November 22, 2019

Innovita (Tangshan) Biological Technology Co., Ltd
% Fiona Wang
Official Correspondent
Huajian US Services
19800 MacArthur Blvd, Ste 420
Irvine, CA 92612

Re: k192843
Trade/Device Name: INNOVITA HCG Pregnancy Rapid Test Strip, INNOVITA HCG Pregnancy Rapid Test Cassette, INNOVITA 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: September 30, 2019
Received: October 3, 2019

Dear Fiona Wang:

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)*
K192843

Device Name
INNOVITA HCG Pregnancy Rapid Test Strip
INNOVITA HCG Pregnancy Rapid Test Cassette
INNOVITA HCG Pregnancy Rapid Test Mistream

Indications for Use *(Describe)*

The INNOVITA HCG Pregnancy Rapid Test Strip detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic use only.

The INNOVITA HCG Pregnancy Rapid Test Cassette detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic use only.

The INNOVITA HCG Pregnancy Rapid Test Midstream detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic 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.

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) K192843 Summary

I. SUBMMITTER

Applicant Information:
Innovita (Tangshan) Biological Technology Co., Ltd.
No. 699 Juxin Street, High-tech Industrial
Development Zone, Qian'an, 064400, Hebei, China.
Phone: +86-10-83681277
Fax: +86-10-83682966

Contact Person: Fang (Fiona) Wang
USA Agent
Email: fwang@huajianus.com
19800 MacArthur Blvd Ste 420
Irvine, CA 92612
Tel: 949-874-9889

Date: 9/29/2019

II. DEVICE

Device Name:
INNOVITA HCG Pregnancy Rapid Test Strip
INNOVITA HCG Pregnancy Rapid Test Cassette
INNOVITA HCG Pregnancy Rapid Test Midstream

Common Name:
Pregnancy Test

Regulatory Information:
1. Regulation Classification section:
Class II: 21 CFR §862.1155 – Human chorionic gonadotropin (hCG)

2. Product Code:
LCX – Kit, Test, Pregnancy, Hcg, Over The Counter

3. Panel:

Clinical Chemistry (75)

III. PREDICATE DEVICE

Predicate device name: One Step HCG Urine Pregnancy Test
Predicate 510(k) number: k043443

510(k) #K192843 Summary

A. Device Description

INNOVITA 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. INNOVITA HCG Pregnancy Rapid Test measures the presence of the hormone Human Chorionic Gonadotrophin (HCG) in human urine for the detection of pregnancy. The test device contains mouse monoclonal anti-αhCG antibody coated membrane and a pad containing mouse monoclonal anti-β-hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG.

B. Indications for Use

The INNOVITA HCG Pregnancy Rapid Test Strip detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic use only.

The INNOVITA HCG Pregnancy Rapid Test Cassette detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic use only.

The INNOVITA HCG Pregnancy Rapid Test Midstream detects human chorionic gonadotropin (hCG) in urine. This test is used to obtain a visual, qualitative result for the determination of pregnancy. It is intended for Over-the-Counter, in vitro diagnostic use only.

C. Device Comparison Chart

Table 11.1 Device comparison chart

Similarities		
Parameter	**INNOVITA HCG Pregnancy Rapid Test**	**Wondfo Pregnancy Test (Predicate Device, k043443)**
Indications for Use	Intended for the qualitative detection of hCG in urine to aid in the early detection of pregnancy	Same
Intended Use	Over-the-Counter	Over-the-Counter, Professional
Format	Strip, Cassette, Midstream	Same
Test Principle	Lateral flow chromatographic immunoassay	Same
Antibodies	Goat, Mouse	Same
Sensitivity	25mIU/mL	Same
Storage Condition	4 – 30 ˚C	Same
Test Time	3-5 minutes	Same

D. Test Principle

When hCG containing urine, sample is applied onto the sample pad, it is diffused through the conjugate pad where hCG forms an antigen-antibody complex with colloidal gold–labeled antibodies. Under the lateral flow action, the complex migrates forward along the test. When passing the T line in the testing zone, the complex is captured and immobilized by pre-coated anti-αhCG antibodies on the T line and form a pink color line. The free Au-anti-βhCG continues to migrate in the testing zone. When passing the C line, the Au-anti-βhCG mouse antibodies is captured and immobilized by goat -anti-mouse IgG antibodies on the C line and form a pink color.

When there is no hCG in the sample, only a pink to purple line appear in the C line, indicating the specimen is negative. The pink line in the control region is to show that the applied specimen is adequate and migrates well. It also serves as an internal control standard for the reagent.

