lot separately. The claimed analytical sensitivity or cutoff is 10 mIU/mL hCG.

   Assay Cut-Off:

   The device's cut-off is 10 mIU/mL. See Precision/Reproducibility (Section VII.A.I.) section Above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

A total of 400 urine samples were collected from women whose ages ranged from 18 – 51 years, who presented to 3 clinics for pregnancy testing. Approximately 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 3 lots of the MissLan® Early Detection Digital Pregnancy Test, 3 lots of the MissLan® Early Result Digital Pregnancy Test, and a single lot of the predicate device (Wondfo® Early Result Pregnancy Test Strip). Two hundred (200) urine samples were tested using the MissLan® Early Detection Digital Pregnancy Test and 200 urine samples were tested using the MissLan® Early Result Digital Pregnancy Test, with each format testing 100 samples in the dip sampling mode and 100 samples tested in midstream sampling mode. A summary of the results is presented in the tables below:

Summary results of MissLan® Early Detection Digital Pregnancy Test (dip sampling mode)

Candidate device	Predicate Device		
	Positive	Negative	Total
Positive	48	0	48
Negative	0	52	52
Total	48	52	100

Summary results of MissLan® Early Detection Digital Pregnancy Test (midstream sampling mode)

Candidate device	Predicate Device		
	Positive	Negative	Total
Positive	51	0	51
Negative	0	49	49
Total	51	49	100

Summary results of MissLan® Early Result Digital Pregnancy Test (dip sampling mode)

Candidate device	Predicate Device		
	Positive	Negative	Total
Positive	49	0	49
Negative	0	51	51
Total	49	51	100

Summary results of MissLan® Early Result Digital Pregnancy Test (midstream sampling mode)

Candidate device	Predicate Device		
	Positive	Negative	Total
Positive	48	0	48
Negative	0	52	52
Total	48	52	100

2. Matrix Comparison:

Not applicable. This assay is only intended for use with human urine samples.

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):

Lay-User Study
A lay user study was performed at three sites with a total of 400 women ranging in age from 18 – 51. Participants had varying educational and occupational backgrounds. Each subject tested her own urine sample using the device according to the instructions for use and provided a sample for professional testing. One hundred (100) subjects tested with the MissLan® Early Detection Digital Pregnancy Test using dip method, 100 subjects tested with the MissLan® Early Detection Digital Pregnancy Test using midstream method, 100 subjects tested with the MissLan® Early Result Digital Pregnancy Test using dip method, and 100 subjects tested with the MissLan® Early Result Digital Pregnancy Test using midstream method. The data demonstrated 100% agreement between lay user results and professional results.

Summary results of MissLan® Early Detection Digital Pregnancy Test (dip sampling mode)

		Professional Results		
		Positive	Negative	Total
Layperson Results	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

Summary results of MissLan® Early Detection Digital Pregnancy Test (midstream sampling mode)

		Professional Results		
		Positive	Negative	Total
Lay person Results	Positive	51	0	51
	Negative	0	49	49
	Total	51	49	100

Summary results of MissLan® Early Result Digital Pregnancy Test (dip sampling mode)

		Professional Results		
		Positive	Negative	Total
Layperson Results	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

Summary results of MissLan® Early Result Digital Pregnancy Test (midstream sampling mode)

		Professional Results		
		Positive	Negative	Total
Lay person Results	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

Participants also completed a questionnaire in which they reported that testing was easy to perform and instructions were easy to follow.

Lay User Spiked Sample Study:

Negative urine sample pools were spiked with 5 mIU/mL, 6 mIU/mL, 7 mIU/mL and 10 mIU/mL hCG. All aliquots were blind-labeled by the person who prepared the samples and didn't take part in the sample testing. A total of 200 laypersons performed the testing, of which 100 used the MissLan® Early Detection Digital Pregnancy Test, and 100 used the MissLan® Early Result Digital Pregnancy Test. Each layperson tested 4 blind-labeled samples (5 mIU/mL, 6 mIU/mL, 7 mIU/mL and 10 mIU/mL), and an aliquot of each of the spiked urine samples was also tested by the professional. The results are summarized in the tables below:

Summary of MissLan® Early Detection Digital Pregnancy Test testing

hCG Concentration (mIU/mL)	Layperson results			Professional Results			Percent Agreement
	# of Positives	# of Negatives	% Positive	# of Positive	# of Negative	% Positive	
5	0	100	0	0	100	0	100%
6	24	76	24%	22	78	22%	98%
7	49	51	49%	51	49	51%	98%
10	100	0	100%	100	0	100%	100%

Summary of MissLan® Early Result Digital Pregnancy Test testing

hCG Concentration (mIU/mL)	Layperson results			Professional Results			Percent Agreement
	# of Positives	# of Negatives	% Positive	# of Positive	# of Negative	% Positive	
5	0	100	0%	0	100	0	100%
6	22	78	22%	23	77	23%	99%
7	48	52	48%	51	49	52%	97%
10	100	0	100%	100	0	100%	100%

Early Pregnancy Detection Study

A total of 650 urine samples were collected from 65 women from the intended use population who were later confirmed to be pregnant via ultrasound. The women ranged in age from 18 – 45 years old and testing was conducted starting on 8 days before the expected menstrual period (EMP-8) to one day after (EMP+1). Each sample was tested using one lot each of the MissLan® Early Detection Digital Pregnancy Test and the MissLan® Early Result Digital Pregnancy Test both in dip and midstream sampling mode. Representative results are summarized in the table below:

MissLan® Early Detection Digital Pregnancy Test (midstream sampling method)

Days Relative to EMP	Total (n)	Positive (n)	% Positive
-8	65	2	3
-7	65	7	11
-6	65	26	40
-5	65	51	79
-4	65	63	97
-3	65	65	100
-2	65	65	100
-1	65	65	100
0	65	65	100
+1	65	65	100

Specificity Study to Determine False-Positive Result Rate:

A study was performed to determine the incidence of false positive test results. Six hundred (600) non-pregnant females in pre-menopausal (18-40 years old), peri-menopausal (41-55 years old) and post-menopausal (>55 years old) age groups at three sites (200 subject per age group) were self-tested. In each age group, 100 subjects tested with MissLan® Early Detection Digital Pregnancy Test (50 using dip method, 50 using midstream method) and the other 100 subjects tested with MissLan® Early Result Digital Pregnancy Test (50 using dip method, 50 using midstream method). Three lots of each device were used in the study. Results of the study are shown in the tables below:

MissLan® Early Detection Digital Pregnancy Test

Age group	Lot I	Lot II	Lot III	Total Results	Total % Positive
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-	0
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-	0
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-	0

MissLan® Early Result Digital Pregnancy Test

Age group	Lot I	Lot II	Lot III	Total Results	Total % Positive
Pre-menopausal	0+/34-	0+/33-	0+/33-	0+/100-	0
Peri-menopausal	0+/33-	0+/34-	0+/33-	0+/100-	0
Post-menopausal	0+/33-	0+/33-	0+/34-	0+/100-	0

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.