March 12, 2018

Guangzhou Wondfo Biotech Co., Ltd.
% Joe Shia
Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: k173229
Trade/Device Name: Preview Digital 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 8, 2018
Received: February 12, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k173229

Device Name
Preview Digital Pregnancy Test

Indications for Use *(Describe)*
Preview Digital Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in 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.

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

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510(k) k173229 SUMMARY

1. Date: February 6, 2018

2. Submitter:
Guangzhou Wondfo Biotech Co., Ltd.
No.8 Lizhishan Road, Science City,
Luogang District, Guangzhou, Guangdong, P.R.
China 510663

3. Contact person:
Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email:shiajl@yahoo.com

4. Device Name: Preview® Digital Pregnancy Test
Classification: Class II
Product Code LCX
CFR 862.1155

5. Predicate Devices: One step HCG Urine Pregnancy Test (K043443)

6. Intended Use

Preview® Digital Pregnancy Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy.

7. Device Description

Preview® Digital Pregnancy Test is designed to be tested in dip and midstream modes. Preview® Digital Pregnancy Test consists of a single test strip encased in plastic device housing, with an absorbent tip. The device is in a ready-to-use format and no longer requires assembly before use.

8. Substantial Equivalence Information

Similarities		
Item	Candidate device	Predicate device
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	Midstream	Midstream
Differences		
Item	Device	Predicate
Readout	Digital/LCD screen	Visual interpretation of colored line(s)

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. Sensitivity

Urine standards containing intact hCG at concentrations of 0 mIU/mL, 5 mIU/mL, 12.5 mIU/mL, 15 mIU/mL, 18.75 mIU/mL, 25 mIU/mL, 50 mIU/mL, and 100 mIU/mL were prepared in negative urine pool and calibrated against the WHO 4th IS for hCG. These samples were tested by nine operators with three lots of Preview® Digital Pregnancy Test.

The results are summarized in the table below:

Summary urine results (dip method)

hCG concentration	Lot I	Lot II	Lot III
0 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
5 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
12.5 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
15 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
18.75 mIU/mL	7% (2+/28-)	10% (3+/27-)	10% (3+/27-)
25 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)
50 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)
100 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)

Summary urine results (in-stream method)

hCG concentration	Lot I	Lot II	Lot III
0 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
5 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
12.5 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
15 mIU/mL	0% (0+/30-)	0% (0+/30-)	0% (0+/30-)
18.75 mIU/mL	10% (3+/27-)	10% (3+/27-)	10% (3+/27-)
25 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)
50 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)
100 mIU/mL	100% (30+/0-)	100% (30+/0-)	100% (30+/0-)

Based on the above results, the sensitivity of Preview® Digital Pregnancy Test is demonstrated to be 25 mIU/mL.

b. Linearity/assay reportable range:
Linearity is not applicable since this is a qualitative test.

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

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
Preview® Digital Pregnancy Test is calibrated against reference material traceable to WHO International Standard 4th edition.
A shelf-life stability test of the devices was performed in real-time and accelerated testing. The results showed that the devices were stable for 30 months when stored at 4~30℃ in the sealed foil pouch.

d. Specificity and cross reactivity
To evaluate specificity, 300 urine samples were collected from normal, 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 in-stream testing are evaluated. All samples were tested with three lots of Preview® Digital Pregnancy Test. The result indicates that the specificity of Preview® Digital Pregnancy Test is 100%, the false positive rate is 0% and there is no deviation between or within lots.

To evaluate cross-reactivity, negative and positive urine samples (0 mIU/mL, 5 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 250,000 pmol/L hCG β-core fragment for both negative and positive urine samples.

e. 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 0, 5 mIU/mL, 25 mIU/mL and 100 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.

