510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k183097

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Lateral flow immunoassay

E. Applicant:

Weihai Kangzhou Biotechnology Engineering Co., Ltd

F. Proprietary and Established Names:

Kangzhou One Step hCG Test Strip
Kangzhou One Step hCG Test Cassette
Kangzhou One Step hCG Test Midstream

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155 Human chorionic gonadotropin (HCG) test system

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The Kangzhou One Step hCG Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

   The Kangzhou One Step hCG Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

   The Kangzhou One Step hCG Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

3. Special conditions for use statement(s):

   For over-the-counter use.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices each contain a pouch with the device and instructions. The Kangzhou One Step hCG Test Strip and Kangzhou One Step hCG Test Cassette are packaged in a pouch with the device, one pipette dropper and one desiccant. The Kangzhou One Step hCG Test Cassette and Kangzhou One Step hCG Test Midstream consist of a single teststrip encased in plastic device housing. The Kangzhou One Step hCG Test Strip includes a supporting interpretation card that allows the user to identify where on the test strip test and control lines should be located.

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 a 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Co-Innovation One Step hCG Test Strip
   Co-Innovation One Step hCG Test Cassette
   Co-Innovation One Step hCG Test Midstream

2. Predicate 510(k) number(s):

   k132085

3. Comparison with predicate:

Similarities		
Item	Candidate Device(k183097)	Predicate Device (k132085)
Intended Use	Qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.	Same
Specimen	Urine	Same
Clinical cut-off	25mIU/mL	Same
Indications/Intended Users	Over the Counter (OTC)	Same
Read time	5 minutes	Same
Test Principle	Lateral Flow Immunoassay	Same
Format	Strip, cassette, midstream	Same
Differences		
Item	Candidate Device(k183097)	Predicate Device (k132085)
Traceability	World Health Organization (WHO) 5th International Standard (IS) material	WHO 3rd IS material

K. Standard/Guidance Document Referenced (if applicable):

Not Applicable.

L. Test Principle:

The Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices utilize a double antibody sandwich method. During the test procedure, hCG in the urine specimen reacts with the dye conjugate (mouse anti-β-hCG antibody-colloidal gold conjugate specific to the beta subunit of hCG) and forms a complex. This complex migrates by capillary action along the test strip to the α-hCG antibody test line; If hCG is present in the sample, the complex is captured onto the test line, where if hCG is present at concentrations above the cutoff, a red line becomes visible indicating a positive result. If hCG is not present in the sample above the cutoff, no line is visible on the test line, indicating a negative result. The control line should develop regardless of the test line result, if the test was correctly used and/or performed correctly, since mouse anti-β-hCG antibody-colloidal gold conjugate is present in excess to bind to the antibodies at the control line, resulting in a visible red line.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Precision studies were performed for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices using 30 urine samples collected from non-pregnant females spiked with hCG traceable to the WHO 5th International Standard (IS). Samples created had concentrations of 0mIU/mL,12.5mIU/mL, 18.75mIU/mL, 25mIU/mL, 50mIU/mL, and 100mIU/mL Samples were masked and randomized prior to testing. The study was conducted over 10 days by multiple operators at 3 sites. Three lots of each of the three devices were tested. The midstream format was tested with both the dip and (simulated) midstream method.

   Summary of results is presented in the table below:

   Kangzhou One Step hCG Test Strip results:

HCG Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0 mIU/mL	0	30	0	30	0	30
12.5 mIU/mL	0	30	0	30	0	30
18.75 mIU/mL	0	30	0	30	0	30
25 mIU/mL	30	0	30	0	30	0
50 mIU/mL	30	0	30	0	30	0
100 mIU/mL	30	0	30	0	30	0

Kangzhou One Step hCG Test Cassette results:

HCG Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0 mIU/mL	0	30	0	30	0	30
12.5 mIU/mL	0	30	0	30	0	30
18.75 mIU/mL	0	30	0	30	0	30
25 mIU/mL	30	0	30	0	30	0
50 mIU/mL	30	0	30	0	30	0
100 mIU/mL	30	0	30	0	30	0

Kangzhou One Step hCG Test Midstream dip method test results:

HCG Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0 mIU/mL	0	30	0	30	0	30
12.5 mIU/mL	0	30	0	30	0	30
18.75 mIU/mL	0	30	0	30	0	30
25 mIU/mL	30	0	30	0	30	0
50 mIU/mL	30	0	30	0	30	0
100 mIU/mL	30	0	30	0	30	0

Kangzhou One Step hCG Test Midstream simulated midstream method

HCG Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0 mIU/mL	0	30	0	30	0	30
12.5 mIU/mL	0	30	0	30	0	30
18.75 mIU/mL	0	30	0	30	0	30
25 mIU/mL	30	0	30	0	30	0
50 mIU/mL	30	0	30	0	30	0
100 mIU/mL	30	0	30	0	30	0

b. *Linearity/assay reportable range:*

Not applicable. The devices provide qualitative results only.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices are traceable to the WHO 5th reference material.

d. *Detection limit:*

See Precision section above (M.1.a).

e. Analytical specificity:

To evaluate the potential for interference by certain exogenous and endogenous compounds and potentially interfering clinical conditions, testing for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices was performed using two urine samples with concentrations of 0 and 25 mIU/ml hCG. These two samples were spiked with each of the known interferents to obtain the desired test concentration. Three different lots of each device format were tested. The results demonstrated that no interferences were observed from substances at the following concentrations for both negative and positive hCG urine samples.

