January 26, 2024

Nantong Egens Biotechnology Co., Ltd.
% Joe Shia
Director
LSI International
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K232864
Trade/Device Name: EGENS Pregnancy Test Midstream I, EGENS Pregnancy Test Midstream II
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: December 26, 2023
Received: December 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Acting Deputy Division Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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)*
k232864

Device Name
EGENS Pregnancy Test Midstream I
EGENS Pregnancy Test Midstream II

Indications for Use *(Describe)*
EGENS Pregnancy Test Midstream I is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

EGENS Pregnancy Test Midstream II is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) SUMMARY

K232864

1. Date: January 22, 2024

2. Submitter:

Nantong Egens Biotechnology Co., Ltd.
Building 15, 1692 Xinghu Avenue
Nantong Economy and Technology Development Zone
Nantong, Jiangsu 226010
China

3. Contact person:

Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4. Device Name: EGENS Pregnancy Test Midstream I
EGENS Pregnancy Test Midstream II

Classification: Class II
Product Code: LCX
CFR: 862.1155

5. Predicate Devices: K150022
Wondfo One Step HCG Urine Pregnancy Test Strip
Wondfo One Step HCG Urine Pregnancy Test Cassette
Wondfo One Step HCG Urine Pregnancy Test Midstream

6. Intended Use

EGENS Pregnancy Test Midstream I is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

EGENS Pregnancy Test Midstream II is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

7. Device Description

EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II

are used for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, and are designed to be tested in dip or midstream mode. The test device consists of a single test strip assembled in a plastic housing, with an absorbent tip. The only difference between EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II is the plastic casing. The device is in a ready-to-use format.

8. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device
Intended use	A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.	Same
Specimen	Urine	Urine
Assay technical	Immunochromatographic assay	Immunochromatographic assay
Sensitivity	10 mIU/mL	10 mIU/mL
Results	Qualitative	Qualitative
Target user	Over the counter use	Over the counter use
Format	Midstream	Strip, cassette, midstream
Differences		
Item	Device	Predicate
Time to result	3-10 minutes	5 minutes

9. Test Principle

EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a sample, the sample is absorbed into the device by capillary action and mixes with the antibody-dye conjugate (mouse anti-beta HCG monoclonal antibody), flowing across the pre-coated (Goat anti HCG polyclonal antibody) membrane. During the test procedures, hCG in the urine specimen reacts with the dye conjugate and forms a complex. The complex migrates along

the membrane to the hCG antibody line (T), and remains captured in the T line. As a result a red colored band develops in the T line, indicating a positive result. If there is no hCG in the urine, there is no red band in the test zone, indicating a negative result. The Control line should develop in the control zone regardless of the test result. If no lines appear, or if only a red band appears in the test zone, indicating the test result is invalid.

10. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility/Sensitivity

Negative female urine was spiked with hCG standard (Traceable to the 5th WHO) to hCG concentrations of 0, 2.5, 5, 6.5, 8, 9, 10, 15, 25 and 50 mIU/mL. Each sample was tested by both dip and midstream methods in 5 replicates per day for 5 days for each device lot. Total of three device lots were tested. Tests were performed by three different operators for each sample concentration. The results summarized in the tables below are combined data for both dip and midstream testing.

EGENS Pregnancy Test Midstream I

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6.5	47	3	46	4	47	3	140	10	93%	7%
8	25	25	22	28	27	23	74	76	49%	51%
9	7	43	5	45	4	46	16	134	11%	89%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

EGENS Pregnancy Test Midstream II

hCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	50	0	50	0	50	0	150	0	100%	0%
2.5	50	0	50	0	50	0	150	0	100%	0%
5	50	0	50	0	50	0	150	0	100%	0%
6.5	48	2	47	3	46	4	141	9	94%	6%
8	27	23	24	26	24	26	75	75	50%	50%

