510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K240643

B Applicant

Guangzhou Decheng Biotechnology Co., Ltd.

C Proprietary and Established Names

MissLan® Early Detection Pregnancy Test Strip; MissLan® Early Detection Pregnancy Test Cassette; MissLan® Early Detection Pregnancy Test Midstream

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 lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

MissLan® Early Detection Pregnancy Test Strip 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.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

MissLan® Early Detection Pregnancy Test Cassette 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.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

MissLan® Early Detection Pregnancy Test Midstream 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.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

C Special Conditions for Use Statement(s):
OTC - Over The Counter

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

The device is intended for home-use only and not intended for clinical-care settings.

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The test comes in three formats (strip, cassette, and midstream) named MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream, respectively. The strip format is a single test strip. The cassette format consists of a single test strip assembled in a plastic housing. A urine collection cup and a dropper are included in the packaging. The strip and cassette formats are designed to be used in dip sampling mode only. 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 in-stream sampling modes. Each device type is packaged sealed with a desiccant and instructions for use. The result is displayed within the test window by two distinct colored lines, one control line (C) and one test line (T).

B Principle of Operation:

The MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream are lateral flow immunoassays for in vitro qualitative detection of human chorionic gonadotropin (hCG) in human urine. The devices utilize a combination of antibodies to detect hCG in urine as well as to serve as a run control. Each device contains mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on the sample pad. Mouse monoclonal anti-α-hCG antibody (on the test line) and goat anti mouse IgG polyclonal antibody (on the control line) are coated and immobilized on a nitrocellulose membrane. The test result is shown in the test window and is read visually between 3 and 10 minutes of urine application. If hCG is present in the sample, a colored line will appear in the test zone (T) indicating a positive test result (pregnant). If there is no hCG or levels are below the claimed cut-off in the urine, a colored line in the test zone (T) will be absent, indicating a negative test result (not pregnant). The control line (C line) should develop in the control zone regardless of the test result on both tests. If the control line (C line) does not appear (no color appears at the control line after application of the sample), the test is invalid.

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):	K240643	K150022
Device Trade Name	MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, MissLan® Early Detection Pregnancy Test Midstream	Wondfo One Step HCG Urine Pregnancy Test Strip, Wondfo One Step HCG Urine Pregnancy Test Cassette, Wondfo One Step HCG Urine Pregnancy Test 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
Early Detection Claim	Pregnancy can be detected 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	Same
Specimen type	Urine	Same
Methodology	Immunochromatographic assay	Same
Claimed analytical sensitivity	10 mIU/mL	Same
Device format	Strip, cassette, midstream	Same

Device & Predicate Device(s):	K240643	K150022
General Device Characteristic Differences		
Target User	Over-the-counter, home use only	Prescription and over-the-counter use
Read Time	3-10 minutes	5 minutes
Traceability	World Health Organization (WHO) 5th International Standard (IS)	World Health Organization (WHO) 4th International Standard (IS)

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A precision study was performed on the MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and the MissLan® Early Detection Pregnancy Test Midstream. For the MissLan® Early Detection Pregnancy Test Midstream format, both in-stream and dip sampling modes were tested. The samples were prepared by spiking negative female urine with hCG traceable to the 5th WHO international standard to obtain samples with hCG contractions of 0, 3, 3.5, 5, 6.5, 7.5, 10, 15 and 25 mIU/mL. Samples were tested in replicates of ten per day for five days for each device lot by three operators. A total of three device lots for each format were tested and each operator tested one lot separately. The results are summarized in the table below.

   Summary of MissLan® Early Detection Pregnancy Test Strip

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
3.5	44	6	45	5	45	5	134	16	89.33%	10.67%
5	36	14	37	13	36	14	109	41	72.67%	27.33%
6.5	27	23	23	27	26	24	76	74	50.67%	49.33%
7.5	10	40	13	37	13	37	36	114	24.00%	76.00%

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Negative	% Positive
	-	+	-	+	-	+	-	+		
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 Pregnancy Test Cassette

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
3.5	45	5	45	5	45	5	135	15	90.00%	10.00%
5	37	13	35	15	35	15	107	43	71.33%	28.67%
6.5	23	27	26	24	24	26	73	77	48.67%	51.33%
7.5	11	39	13	37	10	40	34	116	22.67%	77.33%
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 Pregnancy Test Midstream (in-stream sampling mode)

