March 10, 2022

SPD Swiss Precision Diagnostics GmbH
% Kamila Przedmojska
Senior Regulatory Specialist - Product Lifecycle
SPD Development Company Limited
Priory Business Park, Stannard Way
Bedford, Bedfordshire MK44 3UP
United Kingdom

Re: K210341
Trade/Device Name: One Step Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (hCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: December 1, 2021
Received: December 10, 2021

Dear Kamila Przedmojska:

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.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k210341

Device Name
One Step Pregnancy Test

Indications for Use *(Describe)*
One Step Pregnancy Test is an over-the-counter lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The visual test is intended for home use as an aid in early detection of pregnancy. The test is indicated for use from 4 days before the day of the expected period (5 days before the day of the missed period).

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

A. Submitted By:

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B. Contact Person:

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C. Date Prepared: 09 March 2022

D. Device Name: One Step Pregnancy Test

Product Code:	LCX
Common name:	Kit, Test, Pregnancy, hCG, over the counter
Classification:	Class II
Regulation Description:	Human chorionic gonadotropin (hCG) test system
Regulation number:	21CFR 862.1155
510(k) number:	k210341

E. Predicate Device: K012215, QUIK-CHECK™ Home Pregnancy Test

F. Indication for Use

One Step Pregnancy Test is an over-the-counter lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The visual test is intended for home use as an aid in early detection of pregnancy. The test is indicated for use from 4 days before the day of the expected period (5 days before the day of the missed period).

G. Device Description

The One Step Pregnancy Test is an over-the-counter, visual pregnancy test with sensitivity of 25mIU/mL hCG (human chorionic gonadotropin) and is indicated for use up to 4 days before the expected period (5 days before the missed period). The device employs an immunochromatographic sandwich assay to detect hCG on a lateral flow test strip housed in a cassette. Following sample application using the supplied pipette, the user is required to visually interpret the results displayed as lines in a result window.

H. Substantial Equivalence Information

Predicate device name:

QUIK-CHECK™ Home Pregnancy Test

Predicate (k) number:

K012215

Comparison with predicate:

Similarities and differences between the One Step Pregnancy Test and the predicate QUIK-CHECK™ Home Pregnancy Test

Component	One Step Pregnancy Test **(Proposed Device)**	QUIK-CHECK™ Home Pregnancy Test **(Predicate Device)**
Similarities		
Intended Use	Over-the-counter lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The visual test is intended for home use as an aid in early detection of pregnancy.	Intended for non-professional / over-the-counter use for the qualitative identification of hCG (human chorionic gonadotropin) in urine to aid in the determination of pregnancy.
Target User	Over-the-counter use	Same
Device format	Cassette	Same
Analyte	hCG	Same
Sensitivity	25mIU/mL	Same
Test Principle	Lateral flow qualitative chromatographic immunoassay with visual result display	Same
Sample application	Sample applied as drops to sample well via supplied pipette	Same
Time to results	3 minutes	Same
Result Display	Visual interpretation of coloured lines in result window	Same
Differences		
Traceability	WHO 4th International Standard for hCG	WHO 3rd International Standard for hCG
Early Claim	Pregnancy can be detected as early as 4 days before the date of the expected period (5 days before missed period)	Not tested for this device

I. Test Principle

The One Step Pregnancy Test is a lateral flow sandwich immunoassay employing monoclonal antibodies that are directed against the alpha and beta sub-units of hCG.

To use the test, the user collects their urine in a clean dry container and uses the supplied pipette to draw up and deposit 4 drops of urine into the sample well.

If hCG is present in the urine sample, it is bound by a conjugated monoclonal anti α-hCG antibody forming an anti hCG-antibody-gold complex. The sample is drawn through the nitrocellulose membrane by capillary action. At the test (T) line, any hCG is bound by immobilised anti-β hCG antibody forming a sandwich, immobilising gold particles as the test line. This sandwich gives rise to a coloured line. If no hCG is present in the sample, there is no binding at the test line and subsequently, no coloured line.

