August 2, 2024

INNOVITA (Tangshan) Biological Technology Co., Ltd.
℅ Jenny Xia
Director
LSI International Inc
504 East Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K241919
Trade/Device Name: Innovita HCG Pregnancy Rapid Combo Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: June 28, 2024
Received: July 1, 2024

Dear Jenny Xia:

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.
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.

Submission Number *(if known)*

k241919

Device Name

Innovita HCG Pregnancy Rapid Combo Test

Indications for Use *(Describe)*

Innovita HCG Pregnancy Rapid Combo Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy. The test is for health care professionals use including professionals at point of care (POC).

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.

510(k) SUMMARY
K241919

1. Date: July 30, 2024
2. Submitter: INNOVITA (Tangshan) Biological Technology Co., Ltd.
   No. 699 Juxin Street, High-tech Industrial Development Zone,
   Qian'an, Hebei, 064400, China.

3. Contact person: Jenny Xia
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   504 East Diamond Ave., Suite I
   Gaithersburg, MD 20877
   Telephone: 301-525-6856
   Fax: 301-916-6213
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4. Device Name: Innovita HCG Pregnancy Rapid Combo Test

Classification: ClassII

Product Code	**CFR #**	**Panel**
JHI	862.1155, Human chorionic gonadotropin (HCG) test system	Clinical Chemistry

5. Predicate Devices:
   K203272, Alltest Pregnancy Rapid Combo Test Cassette

6. Intended Use
   The Innovita HCG Pregnancy Rapid Combo Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine or serum to aid in the early detection of pregnancy.
   The test is for health care professionals use including professionals at point of care (POC).

7. Device Description
   The Innovita HCG Pregnancy Rapid Combo Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine or serum for the early detection of pregnancy. During pregnancy, HCG is produced by the placenta shortly after the embryo attaches to the uterine lining. The test device is used as a single cassette device.

8. Substantial Equivalence Information

A summary comparison of features of the Innovita HCG Pregnancy Rapid Combo Test and the predicate device is provided in the following table.

Item	Device	Predicate
Intended Use	Rapid qualitative detection of HCG to aid in the early detection of pregnancy.	Same
Specimen	Urine or serum	Same
Principle	Lateral flow Sandwich Immunochromatographic Assay	Same
Detection reagent	Colloidal gold	Same
Read time	5 minutes for both serum and urine	Serum: 5 minutes Urine: 3 minutes
Usage	For prescription use	Same
Cut-Off Values	10 mIU/mL for serum and 20 mIU/mL for urine	Same
Configurations	Cassette	Same
Storage	4 – 30°C	2 – 30°C

9. Test Principle

The kit is a double antibody sandwich immunochromatographic assay that detects the presence of HCG in human serum or urine specimens. Anti β-HCG antibodies conjugated with colloidal gold is deposited on the conjugate pad, and Anti α-HCG antibodies are immobilized on the test line of the nitrocellulose membrane. When the specimen is applied, the gold-antibody conjugate is rehydrated and the HCG, if there is sufficient HCG in the specimen, interacts with the gold-conjugated antibodies. The antigen-antibody-gold complex then migrates towards the test window until the Test Zone (T) where it gets captured by immobilized antibodies, forming a visible red-purple line (Test line), indicating a positive result. If HCG is absent from the specimen, no red-purple line will be visible in the Test Zone (T), indicating a negative result.

To serve as an internal process control, a control line should always appear at Control Zone (C) after the test is completed. Absence of a red-purple control line in the Control Zone(C) indicates an invalid result.

10. Performance Characteristics

Analytical Performance

a. Precision/Reproducibility/Cut-Off Value

Negative serum or urine specimens from females were spiked with varying HCG (commercially available and traceable to the 5th WHO international Standard)

concentrations. The spiked samples were measured in 6 replicates each day for 5 days using 3 different lots at three testing sites. Tests were performed by six different operators for each sample concentration. Results are shown in the following tables.

Serum

HCG Concentration (mIU/mL)	Site 1 Lot 1		Site 2 Lot 2		Site 3 Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
2.5	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
7.5	13	17	14	16	15	15	42	48	46.7	53.3
10	0	30	0	30	0	30	0	90	0	100
12.5	0	30	0	30	0	30	0	90	0	100
15	0	30	0	30	0	30	0	90	0	100
20	0	30	0	30	0	30	0	90	0	100
50	0	30	0	30	0	30	0	90	0	100

Urine

HCG Concentration (mIU/mL)	Site 1 Lot 1		Site 2 Lot 2		Site 3 Lot 3		Total result		% Negative	% Positive
	-	+	-	+	-	+	-	+		
0	30	0	30	0	30	0	90	0	100	0
5	30	0	30	0	30	0	90	0	100	0
10	30	0	30	0	30	0	90	0	100	0
12.5	23	7	24	6	24	6	71	19	78.9	21.1
15	14	16	14	16	13	17	41	49	45.6	54.4
17.5	6	24	7	23	5	25	18	72	20	80
20	0	30	0	30	0	30	0	90	0	100
30	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

Cut-off values of 10 mIU/mL for serum and 20 mIU/mL for urine are verified.

b. Stability

Stable at 4-30℃ for 24 months based on the shelf time stability study.

c. Specificity / Cross Reactivity

High Dose Effect

Negative urine and serum samples from females were spiked with varying high HCG concentrations ranging from 500 to 2,000,000 mIU/mL. The spiked samples were

tested by 3 different lots and 3 different operators. No hook effect was observed at these concentrations.