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
3.5	45	5	45	5	45	5	135	15	90.00%	10.00%
5	37	13	36	14	37	13	110	40	73.33%	26.67%
6.5	24	26	26	24	24	26	74	76	49.33%	50.67%
7.5	11	39	12	38	14	36	37	113	24.67%	75.33%
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 Pregnancy Test Midstream (dip sampling mode)

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
3	50	0	50	0	50	0	150	0	100%	0%
3.5	45	5	44	6	45	5	134	16	89.33%	10.67%
5	37	13	36	14	35	15	108	42	72.00%	28.00%
6.5	23	27	24	26	26	24	73	77	48.67%	51.33%
7.5	12	38	14	36	9	41	35	115	23.33%	76.67%
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%

Because the device detects low levels of hCG that could be found in some non-pregnant women, the sponsor included a limitation in the labeling (see Section III.C. above).

2. Linearity:

Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

Interference from exogenous and endogenous substances:
To evaluate potential interference from certain exogenous and endogenous substances, negative urine samples from non-pregnant healthy females were used to prepare samples with hCG concentrations of 0 mIU/mL, 3 mIU/mL, and 10 mIU/mL, which were then spiked with potentially interfering substances at the concentrations listed below. Samples were tested by three operators, in triplicate, using three device lots. No interference was observed at the concentrations shown in the table below:

Substance	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
Benzoylecgonine	10 mg/dL
Bilirubin	40 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
Codeine	6 µg/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
β -hydroxybutyrate	2000 mg/dL

Cross-reactivity of Structurally Related Compounds:
To evaluate cross-reactivity, negative urine samples (0 mIU/mL) and negative urine samples spiked with hCG levels of 3 mIU/mL and 10 mIU/mL were spiked with the following potential cross reactants: 500 mIU/mL luteinizing hormone (hLH), 1000 mIU/mL follicle-stimulating hormone (hFSH), and 1 mIU/mL thyroid-stimulating hormone (hTSH). The samples were tested in replicates of ten using three device lots by three different operators. The results demonstrated that no cross-reactivity from potential cross- reactants was observed at the tested concentrations.

Effects of Urine pH:
A study was performed to evaluate the effects of pH on device performance. Negative female urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 3 mIU/mL and 10 mIU/mL were adjusted to have pH values of 4.0, 5.0, 6.0, 7.0, 8.0, and 9.0. The negative and positive hCG samples with the different pH levels were tested in triplicate using three lots of the device by three operators. 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.

Effects of Urine Specific Gravity:
A study was performed to evaluate the effects of urine specific gravity on device performance. Negative female urine samples (0 mIU/mL) and negative samples spiked with hCG to levels of 3 mIU/mL and 10 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The negative and positive hCG samples with the different specific gravity levels were tested in triplicate using three device lots by three operators. 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.

Hook Effect:
Negative female urine samples were spiked with hCG at concentrations of 6,250, 12,500, 25,000, 50,000, 100,000, 200,000, and 500,000 mIU/mL. The samples were tested in replicates of five using three device lots by three operators. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

Effects of hCG β-core fragment:
Interference testing was performed to evaluate whether high levels of β-core (hCGβcf) fragment interfere with device performance. Four different female urine sample pools (spiked to contain 0, 3, 10, and 20,000 mIU/mL hCG) were spiked with hCGβcf at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000 pmol/L, and 500,000 pmol/L. The samples were tested in replicates of ten using three lots of the device by three operators. The results demonstrated that the device is not affected by hCGβcf 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 Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream are calibrated against the World Health Organization (WHO) International Standard (IS) 5th edition, NIBSC code 07/364.

6. Detection Limit:

   A detection limit study was performed using negative female urine samples spiked with 0, 3, 3.5, 5, 6.5, 7.5, 10, 15 and 25 mIU/mL hCG (hCG traceable to the 5th WHO IS). The samples were tested using all three device formats (MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream). For the MissLan® Early Detection Pregnancy Test

Midstream format, both in-stream and dip sampling modes were tested. The samples were tested using three device lots of each test format, with two runs per day, ten replicates per run, by six different operators.

