April 12, 2024

Hangzhou Aichek Medical Technology Co., Ltd.
c/o Dylan Wu, Consultant
Shanghai Sungo Management Consulting Co., Ltd.
14th Floor, 1500# Century Avenue
Shanghai, 200122
China

Re: K233624
Trade/Device Name: HCG One Step Pregnancy Test Strip OTC, HCG One Step Pregnancy Test Strip Rx, HCG One Step Pregnancy Test Midstream OTC, HCG One Step Pregnancy Test Midstream Rx
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: February 29, 2024
Received: February 29, 2024

Dear Dylan Wu:

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)*
K233624

Device Name
HCG One Step Pregnancy Test Strip Rx;
HCG One Step Pregnancy Test Midstream Rx

Indications for Use *(Describe)*
The hCG One Step Pregnancy Test Strip Rx is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.

The hCG One Step Pregnancy Test Midstream Rx is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.

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:

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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)*
K233624

Device Name
HCG One Step Pregnancy Test Strip OTC
HCG One Step Pregnancy Test Midstream OTC

Indications for Use *(Describe)*
The hCG One Step Pregnancy Test Strip OTC is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use..

The hCG One Step Pregnancy Test Midstream OTC is intended for qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use.

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.

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510(K) Summary

K233624

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement by 21 CFR 807.92

Date prepared: 9th, Oct 2023

1 Submitter's Information

Name: Hangzhou Aichek Medical Technology Co., Ltd.
Address: 3rd Floor, Building 9, Hexiang Technology Center, Xiasha Street, Qiantang District, 310018 Hangzhou, Zhejiang, China
Contact Person: Lisa Liu
Title: Manager of the quality department
Tel: +86-571-89055299
Email: ra.rep@aichek.com

2 Official Contact Person Information

Primary contact: Mr. Dylan Wu
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-18616797137
Email: haiyang.wu@sungoglobal.com
Secondary contact: Mr. Raymond Luo
Room 1401, Dongfang Building, 1500# Century Ave., Shanghai 200122, China
Tel: +86-21-68828050
Email: zxfda@sungoglobal.com

3 Subject Device

3.1 Trade Name and Regulatory Information:

No.	Trade name	Regulatory Information
1	HCG One Step Pregnancy Test Strip Rx	Class II §21 CFR 862.1155 Human Chorionic Gonadotropin (HCG) test system
2	HCG One Step Pregnancy Test Strip OTC	
3	HCG One Step Pregnancy Test Midstream Rx	
4	HCG One Step Pregnancy Test Midstream OTC	

3.2 Classification Information

Product Code	Classification	Description	Panel
LCX	Class II	Kit, test, pregnancy, HCG, over the counter	Clinical Chemistry
JHI	Class II	Visual, pregnancy HCG, prescription use	Clinical Chemistry

4 Predicate device

One Step HCG Urine Pregnancy Test (K043443)

5 Indications for use/Intended use

The HCG One Step Pregnancy Test Strip OTC is intended for qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use.
The HCG One Step Pregnancy Test Strip Rx is intended for qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.
The HCG One Step Pregnancy Test Midstream OTC is intended for qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For over-the-counter use.
The HCG One Step Pregnancy Test Midstream Rx is intended for qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in early detection of pregnancy. For in Vitro Diagnostic Use Only. For prescription use.

6 Device Description

The tests are rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal HCG antibody to selectively detect elevated levels of HCG. The assay is conducted by added urine sample and obtaining the result from the colored lines.
The tests will be sold in Midstream and Strip format. The Midstream format consists of a single test strip assembled in a plastic card, with an absorbent tip, and is designed to be tested in dip or midstream mode. The Strip format is a single test strip. The Midstream format contains one Test Midstream sealed in a desiccated aluminum foil pouch and Instructions for Use. The Strip format contains one Test strip sealed in a desiccated aluminum foil pouch, Instructions for Use. The device is in a ready-to-use format and does not require assembly before use.

