April 5, 2024

Aceso Laboratories, Inc.
% Joe Shia
Director
LSI International Inc
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K234152
Trade/Device Name: ACESO Early Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: February 22, 2024
Received: February 22, 2024

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234152

Device Name
ACESO Early Pregnancy Test

Indications for Use *(Describe)*
ACESO Early Pregnancy Test 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.

Important note regarding positive results:
Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

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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510(k) SUMMARY

K234152

1. Date: March 22, 2024

2. Submitter:
Aceso Laboratories, Inc.
14020 Central Avenue
Suite 520
Chino, CA 91710

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: ACESO Early Pregnancy Test

Classification: Class II
Product Code: LCX
CFR: 862.1155

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

6. Intended Use

ACESO Early Pregnancy Test 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.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

7. Device Description

ACESO Early Pregnancy Test is used for in vitro qualitative detection of Human Chorionic Gonadotropin (HCG) in human urine, and is 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 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

ACESO Early Pregnancy Test is 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.

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, 3, 5, 8, 10, 15, 25 and 50 mIU/mL. Each sample was tested by both dip and midstream methods in 10 replicates per day for 10 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 are summarized in the table below:

Midstream Testing

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%
3	50	0	50	0	50	0	150	0	100%	0%
5	24	26	23	27	27	23	74	76	49%	51%
8	3	47	2	48	2	48	7	143	5%	95%
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%

Dip Testing

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%
3	50	0	50	0	50	0	150	0	100%	0%
5	26	24	24	26	26	24	76	74	51%	49%
8	2	48	1	49	2	48	5	145	3%	97%
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%

ACESO Early Pregnancy Test exhibited reproducible results.

Based on the above results, the sensitivity of ACESO Early Pregnancy Test is demonstrated to be 10 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 (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:
ACESO Early Pregnancy Test is 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 35.6-86°F, 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, 3 and 10 mIU/mL hCG) were spiked with potential cross reactants (500 mIU/mL hLH, 1000 mIU/mL hFSH, 1000 μIU/mL hTSH). No cross-reactivity was observed at tested concentration.
To evaluate the effect of the hCG β-core fragment, Negative urine samples (0 and 3 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. The performance of ACESO Early Pregnancy Test is not affected by hCG β-core fragment concentrations up to 500,000 pmol/L.

f. Interfering substance
To evaluate potential interferers with ACESO Early Pregnancy Test, urine samples containing 0, 3 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 ACESO Early Pregnancy Test, urine samples containing 0, 3 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 ACESO Early Pregnancy Test.

To evaluate the effect of urine density on the results of ACESO Early Pregnancy Test, urine samples containing 0, 3 and 10 mIU/mL hCG were tested at density values of 1.000, 1.009, 1.015, 1.017, 1.020, 1.022, 1.028 and 1.035. The results indicated that urine with a relative density of 1.000 to 1.035 does not affect the performance of ACESO Early Pregnancy Test.

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 100 women presenting to test for pregnancy. Approximately half of the 100 women were suspected to be pregnant in the early stage of less than 5 weeks. All samples were tested with candidate and predicate

devices at three POC sites.

Dip Testing

Pregnancy Test (ACESO)	Predicate Test (Wondfo test)		Total
	Positive (+)	Negative (-)	
Positive (+)	53	0	53
Negative (-)	0	47	47
Total	53	47	100

Midstream Testing

Pregnancy Test (ACESO)	Predicate Test (Wondfo test)		Total
	Positive (+)	Negative (-)	
Positive (+)	53	0	53
Negative (-)	0	47	47
Total	53	47	100

The conformity between ACESO Early Pregnancy Test and the predicate device is 100%.

C. Lay person study

100 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

ACESO		**Professional Result**		**Total**
		Positive	**Negative**	
Lay user Result	**Positive**	53	0	53
	Negative	0	47	47
Total		53	47	100

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 3mIU/ml, 5mIU/ml, 8mIU/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 100 lay persons.

Lay person vs Professional

hCG Concentrations	Lay person results		Professional results		Percent Agreement
	No. of Negative	No. of Positive	No. of Negative	No. of Positive	
3 mIU/ml	100	0	100	0	100%
5 mIU/ml	52	48	49	51	97%
8 mIU/ml	4	96	5	95	99%
10mIU/ml	0	100	0	100	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 650 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 both in-stream and dip methods using three lots of the device. The new device detected 76% 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 test methods. The following table is the summary of the data.

Day relative to Expected Menstrual Period(EMP)	Number of Positive	Number of Negative	Number of Total	% Positive
EMP-8	6	59	65	9.2%
EMP-7	16	49	65	24.6%
EMP-6	31	34	65	47.7%
EMP-5	50	15	65	76.9%
EMP-4	63	2	65	96.9%
EMP-3	65	0	65	100.0%
EMP-2	65	0	65	100.0%
EMP-1	65	0	65	100.0%
EMP	65	0	65	100.0%
EMP+1	65	0	65	100.0%

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 ACESO Early Pregnancy Test is substantially equivalent to the predicate.