Effects of hCG β-core fragment

Negative and positive samples (5 and 10 mIU/mL HCG in serum; 10 and 20 mIU/mL HCG in urine) were spiked with various concentrations of β -core fragment HCG (0 to $2x10^6$pmol/L). These samples were tested by 3 different lots and 3 different operators. No difference was observed for different lots and different operators. No interference was observed for these samples with $2x10^6$ pmol/L β-core fragment hCG for the devices.

Effects of glycoprotein LH, FSH and TSH

Negative and positive samples from females (10 and 20 mIU/mL HCG for urine, and 5 and 10 mIU/mL HCG for serum) were spiked with various concentrations of other glycoprotein hormones such as LH, FSH, and TSH. Samples were tested using three different lots by three operators. No interference was observed for these samples for the device at LH concentrations up to 500 mIU/mL, FSH concentrations up to 1000 mIU/mL, and TSH concentrations up to 1000 μIU/mL.

d. Interference

To evaluate potential interference from certain exogenous compounds, each interferent was made at 100X concentrate bulk and spiked in both HCG negative (5mIU/mL for serum, 10mIU/mL for urine) and HCG positive (10mIU/mL for serum, 20mIU/mL for urine) samples. All urine and serum samples were taken from women. Each spiked urine sample was mixed for 5 minutes to ensure a homogeneous solution before testing. Each sample was tested using 3 different lots of the testing kit. Results are shown in the following table which lists the highest concentration tested that did not cause positive or negative interference in either serum or urine samples.

Interferents	Concentration
Acetaminophen	20 mg/dL
Acetoacetic Acid	2000 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Albumin	2000mg/dL
Bilirubin	40mg/dL
Caffeine	20 mg/dL
Codeine	20mg/dL
Ephedrine	20 mg/dL
EDTA	80 mg/dL
Ethanol	1%
Gentisic Acid	20 mg/dL

Glucose	2000mg/dL
Hemoglobin	2000mg/dL
Methadone	20mg/dL
Phenylpropanolamine	20 mg/dL
Phenothiazine	20 mg/dL
Pregnanediol	2 mg/dL
Salicylic Acid	20 mg/dL
B-hydroxybutyrate	2000mg/dL
Benzoylecgonine	10mg/dL
Cannabinol	10mg/dL
Methanol	10%
Estriol-17-beta	2mg/dL
Thiophene	20mg/dL
Ampicillin	20mg/dL
Tetracycline	20mg/dL
Ketone	20mg/dL
Uric Acid	20 mg/dL
High-density lipoprotein (serum only)	70mg/dL
Triglycerides (serum only)	1200mg/dL
Total cholesterol (serum only)	250mg/dL

e. Effect of Urine Specific Gravity and Urine pH

Negative and positive urine samples containing 10 and 20 mIU/mL HCG were tested at pH values from 4 to 9 and at specific gravity values ranging from 1.000 to 1.035 using 3 different lots by 3 different operators. Data show that there is no interference from pH ranging from 4 to 9 and specific gravity ranging from 1.000 to 1.035 of tested urine samples.

f. Comparison Studies

A method comparison study was performed, comparing the results obtained from the Innovita HCG Pregnancy Rapid Combo Test to the results from predicate devices (K203272). 108 urine and 102 serum samples were collected from 210 women (all of these women expect themselves to be pregnant, early stage at less than 5 weeks, and have not undergone any at home or in office pregnancy testing before participating in this study) from three testing sites. Samples were randomly collected at various times throughout the day. Ages ranged from 20 to 49 years old. Samples were tested by different health professionals with the proposed and the predicate devices at each site. The obtained results are shown in the following tables.

Summary Results for Urine Cassette

	Predicate device	+	-
New Device	+	**52**	**0**

	-	**0**	**56**

Summary Results for Serum Cassette

New Device	**Predicate device**	+	**-**
	+	**47**	**0**
	-	**0**	**55**

The study result shows 100% agreement for all samples to the predicate device.

g.Clinical Studies

Not applicable

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, interference, specificity and method comparison of the devices, it's concluded that Innovita HCG Pregnancy Rapid Combo Test is substantially equivalent to the predicate.