At the control (C) line, rabbit IgG sensitised gold particles encounter the immobilised control antibody line (goat anti-rabbit antibody). The rabbit IgG is bound at the control (C) line within the result window and a coloured line forms to show that the test has worked correctly.

At the read time the appearance of two coloured lines in the result window, the test (T) line and control (C) line, indicates a Pregnant result. The appearance of one coloured line in the result window, the control (C) line, indicates a Not Pregnant result. If there is no control (C) line, the test has not run correctly and is classed as an Invalid result.

J. Performance characteristics

1. Analytical Performance

a) Precision/Reproducibility/Sensitivity

A pooled negative urine was spiked with hCG to provide eight urine standards with the hCG concentrations of <0.5, 12.5, 15, 18, 25, 50, 100 and 200mIU/mL. The eight standards were each tested with 180 devices from four different batches. Each batch was tested by 3 operators over 3 non-consecutive days

The results of the precision and sensitivity study at each concentration of hCG are summarised in the tables below. The results demonstrated that the analytical sensitivity of the One Step Pregnancy Test is 25mIU/mL.

Overall Precision Results for One Step Pregnancy Test

hCG Standard (mIU/ml)	Total (n)	Pregnant (n)	Not Pregnant (n)	Pregnant Results (%)
<0.5	180	0	180	0.0
12.5	180	30	150	16.7
15	180	76	104	42.2
18	180	145	35	80.6
25	180	180	0	100.0
50	180	180	0	100.0
100	180	180	0	100.0
200	180	180	0	100.0
Total	**1440**	**971**	**469**	**N/A**

Percentage Pregnant Results for each hCG standard by Batch

hCG Standard (mIU/ ml)	CYG00011		CYG00012		CYG00013		CYG00016	
	Pregnant/ Not Pregnant (n)	Pregnant Results (%)	Pregnant/ Not Pregnant (n)	Pregnant Results (%)	Pregnant/ Not Pregnant (n)	Pregnant Results (%)	Pregnant/ Not Pregnant (n)	Pregnant Results (%)
<0.5	0/45	0.0	0/45	0.0	0/45	0.0	0/45	0.0
12.5	7/38	15.6	8/37	17.8	6/39	13.3	9/36	20.0
15	16/29	35.6	22/23	48.9	19/26	42.2	19/26	42.2
18	35/10	77.8	38/7	84.4	37/8	82.2	35/10	77.8
25	45/0	100	45/0	100	45/0	100	45/0	100
50	45/0	100	45/0	100	45/0	100	45/0	100
100	45/0	100	45/0	100	45/0	100	45/0	100
200	45/0	100	45/0	100	45/0	100	45/0	100

The study indicates that the results returned by the One Step Pregnancy Test are not significantly affected by operator, day of testing or batch across the standards tested in the study. The results demonstrated that the analytical sensitivity of the One Step Pregnancy Test is 25mIU/mL.

b) Linearity/assay reportable range:

Not applicable. This is a qualitative device.

c) High dose hook effect study:

Negative pooled urine was spiked with hCG to concentrations of <0.5, 25, 250000, 500000, 1000000mIU/mL and tested with 5 replicates per each of 3 batches. No hook effect was observed at tested concentrations.

d) Traceability

The devices are calibrated against the WHO 4th International Standard for Chorionic Gonadotropin (hCG) (NIBSC code 75/589).

e) Stability

The claimed shelf life of the device stored in the sealed pouches at room temperature is 24 months. Real time stability studies are ongoing.

f) Detection limit (sensitivity)

See Precision / Reproducibility / Sensitivity section

g) Analytical specificity

Structure not-related compounds

Interfering substances
The One Step Pregnancy Test devices were tested with potentially interfering substances. Each interfering substance was spiked into non-pregnant pooled urine (<0.5mIU/mL) and 25mIU/mL hCG urine standards.