9	5	45	3	47	7	43	15	135	10%	90%
10	0	50	0	50	0	50	0	150	0%	100%
15	0	50	0	50	0	50	0	150	0%	100%
25	0	50	0	50	0	50	0	150	0%	100%
50	0	50	0	50	0	50	0	150	0%	100%

EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II exhibited reproducible results.
Based on the above results, the sensitivity of EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are both demonstrated to be 10mIU/mL.

b. Linearity/assay reportable range:
Linearity is not applicable since this is a qualitative test.
The test device was evaluated for high dose or hook effect.

c. Hook effect test:
Negative urine samples were spiked with varying hCG concentrations (6,250 mIU/mL, 12,500 mIU/mL, 25,000 mIU/mL, 50,000 mIU/mL, 100,000 mIU/mL, 200,000 mIU/mL and 500,000 mIU/mL). All tested concentrations gave a positive result. The results demonstrated that no hook effect was observed at hCG concentration up to 500,000 mIU/mL.

d. Traceability, Stability, Expected values (controls, calibrators, or methods):
Traceability:
EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are calibrated against reference material traceable to WHO International Standard 5th edition, NIBSC code 07/364.

Stability:
Products in sealed foil pouch are stable for 24 months at 2°C and 30°C, based on the real time stability study.

e. Specificity and cross reactivity
To evaluate specificity, 300 urine samples were collected from healthy, non-pregnant female in pre-menopausal (ages 18~40 years old), peri-menopausal (41~55 years old) and post-menopausal (>55 years old) groups. 100 people for each age group. Both dip and midstream testing are evaluated. No false positive results were observed for any of the age groups.

To evaluate cross-reactivity, negative and positive urine samples (0, 5 and 10 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 µIU/mL hTSH). These samples were tested in 30 replicates using three device lots. No cross-reactivity was observed at tested concentration.
To evaluate the effect of the hCG β-core fragment, Negative urine samples (0 and

5 mIU/mL hCG) and positive urine samples (10 and 20,000 mIU/mL hCG) were spiked with hCG β-core fragment (hCGβcf) at concentrations of 50,000 pmol/L, 125,000 pmol/L, 250,000pmol/L and 500,000pmol/L. These samples were tested in 30 replicates using three device lots. The device performance is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

f. Interfering substance

To evaluate potential interferers with EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II, urine samples containing 0, 5 and 10 mIU/mL hCG were spiked with the interfering substance to obtain the certain desired test concentration. No interference effect was observed at the tested concentration shown in table below:

Substance	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic	20 mg/dL
Ascorbic acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	20 mg/dL
Tetracycline	20 mg/dL
Ampicillin	20 mg/dL
Albumin	20 mg/dL
β-hydroxybutyrate	2000 mg/dL
Ephedrine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
EDTA	80 mg/dL
Salicyclic Acid	20 mg/dL
Benzoylecgonine	10 mg/dL
Cannabinol	10 mg/dL
Codeine	6ug/dL
Ethanol	1.0%
Bilirubin	2mg/dL
Pregnanediol	1500μg/dL
Thiophene	20 mg/dL
Ketone	20 mg/dL

To evaluate the effect of urine pH on the results of EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at pH values of 4, 5, 6, 7, 8 and 9. The results indicated that urine pH ranges between 4 and 9 does not affect the performance of EGENS Pregnancy Test Midstream I and EGENS Pregnancy

Test Midstream II.

To evaluate the effect of urine density on the results of EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II, urine samples containing 0, 5 and 10 mIU/mL hCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that urine with a relative density of 1.000 to 1.035 does not affect the performance of EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II.

