510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K212447

B Applicant

Hangzhou Sejoy Electronics & Instruments Co., Ltd.

C Proprietary and Established Names

SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, SEJOY hCG One Step 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 chromatographic immunoassay

III Intended Use/Indications for Use:

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

B Indication(s) for Use:

The SEJOY hCG One Step Pregnancy Test Strip is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

The SEJOY hCG One Step Pregnancy Test Cassette is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

The SEJOY hCG One Step Pregnancy Test Midstream is a rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

1. Device Description:

The SEJOY hCG One Step Pregnancy test will be sold in three formats: strip, cassette, and midstream. Each format is qualitative lateral flow immunoassay for the detection of hCG in human urine samples, as an aid in the detection of pregnancy. The SEJOY hCG One Step Pregnancy Test Strip and SEJOY hCG One Step Pregnancy Test Midstream formats consist of one test device sealed in a desiccated aluminum pouch and a package insert. The SEJOY hCG One Step Pregnancy Test Cassette format consists of one test device, a disposable plastic dropper, and a package insert.

2. Principle of Operation:

The SEJOY hCG One Step Pregnancy Test (strip/cassette/midstream) is a lateral flow sandwich immunoassay employing monoclonal antibodies that are specifically directed against the alpha and beta subunits of hCG. To use the test, the user either dips the device in the urine specimen (strip format), adds the urine specimen to the specimen well (cassette format), or urinates on the absorbent tip or immerses the absorbent tip in urine (midstream format). If hCG is present in the sample, it will reach the test zone ("T") of the membrane and form a colored line. When the test is performed properly, a colored line will always appear in the control zone ("C"). The test result is shown in the result window and read visually between 3 and 5 minutes of urine application. Two distinct colored lines, one in the test region and another in the control line region indicate a positive test result (pregnant). Absence of a colored line in the test region and only a colored line in the control line indicates a negative test result (not pregnant). Absence of a colored line in the control line even in the presence of a colored line in the test line region indicates an invalid test result.

V Substantial Equivalence Information:

A Predicate Device Name(s):
CLUNGENE HCG Pregnancy Rapid Test Cassette, CLUNGENE HCG Pregnancy Rapid Test Strip, CLUNGENE HCG Pregnancy Rapid Test Midstream

B Predicate 510(k) Number(s):
K193132

C Comparison with Predicate(s):

Device & Predicate Device(s):	K212447	K193132
Device Trade Name	SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, SEJOY hCG One Step Pregnancy Test Midstream	CLUNGENE HCG Pregnancy Rapid Test Cassette, CLUNGENE HCG Pregnancy Rapid Test Strip, CLUNGENE HCG Pregnancy Rapid Test Midstream
General Device Characteristic Similarities		
Intended Use/Indications For Use	Aid in the early detection of pregnancy	Same
Type of use	Over the counter use	Same
Methodology	Chromatographic immunoassay	Same
Specimen type	Urine	Same
Assay cut-off	25 mIU/mL	Same
Device format	Strip, Cassette, Midstream	Same
General Device Characteristic Differences		
Reading Time	3-5 minutes	3 minutes

VI Standards/Guidance Documents Referenced:

- CLSI EP07 3rd Edition, Interference Testing in Clinical Chemistry.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   A precision study was performed using negative urine samples spiked with hCG to obtain samples with hCG concentrations of 0, 12.5, 18.75, 22.5, 25, 50, 100 and 200 mIU/mL. Tests were performed by three different operators for each sample concentration in 2 runs per day for 15 days using 3 lots of each device format (strip, cassette, midstream). The device cutoff is 25 mIU/mL hCG. The results are summarized in the tables below:

Strip Format

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Combined lots		% Negative	% Positive
	+	-	+	-	+	-	+	-		
0	90	0	90	0	90	0	270	0	100	0
12.5	90	0	90	0	90	0	270	0	100	0
18.75	74	16	73	17	72	18	219	51	81.1	18.9
22.5	51	39	48	42	40	50	139	131	51.5	48.5
25	0	90	0	90	0	90	0	270	0	100
50	0	90	0	90	0	90	0	270	0	100
100	0	90	0	90	0	90	0	270	0	100
200	0	90	0	90	0	90	0	270	0	100

