510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A. 510(k) Number
K200133

B. Applicant
Safecare Biotech (Hangzhou) Co., Ltd.

C. Proprietary and Established Names
hCG Urine Test Strip
hCG Urine Test Cassette
hCG Urine 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 chromatographic immunoassay

III Intended Use/Indications for Use:

A. Intended Use(s):
See Indications for Use below.

B. Indication(s) for Use:
The hCG Urine Test Strip is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

The hCG Urine Test Cassette is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

The hCG Urine Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

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

D. Special Instrument Requirements:
None

IV Device/System Characteristics:

A. Device Description:
The hCG Urine Test strip and the hCG Urine Test midstream kits consist of one test device and a package insert. The hCG Urine Test cassette kit consists of one test device, a disposable plastic dropper, and a package insert. Each test device contains mouse monoclonal anti-βhCG antibody coated membrane and a pad containing mouse monoclonal anti-α-hCG antibody colloidal gold conjugate. The control antibodies are goat anti-rabbit IgG.

B. Principle of Operation:
This device operates by detecting human chorionic gonadotropin (hCG), the hormone produced during pregnancy, in urine using a lateral flow sandwich chromatographic immunoassay. The assay of each device uses a double antibody sandwich method. During the test procedures, hCG in the urine specimen reacts with the dye conjugate (mouse anti- α -hCG antibody-colloidal gold conjugate specific to the beta subunit of hCG) and forms a complex. Because of capillary and chromatographic effects of the nitrocellulose membrane, the complex migrates along the membrane to the β-hCG antibody line (T) and remains captured in the T line. When hCG is present in the urine sample two red colored bands develops, one in the test (T) region and another in the control (C) region, indicating a positive result. If there is no hCG in the urine, there is only one red line in the control (C) region and no red band in the test (T) region, indicating a negative result. An invalid result produces either no lines on the device (i.e. no test or control lines) or one test line in the test region (i.e. a test line but no control line).

V Substantial Equivalence Information:

A. Predicate Device Name(s):
One Step HCG Urine Pregnancy Test

B. Predicate 510(k) Number(s):
K043443

C. Comparison with Predicate(s):

Device & Predicate Device(s):	K200133	K043443
Device Trade Name	hCG Urine Test Cassette hCG Urine Test Strip hCG Urine Test Midstream	One Step HCG Urine Pregnancy Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	Qualitative detection of hCG to aid in the early detection of pregnancy	Same
General Device Characteristic Differences		
Read time	3-5 minutes	5 minutes

VI Standards/Guidance Documents Referenced:
FDA Guidance for Over-the-Counter (OTC) Hum an Chorionic Gonadotropin (hCG) 510(k)s, dated July 22, 2000.

VII Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Precision/Reproducibility:

   A precision study was performed using urine samples from normal, nonpregnant females spiked with hCG, traceable to the 5th WHO International Standard to obtain samples with hCG concentrations of 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. The tests were performed over the course of 10 days by 3 operators using 3 lots of each device. The samples were blinded and randomized.

Results for the hCG Urine Test Strip

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

Results of precision for the hCG Urine Test Cassette

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

Results of precision for the hCG Urine Test Midstream (using the dip 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

Results of precision for the hCG Urine Test Midstream (using the 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

2. Linearity:
   Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:

   Cross-reactivity:

   To evaluate potential cross-reactivity relevant challenge doses of closely-related human luteinizing hormone (hLH), human follicle stimulating hormone (hFSH) or human thyroid stimulating hormone (hTSH) were tested using 30 fresh urine specimens obtained from healthy non-pregnant females. At each hCG concentration (0 mIU/mL and 25mIU/mL), 3 lots (90 replicates) of urine from non-pregnant female samples for each cross-reactant (hLH/hTSH/hFSH) was tested. The results demonstrated no cross reaction with LH at 500 mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 µIU/mL.

   Interference:

   To evaluate the potential for interference by certain exogenous compounds and potentially interfering clinical conditions, the substances listed were prepared by diluting stock interference material to the desired concentration. Normal, nonpregnant female urine specimens containing 0 and 25 mIU/mL hCG were spiked with the interferents to obtain the desired test concentration. Three lots of each format were tested. The results show that no interferences were observed from substance at the following concentrations for both negative and positive hCG urine samples.