7 Principle of Operation

The tests are rapid, one-step lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in urine to aid in the detection of pregnancy.
The test comes in two formats; 1) Midstream, in which a user can apply a specimen by keeping the absorbent tip in a urine stream for 10-15 seconds or by dipping the absorbent tip (at least 2/3, but not exceed the highest level) into urine collected in a clean and dry container for 10-15 seconds; and 2) test strip format, in which a user dips the absorbent tip(but not exceed the MAX line) into urine collected in a clean and dry container for 5-10 seconds.
After application of the urine specimen, the HCG within the urine reacts with the anti-βHCG antibody-colloidal gold conjugate to form a compound. The compound is captured by the anti-αHCG antibody immobilized on the test area, then a colored line will form in the test line region (T) (i.e., test line). A colored line will always develop in the control line region (C) (i.e., control line) if sufficient sample volume has been applied to the test strip. The test result is shown in the result window and read visually between 3-10 minutes of urine application.
Two distinct colored lines, one line in the control line region (C) and another in the test line region (T) indicate a positive test result (pregnant). Absence of a colored line in the test line region (T) and only a colored line in the control line region (C) indicates a negative test result (not pregnant). Absence of a colored line in the control line region (C), even in the presence of a colored line in the test line region (T), indicates an invalid test.

8 Comparison with the predicate device

8.1 Technological characteristics

Table 1 Comparison of Technological characteristics

Device	Proposed Device	Predicate Device	Result
Manufacturer	Hangzhou Aichek Medical Technology Co., Ltd.	Guangzhou Wondfo Biotech Co., Ltd.	-
510K number	K233624	K043443	-
Device name	**HCG One Step Pregnancy Test Strip Rx** **HCG One Step Pregnancy Test Strip OTC** **HCG One Step Pregnancy Test Midstream Rx** **HCG One Step Pregnancy Test Midstream OTC**	**One Step HCG Urine Pregnancy Test**	**Similar**
Classification	**Class II**	**Class II**	**Same**
Intended use	Aid in early detection of pregnancy. For over-the-counter use and Prescription use.	Aid in early detection of pregnancy. For over-the-counter use and Prescription use.	Same
Analyte	Human Chorionic Gonadotrophin (HCG)	Human Chorionic Gonadotrophin (HCG)	Same
Specimen Type	Human Urine	Human Urine	Same
Technology	Lateral flow immunoassay	Lateral flow immunoassay	Same
Basic Components	Test strip containing nitrocellulose membrane, sample pad, alpha and beta HCG antibodies	Test strip containing nitrocellulose membrane, sample pad, alpha and beta HCG antibodies	Same
Results	Qualitative	Qualitative	Same
Storage Temperature	2-30℃	4-30℃	Similar
Format	Strip/Midstream	Strip/Cassette/Midstream	Similar
Read Time	3-10minutes	3-5minutes	Similar

8.2 Analytical Performance

Table 2 Comparison of Analytical Performance

Device	Proposed Device	Predicate Device	Result
510K number	K233624	K043443	-
Analytical Sensitivity	25 mIU/mL	25 mIU/mL	Same
Analytical Specificity	LH at 500mIU/mL FSH at 1000 mIU/mL TSH at 1 mIU/mL	LH at 300mIU/mL FSH at 300 mIU/mL TSH at 1000 mIU/mL	Similar
High Dosage Hook effect	No high dosage hook effect for HCG up to 2000000mIU/mL.	No high dosage hook effect for HCG up to 100,000 mIU/mL.(100IU/mL)	Similar
Traceability	WHO 6th International Standard	WHO 3rd International Standard	Similar
Urine pH Interference	No interference for urine with pH 4-9	No interference for urine with pH 4-9	Same
Urine Specific gravity Interference	No interference for urine with Specific Gravity 1.000-1.035	No interference for urine with Specific Gravity 1.000-1.050	Similar

8.3 Substantial Equivalence

The proposed device is substantially equivalent to the predicate device, in terms of intended use, Analyte, Specimen Type, Technology, Basic Components, Results, Format, Analytical Sensitivity (LoD) and Urine pH Interference.

The minor difference of analytical performance between the proposed device and the predicate device, i.e., Read Time, Analytical Specificity, High Dosage Hook effect, Storage Temperature, and Urine Specific gravity Interference will not influence the effectiveness of the proposed device.

Therefore, it can be concluded that the proposed device and the proposed device are substantially equivalent.