Interfering Substances	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Albumin	20 mg/dL
Amoxicillin	20 mg/dL
Ampicillin	20 mg/dL
Ascorbic acid	20 mg/dL
Aspirin	80 mg/dL
Atropine	20 mg/dL
Benzoylecgonine	10 mg/dL
B-hydroxybutyrate	2000 mg/dL
Bilirubin	2 mg/dL
Caffeine	20 mg/dL
Cannabinol	10 mg/dL
EDTA	80 mg/dL
Ephedrine	20 mg/dL
Ethanol	1%
Folic Acid	0.03 mg/dL
Gentisic acid	20 mg/dL
Glucose	2000 mg/dL
Hemoglobin	50 mg/dL
Ibuprofen	40 mg/dL
Ketone	20 mg/dL
Phenothiazine	20 mg/dL
Phenylpropanolamine	20 mg/dL
Pregnanediol	1.5 mg/dL
Salicylic acid	20 mg/dL
Tetracycline	20 mg/dL
Thiophene	20 mg/dL
Uric Acid	20 mg/dL
Vitamin B1	80 mg/dL

To evaluate potential interference from changes in pH, urine samples containing 0 mIU/mL, 5 mIU/mL, 25 mIU/mL and 100 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 0 mIU/mL, 5 mIU/mL, 25 mIU/mL and 100 mIU/mL hCG were tested at density values ranging from 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. The results indicated that changes in specific gravity do not interfere in the results that were either positive or negative for hCG.

f. Precision

A precision study was performed using negative human urine samples spiked with varying hCG (commercially available and traceable to the 4th WHO international standard) concentrations. The spiked urine samples were measured in 10 replicates per day using 3 different lots. Tests were performed by three different lab technicians for 5 consecutive days.

The dip method results summary was as below:

Concentration (mIU/mL) / Lot	0	5	12.5	15	18.75	25	50	100	1000
Lot I	0+/50-	0+/50-	0+/50-	0+/50-	4+/46-	50+/0-	50+/0-	50+/0-	50+/0-
Lot II	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot III	0+/50-	0+/50-	0+/50-	0+/50-	6+/44-	50+/0-	50+/0-	50+/0-	50+/0-

The in-stream results summary was as below:

Concentration (mIU/mL) / Lot	0	5	12.5	15	18.75	25	50	100	1000
Lot I	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot II	0+/50-	0+/50-	0+/50-	0+/50-	5+/45-	50+/0-	50+/0-	50+/0-	50+/0-
Lot III	0+/50-	0+/50-	0+/50-	0+/50-	6+/44-	50+/0-	50+/0-	50+/0-	50+/0-

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 300 women presenting to test for pregnancy. Approximately half of the 300 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 at each of the 3 POC sites for a total of 9 POC operators with the proposed and the predicate devices.

Summary dip testing results

(Dip Testing)		Predicate device	
		Positive	Negative
Preview® Digital Pregnancy Test	Positive	83	0
	Negative	0	72

Summary in-stream testing results

(In-stream Testing)		Predicate device	
		Positive	Negative
Preview® Digital Pregnancy Test	Positive	76	0
	Negative	0	69

Conclusion from the above table:
The average positive conformity rate of Digital Pregnancy Test is 100%
The average negative conformity rate of Digital Pregnancy Test is 100%

C. Lay person study

First study:

200 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

		Professional	
		+	-
Lay person	+	86	0
	-	0	114

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

Second study:

200 women's individual pregnancy status was self-tested. Negative urine sample pools were spiked with 5 mIU/mL hCG and 25 mIU/mL hCG. Each concentration sample pools were further aliquot into 100 individual containers. All aliquots were blind labeled by the person who prepared the samples and didn't take part in the sample testing. Half of the above subjects tested the 5 mIU/mL hCG aliquots and another half of the subjects tested the 25 mIU/mL hCG aliquots with the device according to the package insert. Each testing site had a study

administrator to observe or monitor the studies without providing assistance to the participants.

Summary

Number of samples	hCG Concentration (mIU/mL)	Lay person results		The percentage of correct results
		Number of Positive	Number of Negative	
100	5	0	100	100%
100	25	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.

12. Conclusion

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