Interfering substances	Substance concentration
Acetaminophen	20mg/dL
Aspirin	20mg/dL
Ascorbic acid	20mg/dL
Atropine	20mg/dL
Caffeine	20mg/dL
Glucose	2000mg/dL
Hemoglobin	500mg/dL
Tetracycline	20mg/dL
Ampicillin	20mg/dL
Albumin	2000mg/dL
Bilirubin	2 mg/dL
Leukocyte	>500/uL
Erythrocytes	>250/uL
Uric acid	0.58 mMol/L
Ketone	>80 mg/dL
Ethanol	1%

Effects of hCG β-core fragment:

To evaluate potential interference by hCG β-core fragment for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices, an hCG negative urine sample and a urine sample with 25mIU/mL were spiked with the hCG β-core fragment (traceable to WHO reference reagent 99/708) to yield samples with concentrations of 125,000, 250,000, 500,000 and 1,000,000 pmol/mL. These samples were tested with 3 lots of each device. The data obtained demonstrated that there is no interference by hCG β-core fragment at the concentrations tested.

Cross-reactivity:

To evaluate cross-reactivity for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices, hCG negative and hCG positive urines (25 mIU/mL hCG) were spiked with various concentrations of the glycoprotein hormones, Luteinizing Hormone (LH), Follicle

stimulating Hormone (FSH), and thyroid stimulating hormone (TSH). These samples were tested 3 lots of each device. The results demonstrated there is no interference from the tested glycoprotein hormones up to 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH in either negative or positive urine samples.

pH Interference Study:

To evaluate potential interference from changes in urine pH for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices, urine samples containing 0 mIU/mL and 25 mIU/mL hCG were tested with 3 lots of each device using samples at pH values of 3,4,5,6,7,8 and 9. The results demonstrated that samples within the pH range of 3-9 do not interfere with either positive or negative results from the device.

Specific Gravity interference study:

To evaluate potential interference from changes in specific gravity for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices, urine samples containing 0mIU/mL and 25 mIU/mL hCG were adjusted to specific gravities spanning the physiological range and tested with 3 lots of each device. The results indicate that changes in specific gravity do not interfere with either positive or negative results from the device.

Hook effect:

To evaluate the high dose hook effect for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices, hCG free specimens were spiked with varying hCG concentrations: 62,500 mIU/ml, 125,000 mIU/ml, 250,000 mIU/ml, 500,000 mIU/ml, and1,000,000 mIU/ml. These samples were tested using 3 lots of each device. The result show that there is no hook effect observed at the concentrations tested.

f. Assay cut-off:

See precision section above (M.1.a.).

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was conducted for the Kangzhou One Step hCG Test Strip, Kangzhou One Step hCG Test Cassette, and Kangzhou One Step hCG Test Midstream devices using urine samples collected from 360 women (ages 18-45 years), 90 samples were tested per device. Samples were randomly collected at various times throughout the day and were masked and randomized prior to testing. Results of the professional using the candidate device were compared to results

obtained from the predicate device. Summary of results is presented in the table below:

Kangzhou One Step hCG Test Strip

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	43	0
	Negative	0	47

Kangzhou One Step hCG Test Cassette

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	37	0
	Negative	0	53

Kangzhou One Step hCG Test Midstream (using dip method)

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	55	0
	Negative	0	35

Kangzhou One Step hCG Test Midstream (using the simulated midstream method)

		Predicate device professional	
		Positive	Negative
Candidate device	Positive	50	0
	Negative	0	40

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

A lay-user study was conducted with 360 lay users. Each subject tested their own urine on the candidate device following instructions on the package insert. The same sample was tested by a healthcare professional using the candidate devices as well as the predicate device. This included 90 lay users using test strip, 90 using test cassette, 180 using actual midstream method and the dip method respectively. Subject ages ranged from 18 to 45 years. All samples were masked and randomized prior to professional testing.

Summary of results for the comparison between the lay user testing with the candidate device versus the professional testing using the candidate device are presented the table below. Lay user results with the candidate device versus professional results using the candidate device are not shown, but were identical to those shown below.

Kangzhou One Step hCG Test Strip

		Professional	
		Positive	Negative
Lay user	Positive	43	0
	Negative	0	47

Kangzhou One Step hCG Test Cassette

		Professional	
		Positive	Negative
Lay user	Positive	37	0
	Negative	0	53

Kangzhou One Step hCG Test Midstream (using dip method)

		Professional	
		Positive	Negative
Lay user	Positive	55	0
	Negative	0	35

Kangzhou One Step hCG Test Midstream (lay user using the actual midstream method and professional using the simulated midstream method)

		Professional	
		Positive	Negative
Lay user	Positive	50	0
	Negative	0	40

Lay users also completed a user survey, and the results supported that lay users believed that the device was easy to use.

4. Clinical cut-off**:**

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801.10.

O. Conclusion:

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