December 11, 2019

Hangzhou Clongene Biotech Co.,Ltd.
℅ Joe Shia
Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K193132
Trade/Device Name: CLUNGENE HCG Pregnancy Rapid Test Cassette, CLUNGENE HCG Pregnancy Rapid Test Strip, CLUNGENE HCG Pregnancy Rapid 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 8, 2019
Received: November 12, 2019

Dear Joe Shia:

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.
Acting Deputy Director
Division of Chemistry and Toxicology Devices | OHT7:
Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k193132

Device Name
CLUNGENE HCG Pregnancy Rapid Test Cassette
CLUNGENE HCG Pregnancy Rapid Test Strip
CLUNGENE HCG Pregnancy Rapid Test Midstream

Indications for Use *(Describe)*
The CLUNGENE HCG Pregnancy Rapid 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 CLUNGENE HCG Pregnancy Rapid 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 CLUNGENE HCG Pregnancy Rapid Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K193132

510(k) SUMMARY

1. Date: December 09, 2019

2. Submitter:
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3. Contact person:
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4. Device Name: CLUNGENE HCG Pregnancy Rapid Test Cassette
CLUNGENE HCG Pregnancy Rapid Test Midstream
CLUNGENE HCG Pregnancy Rapid Test Strip

Classification: Class II

Product Code	CFR #	Panel
LCX	21 CFR, 862.1155 Human chorionic gonadotropin (hCG) Test System	Clinical Chemistry (75)

5. Predicate Devices: EGENS One Step HCG Urine Pregnancy Test (K123050)

6. Intended Use

CLUNGENE HCG Pregnancy Rapid Test Cassette is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for early detection of pregnancy.

CLUNGENE HCG Pregnancy Rapid Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for early detection of pregnancy.

CLUNGENE HCG Pregnancy Rapid Test Strip is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for early detection of pregnancy.

7. Device Description

Clungene HCG Pregnancy Rapid Test will be sold in three different formats: Cassette, Test Strip, 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.

8. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device K123050
Intended use	Early detection of pregnancy	Early detection of pregnancy
Specimen	Urine	Urine
Assay technical	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	25 mIU/mL	25 mIU/mL
Results	Qualitative	Qualitative
Target user	Over the counter use	Over the counter use
Device format	Strip, Cassette, Midstream	Strip, Cassette, Midstream
Differences		
Item	Device	Predicate
Reading Time	3 minute	5 minute

9. Standard/Guidance Document Reference (if applicable)

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

10. 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.

11. 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:

Strip format

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
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	20
22.5	13	17	14	16	17	13	44	46	48.9	51.1
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)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
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	13	17	13	17	41	49	45.6	54.4
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)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
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	23	7	25	5	71	19	78.9	21.1
22.5	16	14	17	13	14	16	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

Based on the above results, the sensitivity of CLUNGENE HCG Pregnancy Rapid Test is demonstrated to be 25 mIU/mL.

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 (62500, 125000, 250000, 500000, 1000000 and 2000000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentrations ranging from 62500 to 2000,000 mIU/mL.

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

CLUNGENE HCG Pregnancy Rapid Test is calibrated against reference material traceable to WHO International Standard 5th edition.

A shelf-life stability test of the devices was performed by accelerated testing. The results showed that the devices were stable for 24 months when stored at 4~30℃ in the sealed foil pouch. Real time stability studies are ongoing.

e. Specificity and cross reactivity

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

Substances	**Concentration**
Acetaminophen	20mg/dL
Acetoacetic Acid	2000mg/dL
Asorbic 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	1.0%
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

To evaluate potential interference from changes in pH, 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.

To evaluate potential interference from changes in specific gravity, urine samples containing 10 mIU/mL and 25 mIU/mL hCG were tested at density values ranging from 1.000 to 1.035. The results indicated that changes in specific gravity do not interfere in the results that were either positive or negative for hCG.

B. Method comparison study

Method comparison with predicate device

The performance of the new device was compared to the predicate test. Urine samples were collected from 120 women presenting to test for pregnancy. Approximately half of the 120 women were suspected to be pregnant and most of them are in the early stage of less than 5 weeks. 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		Predicate device	
		Positive	Negative
CLUNGENE HCG® Rapid Pregnancy Test	Positive	63	0
	Negative	0	57

Cassette		Predicate device	
		Positive	Negative
CLUNGENE HCG® Rapid Pregnancy Test	Positive	63	0
	Negative	0	57

Midstream	Predicate device	
	Positive	Negative

CLUNGENE HCG® Rapid Pregnancy Test	Positive	63	0
	Negative	0	57

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:

300 women's individual pregnancy status was self-tested, varying educational and occupational backgrounds from three sites 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.

Summary

Rapid Pregnancy Test Strip		Professional	
		+	-
Lay person	+	43	0
	-	0	57

Rapid Pregnancy Test Cassette		Professional	
		+	-
Lay person	+	53	0
	-	0	47

Rapid Pregnancy Test Midstream		Professional	
		+	-
Lay person	+	50	0
	-	0	50

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.

12. Conclusion

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