9 Summary of Non-Clinical Testing

9.1 Analytical performance

a Precision / Reproducibility/Sensitivity

Urine samples from non-pregnant females (negative) were spiked with 0 mIU/mL, 12.5 mIU/mL, 18.75 mIU/mL, 25 mIU/mL, 37.5 mIU/mL, 50 mIU/mL, and 100 mIU/mL of HCG. Three (3) lots of tests (strip/midstream format by immersion sampling method /midstream format by urinate sampling method) were used to test each concentration in replicates of 2 per day, at 3 sites. Testing was repeated for 15 days. For each format of the device, a total of 90 replicates were tested for at each HCG concentration. The results demonstrated that all specimens with HCG concentration equal to or higher than 25mIU/mL show positive results, while HCG concentration lower than 25mIU/mL showed some negative results. Therefore, the sensitivity concentration of the tests is determined to be 25mIU/mL HCG. All devices have 100% positive detection at the claimed sensitivity of 25 mIU/mL and above. There were no significant differences in performance between lots, between operators, between sites, between time of day and between days. Summary of results are presented in the following Table 3 , Table 4 and Table 5.

Table 3 Precision / Reproducibility /Sensitivity results of Strip Format

HCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total Result		% Positive	% Negative
	Site 1		Site 2		Site 3					
	Operator 1		Operator 2		Operator 3					
	+	-	+	-	+	-	+	-		
0	0	30	0	30	0	30	0	90	0.0%	100.0%
12.5	0	30	0	30	0	30	0	90	0.0%	100.0%
18.75	11	19	12	18	11	19	34	56	37.8%	62.2%
25	30	0	30	0	30	0	90	0	100.0%	0.0%
37.5	30	0	30	0	30	0	90	0	100.0%	0.0%
50	30	0	30	0	30	0	90	0	100.0%	0.0%
100	30	0	30	0	30	0	90	0	100.0%	0.0%

Table 4 Precision / Reproducibility /Sensitivity results of Midstream Format (immersion sampling method)

HCG Concentration (mIU/mL)	Lot 4		Lot 5		Lot 6		Total Result		% Positive	% Negative
	Site 1		Site 2		Site 3					
	Operator 4		Operator 5		Operator 6					
	+	-	+	-	+	-	+	-		
0	0	30	0	30	0	30	0	90	0.0%	100.0%
12.5	0	30	0	30	0	30	0	90	0.0%	100.0%
18.75	13	17	12	18	10	20	35	55	38.9%	61.1%
25	30	0	30	0	30	0	90	0	100.0%	0.0%
37.5	30	0	30	0	30	0	90	0	100.0%	0.0%
50	30	0	30	0	30	0	90	0	100.0%	0.0%
100	30	0	30	0	30	0	90	0	100.0%	0.0%

Table 5 Precision / Reproducibility /Sensitivity results of Midstream Format midstream (urinate sampling method)

HCG Concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Total Result		% Positive	% Negative
	Site 1		Site 2		Site 3					
	Operator 1		Operator 2		Operator 3					
	+	-	+	-	+	-	+	-		
0	0	30	0	30	0	30	0	90	0.0%	100.0%
12.5	0	30	0	30	0	30	0	90	0.0%	100.0%
18.75	13	17	12	18	10	20	35	55	38.9%	61.1%
25	30	0	30	0	30	0	90	0	100.0%	0.0%
37.5	30	0	30	0	30	0	90	0	100.0%	0.0%
50	30	0	30	0	30	0	90	0	100.0%	0.0%
100	30	0	30	0	30	0	90	0	100.0%	0.0%

b Linearity/assay reportable range

Linearity is not applicable since this is a qualitative test.

c Traceability, Stability, Expected values (controls, calibrators, or methods):

c.1 Traceability

The tests are calibrated against reference material traceable to WHO International Standard 6th edition, NIBSC code 18/244

c.2 Stability

The stability data supports that the products have the shelf life of 36 months when stored at 2-30℃.

Real time Stability

A 39-month real time stability test is planned to verify the shelf-life stability of the device as 36 months. Three batches for each format in sealed foil pouch are currently stable for 12 months at 2-8°C and 30°C, and the real time stability study is still on-going.

Accelerated Stability

Stable at 2-30℃ for 36 months based on the accelerated stability study at 55℃ for 46 days and real time stability determination at both 2-8℃ and 30℃.

d Detection limit

The detection limit was determined in the precision study (See 9.1.a above)

e Analytical specificity

e.1 Cross-Reactivity

The candidate devices were tested for potential cross-reactivity from luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH). Each potential cross-reactant was spiked into a negative pooled human urine sample (control) and two positive pooled human urine samples containing 25mIU/mL HCG and 100mIU/mL HCG (test). Test and control samples were tested in replicates of 15 on 3 lots of the candidate device for each format (5replicates tested by each lot). Totally n=15 for each concentration of Cross-reactivity substance in each HCG level sample. The results summarized in Table 6 and Table 7 demonstrated that the tests do not interference at 500mIU/mL LH, 1000mIU/mL FSH or 1000μIU/mL TSH.