Each condition was tested with 5 devices from each of three batches for each of the two urine standards. No interference effect was observed at the tested concentration shown in table below:

Interfering Substance	**Concentration**
Acetylsalicylic acid	1.0mg/mL
Acetone	1.0mg/mL (0.125% v/v)
Albumin	5mg/mL

Interfering Substance	Concentration
Ampicillin	200µg/mL
Ascorbic acid	150µg/mL
Atropine	200µg/mL
Bilirubin	200µg/mL
Blood	0.3% v/v
Caffeine	1.2mg/mL
Cannabinol	100µg/mL
Clomiphene citrate	24µg/mL
Cotinine	40µg/mL
Ethanol	5% v/v
E3G	620ng/mL
Glucose	20mg/mL
Gentisic acid	200µg/mL
Haemoglobin	100µg/mL
Hydrochloric acid	1.25mM
Ibuprofen	100µg/mL
Leukocytes	$1x10^6$ cells/mL
Oxytetracycline	300µg/mL
Paracetamol (Acetaminophen)	600µg/mL
P3G	40µg/mL
Phenylpropanolamine	200µg/mL
Semen	5% v/v
Sodium hydroxide	1.25mM
Tetracycline	300µg/mL
Urea	30mg/mL
Uric acid	750µg/mL
Urobilinogen	100µg/mL

Structure related compounds

The One Step Pregnancy Test devices were tested with 3 potential cross reactants. Each potential cross reactant was spiked into non-pregnant pooled urine <0.5mIU/mL and 25mIU/mL hCG urine standard at the following concentration:

Cross Reactant	**Concentration**
Follicle – Stimulating Hormone (FSH)	1000 mIU/mL
Luteinizing Hormone (LH)	500 mIU/mL
Thyroid – Stimulating Hormone (TSH)	1mIU/mL

Specificity of ≥99% was demonstrated when tested with potential cross reactants.

Effects of urine pH

Effect of urine pH was performed by adjusting non-pregnant pooled urine (<0.5mIU/mL) and 25mIU/mL hCG urine standard to a pH range of 4, 5, 6 (unadjusted control), 7, 8, and 9. Each urine standard was tested with 15 devices, 5 from each of 3 batches per pH condition. The results demonstrated that One Step Pregnancy Test will continue to return a correct result when tested with a urine sample in the pH range of 4 – 9.

Effect of urine specific gravity

To test the effect of specific gravity, device was challenged with negative (<0.5mIU/mL) and 25mIU/mL urine standards with the specific gravity of 1.000, 1.005, 1.016, 1.029 and 1.035. The results showed One Step Pregnancy Test will continue to return a correct result in response to changes in specific gravity within the range from 1.000 to ≤1.035.

Effect of hCG beta-core fragment (hCGβcf)

To evaluate the effect of hCGβcf, 11 conditions were tested with 5 devices from each of 3 batches, totalling 165 devices. Pooled pregnant urine collected from 6-7 weeks and 9-12 weeks pregnancy were tested with and without hCGβcf spiked up to 1μM. Pooled negative urine spiked with hCG to a concentration representative of 6-7 weeks and 9-12 weeks pregnant

urine samples were tested with and without hCGβcf spiked up to 1μM. Negative pooled urine spiked to 25mIU/mL hCG then spiked with 375pM hCGβcf (a concentration 5 times the molar concentration of intact hCG) was tested. Positive (negative pooled urine spiked to 25mIU/mL) and non-pregnant (<0.5mIU/mL) controls were also tested.

The results show that the performance of the One Step Pregnancy Test is not affected by high concentrations of hCG β-core fragment.

h) Assay cut-off

See Limit of Detection section.

2. Comparison Study

a. Method comparison with predicate device:

150 urine samples from pregnant women and 150 urine samples from not pregnant women were tested by trained technicians using devices across three batches of the One Step Pregnancy Test. The same samples were also tested using the predicate device QUIK-CHECK™ Home Pregnancy Test.