Interfering substances	**Substances concentration**
Acetaminophen	20 mg/mL
Aspirin	20 mg/dL
Ascorbic acid	20 mg/mL
Caffeine	20 mg/dL
Glucose	200 mg/dL
Hemoglobin	1 mg/mL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Albumin	2000 mg/dL
Bilirubin	2 mg/mL
Erythrocytes	>250 /µL
Leukocyte	>500 /µl
Uric acid	450 mmol/L
Ketone	> 80 mg/dL
Ethanol	1%

Effect of hCG β-core fragment:

To evaluate the effects of the hCG β-core fragment normal nonpregnant female urine specimens containing 0 and 25 mIU/mL hCG were spiked with the hCG β-core fragment at concentrations of 125,000, 250,000, 500,000 and 1,000,000 pmol/mL. Three lots of each format were tested. The data demonstrated that there is no interference when the hCG β-core fragment was tested at a concentration of 1,000,000 pmol/L.

Effect of urine pH and Specific Gravity:

The pH of an aliquot negative urine pool was adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with hCG at 0 and 25 mIU/mL and 3 lots of hCG Urine Test were tested. The results showed no interference in samples ranging from pH 3 to 9.

Specific gravity:

Negative specimen containing 0 mIU/mL and specimen with hCG 25mIU/mL were adjusted to specific gravities of 1.001, 1.020, 1.031, 1.039. Three lots of hCG Urine Test were tested. The results showed no interference in samples with specific gravity ranging from 1.001-1.039.

Hook effect study:

To evaluate high dose hook effect, 30 hCG-free specimens spiked with hCG at 5,000, 10,000, 100,000, 500,000, 650,000, 850,000, 950,000 and 1,000,000 mIU/mL were tested on three lots of devices for each format. The results showed no hook effect up to 850,000 mIU/mL.

4. Assay Reportable Range:
   Not applicable. This is a qualitative test.

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

   Traceability:

   The hCG Urine Test Strip, hCG Urine Test Cassette and hCG Urine Test Midstream are traceable to the WHO 5th IS material.

   Stability:

   The stability data supports that the products have the shelf life of 30 months when stored at 4-30℃.

6. Detection Limit:
   Refer to the Precision and Reproducibility section above for additional information. The sensitivity of hCG Urine Test is 25 mIU/mL.

7. Assay Cut-Off:
   The sensitivity of hCG Urine Test Strip, hCG Urine Test Cassette, and hCG Urine Test Midstream is 25 mIU/mL. See precision section above.

B. Comparison Studies:

1. Method Comparison with Predicate Device:

   Urine samples were collected from 120 women at a hospital laboratory. These samples were collected from women between the ages of 18 to 44 who were suspected they were pregnant, experienced late periods or were pregnant. Samples were collected at various time throughout the day and were randomized prior to testing. Testing was performed by laboratory professionals at two laboratory sites. Results of the professional using the candidate device were compared to results obtained from the predicate device. Summary of results is presented in the tables below:

The results of professional method comparison (strip)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (cassette)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (midstream, using dip method)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (midstream, using the simulated method)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

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 was conducted with women who each tested their own urine with only one test method, and the results of their test were compared to results reported by a laboratory professional. A total of 360 lay users test their own urine by following instructions provided in the package insert (in English). This study included 90 lay users using test strip, 90 lay users using test cassette, 90 lay users using the actual midstream method and 90 lay users using the dip method to test for midstream. Samples were also randomized prior to testing and specimens were collected throughout the day and tested.

Results of the lay user method comparison for the hCG Urine Test Strip

Candidate device		Candidate device - Professional user		Total
		Positive	Negative	
Lay users	Positive	33	0	33
	Negative	0	57	57
Total		33	57	90

Results of the lay user method comparison for the hCG Urine Test Cassette

Candidate device		Candidate device professional		Total
		Positive	Negative	
Lay users	Positive	29	0	29
	Negative	0	61	61
Total		29	61	90

Results of the lay user method comparison for the hCG Urine Test Midstream (using dip method)

Candidate device		Candidate device professional		Total
		Positive	Negative	
Lay users	Positive	23	0	23
	Negative	0	67	67
Total		23	67	90

Results of the lay user method comparison for the hCG Urine Test Midstream (using actual midstream method)

Candidate device		Candidate device professional		Total
		Positive	Negative	
Lay users	Positive	26	0	26
	Negative	0	64	64
Total		26	64	90

D. Clinical Cut-Off:
Not applicable

E. Expected Values/Reference Range:
Not applicable

VIII Proposed Labeling:
The labeling does support 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.