Cassette Format

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Combined lots		% Negative	% Positive
	+	-	+	-	+	-	+	-		
0	90	0	90	0	90	0	270	0	100.0	0.0
12.5	90	0	90	0	90	0	270	0	100.0	0.0
18.75	70	20	75	15	73	17	218	52	80.7	19.3
22.5	50	40	44	46	44	46	138	132	51.1	48.9
25	0	90	0	90	0	90	0	270	0.0	100.0
50	0	90	0	90	0	90	0	270	0.0	100.0
100	0	90	0	90	0	90	0	270	0.0	100.0
200	0	90	0	90	0	90	0	270	0.0	100.0

Midstream Format

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Combined lots		% Negative	% Positive
	+	-	+	-	+	-	+	-		
0	90	0	90	0	90	0	270	0	100	0
12.5	90	0	90	0	90	0	270	0	100	0
18.75	76	14	74	16	72	18	222	48	82.2	17.8
22.5	46	44	46	44	49	41	141	129	52.2	47.8
25	0	90	0	90	0	90	0	270	0	100
50	0	90	0	90	0	90	0	270	0	100

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Combined lots		% Negative	% Positive
	+	-	+	-	+	-	+	-		
100	0	90	0	90	0	90	0	270	0	100
200	0	90	0	90	0	90	0	270	0	100

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

3. Analytical Specificity/Interference:

   Interference from exogenous and endogenous substances
   To evaluate the potential for interference by certain exogenous and endogenous compounds, each interferent was prepared by diluting stock interferent material to the desired concentration. Negative and positive female urine samples containing 0 and 25 mIU/mL hCG, respectively, were spiked with the compounds to obtain the desired test concentration. The samples were tested using 3 lots of each device format (strip, cassette, midstream). The results demonstrated no interference from exogenous compounds at the following concentrations for both negative and positive hCG urine samples.

Analyte	**Concentration**
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Ascorbic Acid	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Caffeine	20 mg/dL
Ephedrine	20 mg/dL
Gentisic Acid	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic Acid	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Acetylsalicylic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6 µg/dL
Ethanol	1.00%
Methanol	10%
Albumin	2000 mg/dL
Glucose	2000 mg/dL
Bilirubin	2 mg/mL
Atropine	20 mg/dL
Estriol-17-beta	1400 µg/dL

Analyte	Concentration
Hemoglobin	500 mg/dL
Pregnanediol	1500 µg/dL
Thiophene	20 mg/dL
Ampicillin	20 mg/dL
Tetracycline	20 mg/dL
Ketone	20 mg/dL

Cross-reactivity of structurally-related compounds

To evaluate specificity and cross-reactivity, negative (0 mIU/mL hCG) and positive female urine samples (25 mIU/mL hCG) were spiked with various concentrations of glycoprotein hormones, including LH (500 mIU/mL), FSH (1000 mIU/mL) and TSH (1 mIU/mL). The samples were tested using 3 lots of each device format (strip, cassette, midstream). The results showed that there is no interference at 500 mIU/mL LH, 1000 mIU/mL FSH, and 1 mIU/mL TSH for both negative and positive urine samples.

Effect of urine pH

To evaluate potential interference from changes in pH, urine samples containing 0 mIU/mL, 10 mIU/mL, and 25 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The samples were tested on all three device formats (strip, cassette, midstream). The results demonstrated that urine samples within the pH range of 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, 12.5 and 25 mIU/mL hCG were adjusted to specific gravities of 1.000, 1.012, 1.020, 1.030, 1.037 and tested using the candidate device. The samples were tested on all three device formats (strip, cassette, midstream). The results demonstrated that samples within the specific gravity range of 1.000 to 1.037 do not interfere with either positive or negative results from the device.