Summary of MissLan® Early Detection Pregnancy Test Strip

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Positive
	-	+	-	+	-	+	-	+	
0	20	0	20	0	20	0	60	0	0%
3	20	0	20	0	20	0	60	0	0%
3.5	18	2	18	2	18	2	54	6	10.00%
5	15	5	14	6	14	6	43	17	28.33%
6.5	10	10	10	10	9	11	29	31	51.67%
7.5	4	16	5	15	4	16	13	47	78.33%
10	0	20	0	20	0	20	0	60	100%
15	0	20	0	20	0	20	0	60	100%
25	0	20	0	20	0	20	0	60	100%

Summary of MissLan® Early Detection Pregnancy Test Cassette

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Positive
	-	+	-	+	-	+	-	+	
0	20	0	20	0	20	0	60	0	0%
3	20	0	20	0	20	0	60	0	0%
3.5	18	2	18	2	17	3	53	7	11.67%
5	14	6	15	5	15	5	44	16	26.67%
6.5	9	11	11	9	10	10	30	30	50.00%
7.5	5	15	4	16	5	15	14	46	76.67%
10	0	20	0	20	0	20	0	60	100%
15	0	20	0	20	0	20	0	60	100%
25	0	20	0	20	0	20	0	60	100%

Summary of MissLan® Early Detection Pregnancy Test Midstream (in-stream sampling mode)

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Positive
	-	+	-	+	-	+	-	+	
0	20	0	20	0	20	0	60	0	0%
3	20	0	20	0	20	0	60	0	0%
3.5	18	2	18	2	17	3	53	7	11.67%
5	14	6	15	5	15	5	44	16	26.67%
6.5	9	11	11	9	10	10	30	30	50.00%
7.5	5	15	4	16	5	15	14	46	76.67%
10	0	20	0	20	0	20	0	60	100%
15	0	20	0	20	0	20	0	60	100%
25	0	20	0	20	0	20	0	60	100%

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

hCG Concentration (mIU/mL)	Lot I		Lot II		Lot III		Total results		% Positive
	-	+	-	+	-	+	-	+	
0	20	0	20	0	20	0	60	0	0%
3	20	0	20	0	20	0	60	0	0%
3.5	17	3	18	2	18	2	53	7	11.67%
5	15	5	15	5	15	5	45	15	25.00%
6.5	9	11	10	10	10	10	29	31	51.67%
7.5	5	15	4	16	4	16	13	47	78.33%
10	0	20	0	20	0	20	0	60	100%
15	0	20	0	20	0	20	0	60	100%
25	0	20	0	20	0	20	0	60	100%

The claimed sensitivity or cut-off of the candidate device is 10 mIU/mL. See also Section VII.A.1. above for additional precision/reproducibility information.

7. Assay Cut-Off:

The device claimed cut-off is 10 mIU/mL hCG. See Detection Limit (Section VII.A.6) and Precision/Reproducibility (Section VII.A.1) sections above.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Urine samples were collected from a total of 400 women suspected of pregnancy with ages ranging from 18 to 51 years. Approximately half of the pregnant subjects were in the early stage of pregnancy (less than 5 weeks). Samples were masked and randomized by people

who labeled the samples but did not participate in the testing. A total of 100 samples were tested for each format of the device (MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream). For the MissLan® Early Detection Pregnancy Test Midstream format, both in-stream and dip sampling modes were tested. All samples were tested by three professionals at each site using the candidate device and by one professional at each site using the predicate device.

Summary of MissLan® Early Detection Pregnancy Test Strip

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

Summary of MissLan® Early Detection Pregnancy Test Cassette

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

Summary of MissLan® Early Detection Pregnancy Test Midstream (in-stream sampling mode)

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

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

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

The test performance of the MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and the MissLan® Early Detection Pregnancy Test Midstream are 100% concordant when compared to the predicate.

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):

Detection of hCG in Early Pregnancy Clinical Samples:
A total of 650 urine samples were collected from 65 women between the ages of 18 to 45 who planned to become pregnant and were later confirmed via ultrasound to be pregnant. The testing was conducted starting from 8 days before the expected menstrual period to the first day after the expected menstrual period (EMP+1). Each sample was tested using the MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and the MissLan® Early Detection Pregnancy Test Midstream. For the MissLan® Early Detection Pregnancy Test Midstream format, both in-stream and dip sampling modes were tested. The same results were observed for all three device formats and both sampling modes of the Midstream format. The following is a representative summary for the result for all conditions tested which supports the claim of detecting pregnancy 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).