Table 6 Cross-Reactivity results of Strip Format

Cross-reactivity substance	Concentration	HCG (mIU/mL)		
		0	25	100

		+	-	+	-	+	-
TSH	500 μIU/mL	0	15	15	0	15	0
	750 μIU/mL	0	15	15	0	15	0
	1000 μIU/mL	0	15	15	0	15	0
FSH	500 mIU/mL	0	15	15	0	15	0
	750 mIU/mL	0	15	15	0	15	0
	1000 mIU/mL	0	15	15	0	15	0
LH	250 mIU/mL	0	15	15	0	15	0
	500 mIU/mL	0	15	15	0	15	0
	750 mIU/mL	5	10	15	0	15	0

Table 7 Cross-Reactivity results of Midstream Format

Cross-reactivity substance	**Concentration**	**HCG (mIU/mL)**					
		0		**25**		**100**	
		+	-	+	-	+	-
TSH	500 μIU/mL	0	15	15	0	15	0
	750 μIU/mL	0	15	15	0	15	0
	1000 μIU/mL	0	15	15	0	15	0
FSH	500 mIU/mL	0	15	15	0	15	0
	750 mIU/mL	0	15	15	0	15	0
	1000 mIU/mL	0	15	15	0	15	0
LH	250 mIU/mL	0	15	15	0	15	0
	500 mIU/mL	0	15	15	0	15	0
	750 mIU/mL	8	7	15	0	15	0

e.2 Interference Study

To evaluate potential interference for the tests, urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples). All samples were spiked with final concentrations of potential interferents listed in Table 8 below. For each condition 15 replicates were tested on 3 device lots of each format (5replicates tested by each lot). The results demonstrated that no interference from substances at the concentrations shown in Table 8 below.

Table 8 Interfering substances and concentrations

Interfering Substance	**Concentration**	**Interfering Substance**	**Concentration**
Acetaminophen	20mg/dL	Hydroxybutyric acid	2000mg/dL
Acetone	20mg/dL	Ibuprofen	40mg/dL
Acetylsalicylic acid	20mg/dL	L-ephedrine hydrochloride	20mg/dL
Albumin	2000mg/dL	Methadone	20mg/dL
Ampicillin	20mg/dL	Morphin	10mg/dL
Ascorbic acid	20mg/dL	Nicotine	10mg/dL
Atropine	20mg/dL	Phenylpropanolamine	20mg/dL
Bilirubin	2mg/dL	Proephedrine hydrochloride	20mg/dL
Caffeine	20mg/dL	Salicylic acid	20mg/dL
Cannabinol	10mg/dL	Tetracycline	20mg/dL
Gentisic acid	20mg/dL	Uric acid	20mg/dL

Interfering Substance	Concentration	Interfering Substance	Concentration
Glucose	2000mg/dL	Ethanol	1%
Hemoglobin	250mg/dL	Vitamin B	800μg/mL
Blood urine	15%		

e.3 Effect of HCG β-core fragment

Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples). The positive and negative samples then were spiked with HCG β-core fragment at concentrations of 62500, 125000, 250000, 500000, 1000000 pmol/L. All samples were tested in 15 replicates on 3 device lots of each format (5replicates tested by each lot). The results demonstrated that the candidate devices are not affected by concentrations of HCG β-core fragment up to 1000,000 pmol/L.

e.4 Effect of urine pH

To evaluate potential interference from changes in urine pH, urine samples containing 0 mIU/mL and 25 mIU/mL HCG were tested in 15 replicates on 3 lots each format of device (5replicates tested by each lot) using samples at pH values of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0. The results demonstrated that samples within the pH range of 4.0-9.0 do not interfere with either positive or negative results from the devices.

e.5 Effect of urine specific gravity

To evaluate potential interference from changes in urine specific gravity, urine samples containing 0 mIU/mL and 25 mIU/mL HCG were tested in 15 replicates on 3 lots each format of device (5 replicates tested by each lot) using samples at specific gravity values of 1.000, 1.015, 1.018, 1.020, 1.022, 1.026, 1.031, 1.035. The results demonstrated that samples within the specific gravity range of 1.000-1.035 do not interfere with either positive or negative results from the devices.