High dose hook effect study

Negative urine samples were spiked with varying hCG concentrations (25, 100, 1,000, 10,000, 100,000, 150,000, 500,000, 1,000,000, and 2,000,0000 mIU/mL) using 3 lots of each device format (strip, cassette, midstream). The results showed no hook effect up to 2,000,000 mIU/mL hCG.

Effect of hCG β-core fragment

To evaluate potential interference from hCG β-core fragment, negative and positive urine samples containing 0 and 25 mIU/mL hCG were spiked with 2,000,000 pmol/L hCG β-core fragment. The samples were tested using 3 lots of each device format (strip, cassette, midstream). The results demonstrated that there is no interference at 2,000,000 pmol/L hCG-β-core fragment in either negative or positive urine samples.

4. Assay Reportable Range:
   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
The SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, and SEJOY hCG One Step Pregnancy Test Midstream are traceable to the World Health Organization (WHO) 5th International Standard (IS) for hCG (NIBSC code 07/364).

6. Detection Limit:
Refer to the Precision and Reproducibility section VII.A.1 above.

7. Assay Cut-Off:
The cut-off of the SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, SEJOY hCG One Step Pregnancy Test Midstream is 25mIU/mL hCG. Refer to the Precision and Reproducibility section VII.A.1 above.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   a) The performance of the three device formats (strip, cassette, midstream) of the SEJOY hCG One Step Pregnancy test was compared to the predicate device. Testing was performed by laboratory professionals at three point-of-care (POC) sites with urine samples from 150 women between the ages of 18 to 60. About half of the women were suspected to be pregnant. All samples were masked and randomized prior to testing using each device format (strip, cassette, midstream). The data show that the agreement of the SEJOY hCG One Step Pregnancy Test (strip, cassette, and midstream) with the predicate device was 100%.

Strip format

Product		Predicate device	
		Negative	Positive
SEJOY hCG One Step Pregnancy Test Strip	Negative	72	0
	Positive	0	78

Cassette format

Product		Predicate device	
		Negative	Positive
SEJOY hCG One Step Pregnancy Test Cassette	Negative	72	0
	Positive	0	78

Midstream format (dip method)

Product		Predicate device	
		Negative	Positive
SEJOY hCG One Step Pregnancy Test Midstream	Negative	72	0
	Positive	0	78

   b) The performance of the SEJOY hCG One Step Pregnancy Test Midstream, using the dip method and simulated stream methods, was compared to the predicate device. Testing was performed by laboratory professionals at three POC sites with urine samples from 135 women between the ages of 18 to 60. About half of the women were suspected to be pregnant. All samples were masked and randomized prior to testing using the dip method

and simulated stream method for midstream format. The data show that the agreement of hCG Test Midstream with the predicate device was 100%.

Midstream format (dip method):

Product		Predicate device	
		Negative	Positive
SEJOY hCG One Step Pregnancy Test Midstream	Negative	72	0
	Positive	0	63

Midstream format (simulated stream method):

Product		Predicate device	
		Negative	Positive
SEJOY hCG One Step Pregnancy Test Midstream	Negative	72	0
	Positive	0	63

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):

   Lay user study
   A total of 440 lay users with varying ages and educational backgrounds were recruited at three sites. At each testing site, 110 lay users tested their own urine sample using one test method (strip, cassette, midstream (stream method), or midstream (dip method)) according to the package insert, provided a sample for professional testing, and took a questionnaire regarding their experience with the candidate device. 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%.

Strip format

SEJOY hCG One Step Pregnancy Test Strip		Professional	
		Positive	Negative
Lay person	Positive	46	0
	Negative	0	64

Cassette format

SEJOY hCG One Step Pregnancy Test Cassette		Professional	
		Positive	Negative
Lay person	Positive	44	0
	Negative	0	66

Midstream format (dip method):

SEJOY hCG One Step Pregnancy Test Midstream		Professional	
		Positive	Negative
Lay person	Positive	42	0
	Negative	0	68

Midstream format (simulated stream method):

SEJOY hCG One Step Pregnancy Test Midstream		Professional	
		Positive	Negative
Lay person	Positive	45	0
	Negative	0	65

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.