The One Step Pregnancy Test had 100% agreement with the QUIK-CHECK™ Home Pregnancy Test and 100% agreement with the clinical status of the volunteers' urine samples.

b. Matrix comparison:

Not Applicable. The device is intended for urine sample only.

3. Clinical Studies

a. Clinical Sensitivity:

Not Applicable

b. Clinical Specificity:

Not Applicable

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

Detection of hCG in Early Pregnancy Clinical Samples

1197 One Step Pregnancy Test devices were tested across 3 batches with early pregnancy urine samples collected from days 0 to -9 relative to the day of the missed period.

The early pregnancy detection results are summarised in table below:

Days Relative to Missed Period	Total (n)	Pregnant (n)	Pregnant (%)
-9	51	0	0.0
-8	66	0	0.0
-7	90	12	13.3
-6	132	57	43.2
-5	132	85	64.4
-4	132	121	91.7
-3	132	124	93.9
-2	132	130	98.5
-1	132	131	99.2
0	132	132	100
Not Pregnant Control	66	0	0.0

Lay User Study

Pregnant and not pregnant women volunteers with diverse educational and professional backgrounds and aged over 18 years old participated in the Lay User Study. They tested their own urine sample with the One Step Pregnancy Test according to the instructions for use (IFU) provided.

The same urine sample was also tested by a technician. Volunteer results were compared to their clinical pregnancy status and to the results obtained from trained technicians.

The agreement between lay-user volunteer results and their clinical status with the One Step Pregnancy Test was 100%. There was also 100% agreement between lay-user volunteer results and technician results.

The results are summarised in tables below:

Agreement Between Volunteer Device Results and Clinical Pregnancy Status

		Volunteer Result		
		Pregnant	**Not Pregnant**	**Total**
Clinical Status	**Pregnant**	21	0	21
	Not Pregnant	0	99	99
	Total	21	99	120

Agreement Between Volunteer and Technician Results

		Volunteer Result		
		Pregnant	**Not Pregnant**	**Total**
Clinical Status	**Pregnant**	21	0	21
	Not Pregnant	0	99	99
	Total	21	99	120

Overall, this study demonstrated that volunteers were able to use the product following the IFU to obtain a valid result.

Lay User Study on Biobank Samples

This study supports the lay user study by presenting examples of lay users reading genuine pregnant results from samples with a confirmed clinical pregnancy status.

Women volunteers aged over 18 years old participated in the Lay User Study on Biobank Samples. Volunteers tested and read the result of a single randomly selected sample (either clinically confirmed pregnant or not pregnant).

The agreement between lay-user volunteer results and the clinical status of the biobank sample with the One Step Pregnancy Test was 100%.

The results are summarised in table below:

Agreement Between Volunteer Device Results and Clinical Pregnancy Status

		Pregnant	Not Pregnant	Total
Clinical Status	Pregnant	70	0	70
	Not Pregnant	0	9	9
	Total	70	9	79

The overall accuracy for the One Step Pregnancy Test in the hands of volunteers was therefore 100% relative to the clinical pregnancy status of the samples tested.

Specificity study to determine false-positive result rate

A study was performed to determine the incidence of false positive results among non-pregnant women of peri-menopausal age (41-55 years) and post-menopausal age (>55 years).
150 urine samples were collected from individual women of each cohort and tested by technicians with three batches of the One Step Pregnancy Test.

The results are summarised in table below:

Cohort	Specificity (Proportion)	Specificity (%)
Peri-menopausal	150	100.0
Post-menopausal	150	100.0

The incidence of false positive results among non-pregnant women of pre-menopausal age were evaluated as part of the Comparison to the Predicate Study.

133 urine samples from not pregnant women aged 18-40 were tested by trained technicians using devices across three batches of the One Step Pregnancy Test. The results are summarised in table below:

Cohort	Specificity (Proportion)	Specificity (%)
Pre-menopausal	133	100.0

Clinical Cut-off

Not applicable.

Expected value /Reference range

Not applicable.

Conclusions

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is safe, effective and performs in accordance with its intended use. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.