Days Relative to EMP	Total (n)	Positive (n)	% Positive
-8	65	1	1.54
-7	65	8	12.31
-6	65	25	38.46
-5	65	50	76.92
-4	65	63	96.92
-3	65	65	100.00
-2	65	65	100.00
-1	65	65	100.00
0	65	65	100.00
+1	65	65	100.00

Lay User Study:
A lay-user study was performed with a total of 400 women with varying educational and occupational backgrounds with an age range of 18 to 51 years old at three clinical sites. A

total of 100 lay users tested MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, MissLan® Early Detection Pregnancy Test Midstream. For the MissLan® Early Detection Pregnancy Test Midstream format, both in-stream and dip sampling modes were tested. Lay users tested their own urine specimen. Each lay user also provided a sample for professional testing. Lay-user results compared professional user results are shown below. The data demonstrated 100% agreement between lay-user results and professional results.

Summary of MissLan® Early Detection Pregnancy Test Strip

Strip format		Professional		
		Positive	Negative	Total
Layperson	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

Summary of MissLan® Early Detection Pregnancy Test Cassette

Cassette format		Professional		
		Positive	Negative	Total
Layperson	Positive	51	0	51
	Negative	0	49	49
	Total	51	49	100

Summary of MissLan® Early Detection Pregnancy Test Midstream (in-stream sampling mode)

Midstream format (in-stream method)		Professional		
		Positive	Negative	Total
Layperson	Positive	49	0	49
	Negative	0	51	51
	Total	49	51	100

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

Midstream format (dip method)		Professional		
		Positive	Negative	Total
Layperson	Positive	48	0	48
	Negative	0	52	52
	Total	48	52	100

Ease of use of each device format was also assessed and demonstrated that users found the test easy to perform and that all of the lay persons carried out the test correctly.

Lay User Spiked Sample Study:
In a separate study, a total of 300 lay users (100 each using MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, MissLan® Early

Detection Pregnancy Test Midstream using the dip sampling mode) tested four urine samples spiked with 3, 3.5, 6.5, and 10 mIU/mL hCG. Samples were blinded and the order of testing was randomized. Professionals also conducted testing with the spiked urine samples. A comparison of lay user and professional results for each urine sample and sampling method is shown below.

Summary of MissLan® Early Detection Pregnancy Test Strip

hCG Concentration (mIU/mL)	Layperson result		Professional result		
	Number of Positive	Number of Negative	Number of Positive	Number of Negative	Percent Agreement
3	0	100	0	100	100%
3.5	9	91	10	90	95%
6.5	49	51	51	49	96%
10	100	0	100	0	100%

Summary of MissLan® Early Detection Pregnancy Test Cassette

hCG Concentration (mIU/mL)	Layperson result		Professional result		
	Number of Positive	Number of Negative	Number of Positive	Number of Negative	Percent Agreement
3	0	100	0	100	100%
3.5	10	90	11	89	95%
6.5	48	52	52	48	96%
10	100	0	100	0	100%

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

hCG Concentration (mIU/mL)	Layperson result		Professional result		
	Number of Positive	Number of Negative	Number of Positive	Number of Negative	Percent Agreement
3	0	100	0	100	100%
3.5	10	90	11	89	95%
6.5	49	51	52	48	97%
10	100	0	100	0	100%

Testing of Non-Pregnant Women:
A study was performed to evaluate the number of false positive test results obtained using the MissLan® Early Detection Pregnancy Test Strip, MissLan® Early Detection Pregnancy Test Cassette, and MissLan® Early Detection Pregnancy Test Midstream. For the MissLan® Early Detection Pregnancy Test Midstream format, both in-stream and dip sampling modes were tested. Urine sampled from 900 non-pregnant females were tested from each of the following three cohorts: pre-menopausal (18-40 years, n=300), peri-menopausal (41-55 years, n=300), and post-menopausal (>55 years, n=300). In each age group, 100 participants were tested with test strip, 100 participants were tested with test cassette, 50 participants were tested with test midstream using in-stream sampling method, and 50 participants tested with test

midstream using dip sampling method. Three lots of each test format were used and the lay users performed their own tests. The results are summarized in the tables below.

Summary of MissLan® Early Detection Pregnancy Test Strip

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

Summary of MissLan® Early Detection Pregnancy Test Cassette

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

Summary of MissLan® Early Detection Pregnancy Test Midstream

	Dip method			In-stream method			Total results	Total % Positive
Group	Lot I	Lot II	Lot III	Lot I	Lot II	Lot III		
Pre-menopausal	0+/17-	0+/16-	0+/17-	0+/17-	0+/17-	0+/16-	0+/100-	0
Peri-menopausal	0+/17-	0+/17-	0+/16-	0+/16-	0+/17-	0+/17-	0+/100-	0
Post-menopausal	0+/16-	0+/17-	0+/17-	0+/17-	0+/16-	0+/17-	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.