e.6 High dose hook effect study

Urine samples from non-pregnant females (negative samples) were used to prepared samples with HCG concentrations of 25mIU/mL, 100mIU/mL, 1IU/mL, 100IU/mL, 500IU/mL, 1000IU/mL, and 2000IU/mL HCG, each concentration of the samples was test in 15 replicates on 3lots of each format of the device (5replicates tested by each lot). The test results demonstrated no hook effect at HCG concentrations up to 2000 IU/mL.

f Assay Cut-off

The cutoff for a positive test is 25 mIU/mL. See detection limit in 9.1d.

g Read Time Flex

Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples). All samples were tested in 5 replicates by 1 lot of each format of the device and then read the results at 3 minutes, 5 minutes, 10 minutes, and 30 minutes after sample addition. The results summarized in Table 9 indicated that the test results all met criteria acceptance at 3min~30min and the background was clear. We recommend reading the results at 3 – 10 minutes and do not read the result after 10 minutes.

Table 9 Read time flex results of the tests

Sample	3minutes				5minutes				10minutes				30minutes			
	Strip		Midstream		Strip		Midstream		Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0	5	0	5	0	5	0	5	0

h Temperature Flex

To determine the operating temperature of the test by studying different operating temperatures. Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples)and 25 mIU/mL

HCG (positive samples). The tests were equilibrated for 2 hours in 2-8℃, 10-30℃, and 37℃. All samples were tested in 5 replicates by 1 lot of above 3 different equilibrated devices of each format and then read the results at 3 minutes, 5 minutes, and 10 minutes after sample addition. The results summarized in Table 10 to Table 12 indicated that when test at 2~30℃, the results were not obvious difference and meet the criteria acceptance. So, the test can be operated at home situation.

Table 10 The temperature flex results of the tests*: 2-8 ℃*

Sample	3minutes				5minutes				10minutes			
	Strip		Midstream		Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-	+	-	+	-
0 mIU/mL HCG	0	5	0	5	0	5	0	5	0	5	0	5
25 mIU/mL HCG	5	0	5	0	5	0	5	0	5	0	5	0

Table 11 The temperature flex results of the tests*: 10-30 ℃*

Sample	3minutes				5minutes				10minutes			
	Strip		Midstream		Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-	+	-	+	-
0 mIU/mL HCG	0	5	0	5	0	5	0	5	0	5	0	5
25 mIU/mL HCG	5	0	5	0	5	0	5	0	5	0	5	0

Table 12 The temperature flex results of the tests*: 37 ℃*

Sample	3minutes				5minutes				10minutes			
	Strip		Midstream		Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-	+	-	+	-
0 mIU/mL HCG	0	5	0	5	0	5	0	5	0	5	0	5
25 mIU/mL HCG	5	0	5	0	5	0	5	0	5	0	5	0

i Sample Volume Flex

To determine the appropriate sample volume of the tests by studying different sample volume. Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples).

1) Dip only the Absorbent tip (but not exceed the MAX line) of the Strip test into the urine for 3s, 5s, 10s, and 15s.
2) Dip only the Absorbent tip (at least 2/3, but not exceed the highest level) of the midstream test into the urine for 8s, 10s, 15s, and 20s.
3) To evaluate product performance and test the tightness of the midstream window. A peristaltic pump was used to simulate urine stream, hold the midstream by the Thumb Grip with the Absorbent tip pointing downward directly into urine stream for 8s, 10s, 15s, and 20s.
4) For each condition all samples were tested in 5 replicates and then read the results at 3 minutes after sample addition.

The results summarized in Table 13 to Table 15 indicated that the test results all met criteria acceptance when sample addition time was 3s, 5s, 10s, 15s for strip and 8s, 10s, 15s, and 20s for midstream (both immerse sample and simulate urine stream). Referring to the instructions for use of similar products on the market, for the convenience of users, we recommended to immerse or urinate sample for 10-15s using midstream and to immerse sample for 5-10s using strip.