E. Performance Data

1. Analytical Performance

a. Precision/Sensitivity

Precision and Sensitivity study was performed by spiking the negative urine with hCG to obtain at concentrations at 0, 12.5, 18.75, 25, 37.5, 50 and 100mIU/mL Thirty replicates were tested with each spiked urine sample. Three (3) different Lots for each test format were used to perform the testing. The result of the precision/sensitivity test at each concentration of hCG is summarized in the following table. The results demonstrated that the analytical sensitivity of the INNOVITA HCG Pregnancy Rapid test is 25mIU/mL.

Table 11.2 INNOVITA One Step HCG Test Strip results

Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	1	29	0	30	0	30
18.75mIU/ml	14	16	13	17	14	16
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

Table 11.3 INNOVITA One Step HCG Test Cassette results

Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	1	29	1	29
18.75mIU/ml	13	17	15	15	14	16
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

Table 11.4 INNOVITA One Step HCG Test Midstream results

Concentration	Lot 1		Lot 2		Lot 3	
	Positive	Negative	Positive	Negative	Positive	Negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	12	18	10	20	14	16
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

b. Linearity and Reportable Range

This device provides qualitative results only.

c. Traceability and Stability

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

Stressed Stability Study and Real-Time Shelf-Life Study were conducted to monitor the integrity of the INNOVITA HCG Pregnancy Rapid Test. Testing results demonstrate that the shelf-life of the test is 3 years when stored at $4^{o}C$-$30^{o}C$ in a sealed foil pouch.

d. Detection Limit

See precision section above (F.1.a)

e. Analytical Specificity

i. Cross Reactivity

To evaluate the cross reactivity with similar hormone compounds, negative urine samples and different levels of HCG negative and HCG positive (25mIU/ml and 100mIU/ml) urine were spiked with different levels of hormone LH (250, 500 and 750mIU/ml), FSH (500, 750 and 1000mIU/ml) and TSH (500, 750 and 1000μIU/ml). Five devices from each format were tested with each spiked urine samples. The results summarized below demonstrated no cross-reactivity at 500mIU/ml LH, 1000mIU/ml FSH or 1000μIU/ml TSH.

Table 11.5 Cross-reactivity study of LH, FSH and TSH

Hormone	Concentration	HCG		
		0 mIU/mL Negative Urine	25 mIU/mL	100 mIU/mL
LH	250 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	500 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	750 mIU/mL	- (8/15)	+ (15/15)	+ (15/15)
FSH	500 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	750 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	1000 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
TSH	500 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	750 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)
	1000 mIU/mL	- (15/15)	+ (15/15)	+ (15/15)

ii. Endogenous / Exogenous Compounds

Potential endogenous interferents and drugs commonly found in urine were evaluated their effect on the performance of INNOVITA HCG Pregnancy Rapid test. Negative urine samples and HCG positive (25mIU/ml) urine were spiked with at least 2 levels of the listed interferents. Five devices from each format were tested with each spiked urine samples. Results demonstrated that no interference was observed at the highest concentrations of the following chemicals tested.

Table 11.6 Summary of the interference study

Interferents	Highest Concentration tested that demonstrated no interference
acetaminophen	20mg/dL
acetone	20mg/dL
acetylsalicylic acid	20mg/dL
albumin	2000mg/dL
ampicillin	5.3mg/dL
ascorbic acid	20mg/dL
atropine	20mg/dL
bilirubin	2mg/dL
caffeine	20mg/dL
cannabinol	10mg/dL
gentisic acid	20mg/dL
Glucose	2000mg/dL
hemoglobin	250mg/dL
hydroxybutyric acid	2000mg/dL
ibuprofen	40mg/dL
L-ephedrine hydrochloride	20mg/dL
methadone	20mg/dL
morphine	10mg/dL
nicotine	10mg/dL
phenylpropanolamine	20mg/dL
Proephedrine hydrochloride	20mg/dL
salicylic acid	20mg/dL
tetracycline	1.5mg/dL
uric acid	20mg/dL
Ethanol	1%

iii. Urine pH

To evaluate the effect of urine pH on the INNOVITA HCG Pregnancy Rapid test, negative urine samples and positive urine containing 25mIU/mL of hCG was adjusted for pH values between 4.0 and 9.0. Five devices from each format were

tested with each urine sample. Results demonstrated that test results were not affected by urine pH across 4 to 9.

