February 18, 2022

Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Yanyan Zhang
Regulation Affair
Area C, Building 2, No.365
Hangzhou, Zhejiang 311100
China

Re: K212447
Trade/Device Name: SEJOY hCG One Step Pregnancy Test Strip, SEJOY hCG One Step Pregnancy Test Cassette, SEJOY hCG One Step Pregnancy Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: November 18, 2021
Received: November 23, 2021

Dear Yanyan Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k212447

Device Name
SEJOY hCG One Step Pregnancy Test Strip
SEJOY hCG One Step Pregnancy Test Cassette
SEJOY hCG One Step Pregnancy Test Midstream

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

510(k) number:K212447

1. Contact Details

Applicant Name	Hangzhou Sejoy Electronics & Instruments Co., Ltd.
Address	Area C,Building 2,No.365,Hangzhou City,311100 Zhejiang,China
Phone No.	+86 571-81957767
Fax.	+86 571-8195 7750
Contact person	Yanyan Zhang
Date Prepared	February 09, 2022
Website	http://www.sejoy.com

2. Device information

Trade name	SEJOY hCG One Step Pregnancy Test Strip SEJOY hCG One Step Pregnancy Test Cassette SEJOY hCG One Step Pregnancy Test Midstream
Format	Strip,Cassette,Midstream
Classification	2
Classification name	Kit, Test, Pregnancy, Hcg, Over The Counter
510(k) Number	K212447
Product code	LCX
Regulation No.	862.1155

3. Legally Marketed Predicate Device

Trade Name	CLUNGENE HCG Pregnancy Rapid Test Cassette, CLUNGENE HCG Pregnancy Rapid Test Strip, CLUNGENE HCG Pregnancy Rapid Test Midstream
510(k) Number	K193132
Product Code	LCX
Manufacturer	Hangzhou Clongene Biotech Co.,Ltd.

4. Device Description

Sejoy HCG One Step Pregnancy Test will be sold in three different formats:Strip,Cassette,and Midstream.The Test Strip and Midstream format contain a test device sealed in a desiccated aluminum pouch and a package insert. The Cassette format contains one test device,a disposable plastic dropper,and a package insert.

5. Intended Use/Indication 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.

6. Substantial Equivalence Comparison

Item	Proposed Device: SEJOY HCG One Step Pregnancy Test	Predicate Device: (K193132)
Regulation number	862.1155	862.1155
Classification	2	2
Product Code	LCX	LCX
Intended use/Indications for use	Aid in the detection of pregnancy	Aid in the detection of pregnancy
Methodology	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	25 mIU/mL	25 mIU/mL
Specimen	Urine	Urine
Results	Qualitative	Qualitative
Target user	Over the counter use	Over the counter use
Device format	Strip,Cassette,Midstream	Strip,Cassette,Midstream
Reading Time	3-5 minutes	3 minute

7. Standard/Guidance Document Reference (if applicable)

Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s, July 22, 2000

8. Test Principle

This device operates by detecting human chorionic gonadotropin (hCG), the hormone produced during pregnancy in urine,using a lateral flow sandwich immunochromatographic assay.

9. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility/Sensitivity

Negative urine was spiked with hCG standard (Traceable to the 5th WHO) to hCG concentrations of 0, 12.5, 18.75, 22.5, 25, 50, 100 and 200mIU/mL.The spiked samples were measured in replicates using 3 different lots for each format.Tests were performed by three different operators for each sample concentration in 2 runs per day for 15 days.

The results are summarized in the table below:

Operator 1:

Strip Format

hCG Concentration (mIU/mL)	hCG190401		hCG190402		hCG190403		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	25	5	26	4	23	7	74	16	82.2	17.8
22.5	18	12	16	14	13	17	47	43	52.2	47.8
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Cassette Format

hCG Concentration (mIU/mL)	hCG190501		hCG190502		hCG190503		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	23	7	26	4	24	6	73	17	81.1	18.9
22.5	17	13	15	15	14	16	46	44	51.1	48.9
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Midstream Format

hCG Concentration	hCG190601	hCG190602	hCG190603	The total of the results	Negative compliance rate	Positive compliance Rate

(mIU/mL)	-	+	-	+	-	+	-	+	(%)	(%)
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	26	4	26	4	24	6	76	14	84.4	15.6
22.5	16	14	16	14	16	14	48	42	53.3	46.7
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Operator 2:

Strip Format

hCG Concentration (mIU/mL)	hCG190401		hCG190402		hCG190403		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	22	8	25	5	25	5	72	18	80.0	20
22.5	18	12	16	14	13	17	47	43	52.2	47.8
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Cassette Format

hCG Concentration (mIU/mL)	hCG190501		hCG190502		hCG190503		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	24	6	23	7	25	5	72	18	80.0	20
22.5	16	14	14	16	16	14	46	44	51.1	48.9
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Midstream Format

hCG Concentration (mIU/mL)	hCG190601		hCG190602		hCG190603		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	25	5	24	6	24	6	73	17	81.1	18.9
22.5	15	15	14	16	18	12	47	43	52.2	47.8
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Operator 3:

Strip Format

hCG Concentration (mIU/mL)	hCG190401		hCG190402		hCG190403		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	27	3	22	8	24	6	73	17	81.1	18.9
22.5	15	15	16	14	14	16	45	45	50.0	50.0
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Cassette Format

hCG Concentration (mIU/mL)	hCG190501		hCG190502		hCG190503		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	23	7	26	4	24	6	73	17	81.1	18.9
22.5	17	13	15	15	14	16	46	44	51.1	48.9
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Midstream Format

hCG Concentration (mIU/mL)	hCG190601		hCG190602		hCG190603		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
12.5	30	0	30	0	30	0	90	0	100	0
18.75	25	5	24	6	24	6	73	17	81.1	18.9
22.5	15	15	16	14	15	15	46	44	51.1	48.9
25	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100
100	0	30	0	30	0	30	0	90	0	100
200	0	30	0	30	0	30	0	90	0	100