Table 13 Sample Volume Flex results of the tests

Sample	3s		5s		10s		15s	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0
Appearance inspection (If sample splash the window)	No		No		No		No	

Table 14 Sample Volume Flex results of the tests*: Immerse sample*

Sample	8s		10s		15s		20s	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0
Appearance inspection (If sample splash the window)	No		No		No		No	

Table 15 Sample Volume Flex results of the tests*: Simulate urine stream*

Sample	8s		10s		15s		20s	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0
Appearance inspection (If sample splash the window)	No		No		No		No	

j Sample Storage study

To study the effects of different sample storage conditions at 2-8℃ for 0h / 48h and at room temperature (10-30℃) for 0h / 12h on performance of tests. Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples). The samples were separated in two parts, one part was stored at 2-8℃ for 0h and 48h while another part was stored at room temperature (10-30℃) for 0h and 12h. All samples were tested in 5 replicates by 1 lot of each format of the device and then read the results at 3 minutes after sample addition. The results summarized in Table 16 indicated that the test results all met criteria acceptance when urine sample stored at 10-30℃ for 12 hours and 2-8℃ for 48 hours.

Table 16 Sample Storage results of the tests

Sample	2-8℃								10-30℃							
	0h				48h				0h				12h			
	Strip		Midstream		Strip		Midstream		Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0	5	0	5	0	5	0	5	0

k Sample container material study

To evaluate the effect of tests samples stored in different sample container material (paper cups (coated), paper cups (uncoated), plastic urine cups and glass cups) on performance at 2-8℃ for 48h and at room temperature (10-30℃) for 12h. Urine samples from non-pregnant females (negative samples) were spiked with 0 mIU/mL HCG (negative samples) and 25 mIU/mL HCG (positive samples). The samples were separated in two parts, one part of samples was stored at 2-8℃ for 48h while another part was stored at room temperature (10-30℃) for 12h, both part of samples was stored using paper cups (coated), paper cups (uncoated), plastic urine cups, and glasses in two

temperature storage conditions. For each condition, all samples were tested in 5 replicates by 1 lot of each format of the device and then read the results at 3 minutes after sample addition. The results summarized in Table 17 to Table 20 indicated that no sample container material effect was observed when tested with up to a concentration of 0mIU/mL and 25mIU/mL of human chorionic gonadotropin with the test.

Table 17 Sample container material results of the tests

Storage Material	Paper cups(coated)							
Sample	2-8℃				10-30℃			
	48h				12h			
	Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0

Table 18 Sample container material results of the tests

Storage Material	Paper cups(no coated)							
Sample	2-8℃				10-30℃			
	48h				12h			
	Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0

Table 19 Sample container material results of the tests

Storage Material	Plastic urine cups							
Sample	2-8℃				10-30℃			
	48h				12h			
	Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0

Table 20 Sample container material results of the tests

Storage Material	Glasses							
Sample	2-8℃				10-30℃			
	48h				12h			
	Strip		Midstream		Strip		Midstream	
	+	-	+	-	+	-	+	-
0mIU/mL HCG	0	5	0	5	0	5	0	5
25mIU/mL HCG	5	0	5	0	5	0	5	0

9.2 Comparison Studies

a Method comparison with predicate device

The performance of the two device formats (Strip, midstream) of the test was compared to the predicate device. Testing was performed by laboratory professionals at three point-of care (POC) sites with urine samples from 330 women between the age of 18-45, Urine samples were collected from 330 women presenting to test for pregnancy. Approximately half of the 330 women were suspected to be pregnant. All samples were tested with candidate and predicate devices at three POC sites, each format of device was tested in 3 sites(3 different professionals using the

candidate device and the predicate device at each site, totally 9 different professionals conducted the study). The results are summarized in Table 21 - Table 23 below.

Table 21 Test Strip Format method comparison results

Candidate Device		Predicate Device		Total
		Positive	Negative	
Strip Format	Positive	58	0	58
	Negative	0	52	52
Total		58	52	110

Sensitivity:100.00% (58/58), Wilson 95%Cl:93.79%-100.00%.

Specificity:100.00% (52/52), Wilson 95%Cl:93.12%-100.00%.

Accuracy:100.00% (110/110), Wilson 95%Cl:96.63%-100.00%.

Positive predictive value:100.00% (58/58), Wilson 95%Cl:93.79%-100.00%.

Negative predictive value:100.00% (52/52), Wilson 95%Cl:93.12%-100.00%.

Table 22 Test Midstream Format Immersion sample method comparison results

Candidate Device		Predicate Device		Total
		Positive	Negative	
Midstream (Immersion sample)	Positive	59	0	59
	Negative	0	52	52
Total		59	52	111

Sensitivity:100.00% (59/59), Wilson 95%Cl:93.89%-100.00%.