B. Method comparison study

Method comparison with predicate device

The performance of the new device was compared to the predicate test. A total of 206 urine samples were first collected from 206 women presenting to test for pregnancy. Of the total 206 samples, 100 samples were tested by EGENS Pregnancy Test Midstream I device and the remaining 106 samples were tested by EGENS Pregnancy Test Midstream II device. Another 100 urine samples were collected from an additional 100 women presenting to test for pregnancy. These additional 100 urine samples were tested by both EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II devices using both the in-stream method and dip method, yielding 200 testing results for each device from the additional 100 urine samples. Test results showed 100% conformity between the candidate device and the predicate device.

Summary EGENS Pregnancy Test Midstream I Testing Results

EGENS Pregnancy Test Midstream I (Dip)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	74	0	74
	Negative	0	75	75
	Total	74	75	149

EGENS Pregnancy Test Midstream I (In-stream)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	77	0	77
	Negative	0	74	74
	Total	77	74	151

Summary EGENS Pregnancy Test Midstream II Testing Results

EGENS Pregnancy Test Midstream II (Dip)		Predicate device		
		Positive	Negative	Total
Candidate device	Positive	78	0	78
	Negative	0	75	75
	Total	78	75	153

	Predicate device

EGENS Pregnancy Test Midstream II (In-stream)		Positive	Negative	Total
Candidate device	Positive	76	0	76
	Negative	0	77	77
	Total	76	77	153

C. Lay person study

306 women's individual pregnancy status was self-tested. Individuals with 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

EGENS Pregnancy Test Midstream I (in-stream or dip method)		**Professional Result**		**Total**
		Positive	**Negative**	
Lay user Result	**Positive**	101	0	101
	Negative	0	99	99
Total		101	99	200

EGENS Pregnancy Test Midstream II (in-stream or dip method)		**Professional Result**		**Total**
		Positive	**Negative**	
Lay user Result	**Positive**	54	0	54
	Negative	0	52	52
Total		54	52	106

From the above tables, the lay person results showed 100% positive and 100% negative conformity with the professional results.

Spiked urine samples were also tested by lay person. Urine samples were prepared at 5mIU/ml, 6.5mIU/ml, 8.0mIU/ml and 10mIU/ml hCG concentrations by spiking hCG into negative pooled urine specimens. Each sample was aliquoted into individual containers and blind-labeled. These samples were tested by 200 lay persons using either EGENS Pregnancy Test Midstream I or EGENS Pregnancy Test Midstream II devices.

For EGENS Pregnancy Test Midstream I

Number of samples	hCG concentration (mIU/mL)	Lay user result		Professional Result		Percent Agreement
		Number of positive	Number of negative	Number of positive	Number of negative	
100	5	0	100	0	100	100%
100	6.5	5	95	7	93	98%
100	8	49	51	51	49	98%
100	10	100	0	100	0	100%

For EGENS Pregnancy Test Midstream II

Number of samples	hCG concentration (mIU/mL)	Lay user result		Professional Result		Percent Agreement
		Number of positive	Number of negative	Number of positive	Number of negative	
100	5	0	100	0	100	100%
100	6.5	6	94	7	93	99%
100	8	50	50	52	48	98%
100	10	100	0	100	0	100%

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.

D. Early Pregnancy Test Study

In this study, total 585 urine samples from 65 characterized cycle segments of conceptive cycles were collected from 65 pregnant women. All samples were masked and randomized. Each sample was tested by two formats of the device. The new device detected 68% positive hCG five days before the
Expected Menstrual Period (EMP), and 100% positive hCG on the day of EMP. No differences were observed between different device formats. The following table is the summary of the data.

Day relative to EMP	EMP-8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP
# of cycles positive for hCG	3/65	9/65	25/65	45/65	59/65	63/65	64/65	65/65	65/65
% cycles positive for hCG	5%	14%	38%	69%	91%	97 %	98%	100%	100%

11. Conclusion

Based on the test principle and performance characteristics of the device

including precision, cut-off, interference, specificity, method comparison and lay-user studies of the device, it's concluded that EGENS Pregnancy Test Midstream I and EGENS Pregnancy Test Midstream II are substantially equivalent to the predicate.