Strip Format:Operator 1&2&3

hCG Concentration (mIU/mL)	hCG190401		hCG190402		hCG190403		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
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:Operator 1&2&3

hCG Concentration (mIU/mL)	hCG190501		hCG190502		hCG190503		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
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:Operator 1&2&3

hCG Concentration (mIU/mL)	hCG190601		hCG190602		hCG190603		The total of the results		Negative compliance rate (%)	Positive compliance Rate (%)
	-	+	-	+	-	+	-	+		
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
100	0	90	0	90	0	90	0	270	0	100
200	0	90	0	90	0	90	0	270	0	100

b. Linearity/assay reportable range:

Linearity is not applicable since this is a qualitative test.

c. Hook effect test:

Negative urine samples were spiked with varying hCG concentrations (25mIU/mL,100mIU/mL, 1IU/mL,10IU/mL,100IU/mL,150IU/mL,500IU/mL,1000IU/mL,2000IU/mL).All tested concentrations gave a positive result.The results demonstrated that no hook effect up to 2000IU/mL.

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

SEJOY hCG One Step Pregnancy Test is calibrated against reference material traceable to WHO International Standard 5th edition.

The stability data supports that the products have the shelf life of 24 months when stored at 2-30℃.

e. Cross-reactivity

To evaluate cross-reactivity, 0 mIU/mL negative urine samples,10 mIU/mL positive urine samples and 25 mIU/mL positive urine samples were spiked with various concentrations of LH, FSH, TSH and hCG β-core fragment. The results showed that there is no cross reaction at 500mIU/mL LH, 1000mIU/mL FSH,1000mIU/L TSH and 2000,000pmol/L hCG β-core fragment for both negative and positive samples.

f. Interfering substance

To evaluate the potential for interference by certain exogenous compounds, each interfering substance was prepared by diluting stock interfering material to the desired concentration.Negative urine samples and positive urine samples containing 10 mIU/mL and 25 mIU/mL hCG were spiked with the interfering substance to obtain the desired test concentration.No interferences were observed from exogenous compounds at the following concentrations for both negative and positive hCG urine

samples.

Analyte	Concentration
Acetaminophen	20mg/dL
Acetoacetic Acid	2000mg/dL
Ascorbic Acid	20mg/dL
B-hydroxybutyrate	2000mg/dL
Caffeine	20mg/dL
Ephedrine	20mg/dL
Gentisic Acid	20mg/dL
Phenylpropanolamine	20mg/dL
Salicylic Acid	20mg/dL
Phenothiazine	20mg/dL
EDTA	80mg/dL
Acetylsalicylic Acid	20mg/dL
Benzoylecgonine	10mg/dL
Cannabinol	10mg/dL
Codeine	6ug/dL
Ethanol	1.00%
Methanol	10%
Albumin	2000mg/dL
Glucose	2000mg/dL
Bilirubin	2mg/dL
Atropine	20mg/dL
Estriol-17-beta	1400ug/dL
Hemoglobin	500mg/dL
Pregnanediol	1500ug/dL
Thiophene	20mg/dL
Ampicillin	20mg/dL
Tetracycline	20mg/dL
Ketone	20mg/dL

g. Effect of urine pH

To evaluate potential interference from changes in pH, negative urine samples and positive urine samples containing 10 mIU/mL and 25 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that changes in pH range of 4~9 do not interfere in the results that were either positive or negative for hCG.

h. Effect of Specific Gravity

Negative specimen containing 0 mIU/mL,12.5 mIU/mL and 25mIU/mL hCG were adjusted to specific gravities of 1.000, 1.012, 1.020, 1.030,1.037.One different lots for each format were tested. The results showed no interference in samples with specific gravity ranging from 1.000-1.037.

B. Method Comparison Study

Method comparison with predicate device

The performance of the proposed device was compared to the predicate test. For strip and cassette format,urine samples were collected from 150 women presenting to test for pregnancy. Approximately half of the 150 women were suspected to be pregnant. For midstream format,urine samples were collected from 135 women presenting to test for pregnancy. Approximately half of the 135 women were suspected to be pregnant.All samples were tested by three different health professionals for each format at the 3 POC sites for a total of 12 POC operators with the proposed and the predicate devices.

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	63

Midstream format (simulate stream method)

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

Conclusion from the above table:

The average positive conformity rate of Rapid Pregnancy Test is 100%.
The average negative conformity rate of Rapid Pregnancy Test is 100%.

C. Lay person study:
440 women's individual pregnancy status was self-tested, varying educational and occupational backgrounds were chosen for the study. Each subject tested her own urine sample using the device according to the package insert and provided a sample for professional testing.

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 (simulate stream method)

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

From the above tables, the lay person results showed 100% positive and 100% negative conformity with the professional results.
Each lay person was given a questionnaire to assess the readability of the labeling. The results of the questionnaire reflected that the consumers found the test easy to use and that they did not have trouble understanding the labeling and interpreting the results.

10. Conclusion

The SEJOY hCG One Step Pregnancy Test is substantially equivalent to the legally marketed predicative device CLUNGENE HCG Pregnancy Rapid Test (K193132)