Specificity:100.00% (52/52), Wilson 95%Cl:93.12%-100.00%.

Accuracy:100.00% (111/111), Wilson 95%Cl:96.65%-100.00%.

Positive predictive value:100.00% (59/59), Wilson 95%Cl:93.89%-100.00%.

Negative predictive value:100.00% (52/52), Wilson 95%Cl:93.12%-100.00%.

Table 23 Test Midstream Format Urinate sample method comparison results

Candidate Device		Predicate Device		Total
		Positive	Negative	
Midstream (Urinate sample)	Positive	58	0	58
	Negative	0	51	51
Total		58	51	109

Sensitivity:100.00% (58/58), Wilson 95%Cl:93.79%-100.00%.

Specificity:100.00% (51/51), Wilson 95%Cl:93.00%-100.00%.

Accuracy:100.00% (109/109), Wilson 95%Cl:96.60%-100.00%.

Positive predictive value:100.00% (58/58), Wilson 95%Cl:93.79%-100.00%.

Negative predictive value:100.00% (51/51), Wilson 95%Cl:93.00%-100.00%.

The data shows that the agreement of the tests with the predicate device was 100%.

b Matrix comparison

Not applicable. This device is for testing with human urine only.

10 Clinical studies

a Clinical Sensitivity

Not applicable

b Clinical specificity

Not applicable

c Other clinical supportive data (when a. and b. are not applicable)

c.1 Lay-User Study

A lay user study was conducted at 3 sites with 330 volunteers with diverse educational and occupational backgrounds who were between the ages of 18 and 45. This included 110 lay-users using the HCG One Step Pregnancy Test Strip OTC, 220 lay-users using the HCG one step Pregnancy Test Midstream OTC, split between 111 users performing Immersion sample and 109 users performing Urinate sample. The lay users tested their own urine sample and provided a sample for professional testing. Ease of use of the candidate devices was assessed through a questionnaire that was completed at the end of the study. The questionnaire results indicated that lay-users found the tests easy to use, the results clear and easy to read and the instructions for use easy to understand. The data shows that the agreement between lay-user results and professional results was 100% in Table 24 to Table 26 below.

Table 24 Lay user and professional test results for Strip OTC

Strip Format		Professional test results		Total
		Positive	Negative	
Lay user test results	Positive	58	0	58
	Negative	0	52	52
Total		58	52	110

Positive coincidence rate=100%×58/ (58+0)=100.00%,Wilson 95%Cl:93.79%-100.00%.

Negative coincidence rate=100%×52/ (0+52)=100.00%,Wilson 95%Cl:93.12%-100.00%.

Total coincidence rate=100%×(58+52)/ (58+0+0+52)=100.00%,Wilson 95%Cl:96.63%-100.00%.

Table 25 Lay user and professional test results for Midstream OTC (Immersion sample)

Midstream (Immersion sample)		Professional test results		Total
		Positive	Negative	
Lay user test results	Positive	59	0	59
	Negative	0	52	52
Total		59	52	111

Positive coincidence rate=100%×59/ (59+0)=100.00%,Wilson 95%Cl:93.89%-100.00%.

Negative coincidence rate=100%×52/ (0+52)=100.00%,Wilson 95%Cl:93.12%-100.00%.

Total coincidence rate=100%×(59+52)/ (59+0+0+52)=100.00%,Wilson 95%Cl:96.65%-100.00%.

Table 26 Lay user and professional test results for Midstream OTC (Urinate sample)

Midstream (Urinate sample)		Professional test results		Total
		Positive	Negative	
Lay user test results	Positive	58	0	58
	Negative	0	51	51
Total		58	51	109

Positive coincidence rate=100%×58/ (58+0)=100.00%,Wilson 95%Cl:93.79%-100.00%.

Negative coincidence rate=100%×51/ (0+51)=100.00%,Wilson 95%Cl:93.00%-100.00%.

Total coincidence rate=100%×(58+51)/ (58+0+0+51)=100.00%,Wilson 95%Cl:96.60%-100.00%.

A Flesch-Kincaid reading analysis is performed on each package insert for the OTC devices and the score of the tests demonstrates a reading Grade Level of 7, the results show that the labels can be understood by people with no more than 7th grade education.

d Clinical Cut-off

Not applicable

11 Conclusion

Based on the test principle and performance characteristics of the device including precision, sensitivity, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that the tests are substantially equivalent to the predicate.

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