Table 11.7 Results of the urine pH effect study

pH	HCG	
	Negative	Positive
4.0	- (15/15)	+ (15/15)
5.0	- (15/15)	+ (15/15)
6.0	- (15/15)	+ (15/15)
7.0	- (15/15)	+ (15/15)
8.0	- (15/15)	+ (15/15)
9.0	- (15/15)	+ (15/15)

iv. Urine Specific Gravity

To evaluate the effect of urine specific gravity (S.G.) on the INNOVITA HCG Pregnancy Rapid test, negative urine samples and positive urine samples with different specific gravities (1.000 – 1.010, 1.011 – 1.020 and 1.021 – 1.030) were collected. hCG was spiked into these urine samples to generate positive urine sample containing 25mIU/mL hCG. Five devices from each format were tested with each urine sample. Results demonstrated that test results were not affected by urine specific gravity between 1.003 and 1.030.

Table 11.8 Results of the urine SG effect study

SG	HCG	
	Negative	Positive
1.003-1.010	- (15/15)	+ (15/15)
1.011-1.020	- (15/15)	+ (15/15)
1.021-1.030	- (15/15)	+ (15/15)

v. hCG β–core Fragment

Presence of hCG β–core fragment in urine were evaluated their effect on the performance of INNOVITA HCG Pregnancy Rapid test. Negative urine samples and hCG positive (25mIU/ml) urine samples were spiked with hCG-β core fragment at the concentrations of 0.5μmol/L and 1μmol/L. Three devices from each format were tested with each spiked urine samples. The results demonstrated that no interference was observed for hCG-β core fragment concentrations up to 1μmol/L equivalent to 1000, 000 pmol/L.

Table 11.9 Results of effect of hCGβ-core fragment study

HCG-β core fragment	HCG	
	Negative	Positive
0.5μmol/L	- (15/15)	+ (15/15)
1μmol/L	- (15/15)	+ (15/15)

vi. High Dose Hook Effect

High concentrations of hCG in urine were evaluated for their effect on the performance of INNOVITA HCG Pregnancy Rapid test. Negative urine samples were spiked with hCG standard to make samples that contain hCG concentration at 25mIU/mL, 100mIU/mL, 1IU/mL, 10IU/mL, 100IU/mL, 150IU/mL, 500IU/mL, 1000IU/mL and 2000IU/mlL. Three devices from each format were tested with each spiked urine samples. The results demonstrated that no hook effect was observed for hCG concentrations up to 2000IU/mL.

Table 11.10 Results of high dose hook effect study

hCG concentration	Strip	Cassette	Midstream
25 mIU/mL	+ (3/3)	+ (3/3)	+ (3/3)
100 mIU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
1IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
10IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
100 IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
150 IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
500IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
1000IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)
2000IU/mL	+++ (3/3)	+++ (3/3)	+++ (3/3)

2. Comparison Study

a. Method Comparison with Predicate

Method Comparison was performed at three sites where 300 fresh urine samples were collected from females with ages ranging from 18 to 49. For each of urine sample, HCP perform one test using the INNOVITA HCG Pregnancy Rapid Test and one test using the One Step Pregnancy Test (predicate). Total 5 HCP were involved in this study. Three lots of devices were used for comparison study. Tests were carried out with the matched test format. Test results obtained are summarized in the table below:

Table 11.11 Summary of the comparison study with the predicate

		Predicate	
		Positive	Negative
INNOVITA HCG Pregnancy Rapid test	Positive	153	0
	Negative	0	147
	Total	153	147
	% Agreement	100%	

b. Matrix Comparison: Not applicable.

3. Clinical Study

a. Clinical sensitivity: Not applicable.

b. Clinical specificity: Not applicable.

c. Other Clinical Supporting Data:

Lay user study was carried out at three sites. Each site recruited females with diverse ethnical and educational backgrounds with ages ranging from 18 to 49. The study subjects followed the package insert instructions and performed the test without any additional assistance. Study subjects were also asked to collect their own urine sample in a urine collection cup, which was used by the healthcare professional to perform the test with matched format of the new device. The results obtained are summarized in the table below:

Table 11.12 Summary of the OTC study

		Professional	
		Strip	
		Positive	Negative
Lay user	Positive	45	0
	Negative	0	47

		Predicate device professional	
		Cassette	
		Positive	Negative
Lay user	Positive	51	0
	Negative	0	42

		Predicate device professional	
		Midstream	
		Positive	Negative
Lay user	Positive	57	0
	Negative	0	58

All participants completed a post-study questionnaire. Questionnaire Analysis demonstrated the diversity of age, race and educational background of the study participants. The results of the questionnaire also demonstrate that most of participants found INNOVITA HCG Pregnancy Rapid Test easy to use, the instruction easy to understand, and the result easy to interpret. A Flesch-Kincaid reading analysis was also performed on the package insert for each device format for OTC use and shown 7^{th} grade of the reading level.

F. CONCLUSIONS

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