510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210341

B Applicant

SPD Swiss Precision Diagnostics GmbH

C Proprietary and Established Names

One Step Pregnancy Test

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LCX	Class II	21 CFR 862.1155 - Human Chorionic Gonadotropin (Hcg) Test System	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:
New device

B Measurand:
Human chorionic gonadotropin (hCG)

C Type of Test:

Qualitative chromatographic immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
See Indications for Use below.

B Indication(s) 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 expected period (5 days before the missed period).

C Special Conditions for Use Statement(s):
OTC - Over The Counter

D Special Instrument Requirements:
None

IV Device/System Characteristics:

A Device Description:
The One Step Pregnancy Test is an immunochromatographic sandwich assay containing a lateral flow test strip housed in a cassette. Each test contains one cassette packaged in a pouch and one pipette dropper.

B Principle of Operation:
The test strip contains monoclonal anti-hCG antibodies and goat anti-mouse polyclonal antibody. The test result is shown in the result window and read visually between 3 - 10 minutes of urine application. 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 present is bound by immobilized anti-β hCG antibody forming a sandwich, immobilizing gold particles, and giving rise to a colored line. If no hCG is present in the sample, there is no binding at the test line and subsequently, no colored line. The appearance of two colored lines in the result window, the test (T) line and control (C) line, indicates a positive result. The appearance of one colored line in the result window, the control (C) line, indicates a negative result. If there is no control (C) line, the test has not run correctly and is an invalid result.

V Substantial Equivalence Information:

A Predicate Device Name(s):
QUIK-CHECK Home Pregnancy Test

B Predicate 510(k) Number(s):
K012215

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210341	K012215
Device Trade Name	One Step Pregnancy Test	QUIK-CHECK Home Pregnancy Test
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative detection of hCG in urine as an aid in the early detection of pregnancy	Same
Type of use	Over-the-counter use	Same
Methodology	Chromatographic immunoassay	Same
Specimen type	Urine	Same
Sensitivity	25 mIU/mL	Same
General Device Characteristic Differences		
Early Detection 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

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A. Analytical Performance:

1. Precision/Reproducibility:

A pooled negative urine sample was spiked with hCG to provide eight urine samples with hCG concentrations of <0.5, 12.5, 15, 18, 25, 50, 100 and 200 mIU/mL. Each sample was tested in replicates of five by three operators using four test lots over 3 non-consecutive days. A total of 180 replicates per hCG concentration were tested across 4 lots. The device cutoff is 25 mIU/mL hCG.

Overall precision results

hCG Concentration (mIU/mL)	Total (n)	Positive (n)	Negative (n)	% Positive 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

Precision results for each device lot

hCG concentration (mIU/mL)	Lot 1		Lot 2		Lot 3		Lot 4	
	#Positive / #Negative	% Positive	#Positive / #Negative	% Positive	#Positive / #Negative	% Positive	#Positive / #Negative	% Positive
<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

2. Linearity:
   Not applicable. This is a qualitative device.

3. Analytical Specificity/Interference:

   Cross-reactivity:
   The One Step Pregnancy Test device was tested for potential cross-reactivity from luteinizing hormone (LH), follicle-stimulating hormone (FSH), and thyroid-stimulating hormone (TSH). Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels <0.5 mIU/mL and 25 mIU/mL that were then spiked with 500 mIU/mL LH, 1000 mIU/mL FSH, and 1 mIU/mL TSH.
   The results demonstrated no cross-reactivity up to 500 mIU/mL LH, 1000 mIU/mL FSH, and 1 mIU/mL TSH in either negative or positive urine samples.

   Interference:
   The One Step Pregnancy Test device was tested with potentially interfering substances. Urine specimens from non-pregnant females were pooled and used to prepare samples with hCG levels <0.5mIU/mL and 25mIU/mL that were then spiked with interfering substances. Each condition was tested with five devices from each of three lots for each of the two hCG concentrations. No interference effect was observed at the tested concentrations shown in table below:

Interfering Substance	Concentration	Interfering Substance	Concentration
Acetylsalicylic acid	1.0mg/mL	Gentisic acid	200µg/mL
Acetone	1.0mg/mL (0.125% v/v)	Hemoglobin	100µg/mL
Albumin	5mg/mL	Hydrochloric acid	1.25mM
Ampicillin	200µg/mL	Ibuprofen	100µg/mL
Ascorbic acid	150µg/mL	Leukocytes	$1x10^6$ cells/mL
Atropine	200µg/mL	Oxytetracycline	300µg/mL
Bilirubin	200µg/mL	Acetaminophen	600µg/mL
Blood	0.3% v/v	Pregnanediol-3-glucuronide	40µg/mL
Caffeine	1.2mg/mL	Phenylpropanolamine	200µg/mL
Cannabinol	100µg/mL	Semen	5% v/v
Clomiphene citrate	24µg/mL	Sodium hydroxide	1.25mM
Cotinine	40µg/mL	Tetracycline	300µg/mL
Ethanol	5% v/v	Urea	30mg/mL
Estrone-3-glucoronide	620ng/mL	Uric acid	750µg/mL
Glucose	20mg/mL	Urobilinogen	100µg/mL

Effect of hCG β-core fragment:

To evaluate potential interference from hCG β core fragment (hCGβcf), several combinations and concentrations of hCG and hCGβcf were tested using multiple devices from 3 lots. No hCGβcf interference was observed for the following test conditions:

- Positive urine samples (pooled from pregnant females that were at weeks 6-7 from last menstrual period) spiked up to 1µM hCGβcf.
- Negative pooled urine (<0.5mIU/mL hCG) spiked with hCG to a concentration representative of a sample from a 6-7 weeks pregnant female (25,362 mIU/mL), then spiked with 1µM hCGβcf.
- Positive urine samples (pooled from pregnant females that were at weeks 9-12 from last menstrual period) spiked up to 1µM hCGβcf.
- Negative pooled urine spiked with hCG to a concentration representative of a sample from a 9-12 weeks pregnant female (46,920 mIU/mL), then spiked with 1µM hCGβcf.
- Negative pooled urine spiked to 25 mIU/mL hCG, then spiked with hCGβcf to a concentration 5x the molar concentration of hCG (i.e., 375 pM hCGβcf).

Effect of urine pH:

To evaluate potential interference from changes in pH, urine samples containing 0 mIU/mL and 25mIU/mL hCG were tested at pH values of 4.0 to 9.0. Each hCG concentration was tested with 15 devices, five from each of three lots per pH condition. The results demonstrated that samples within the pH range of 4.0 to 9.0 do not interfere with either positive or negative results from the device.

Effect of urine specific gravity:

To evaluate potential interference from changes in specific gravity, urine samples containing <0.5mIU/mL and 25mIU/mL hCG were adjusted to a specific gravity values from 1.000 to 1.035. Each hCG concentration was tested with 15 devices, five from each of three lots per

specific gravity condition. The results demonstrated that samples within the specific gravity range of 1.000 to 1.035 do not interfere with either positive or negative results from the device.

Hook effect study:
Negative pooled urine was spiked with hCG to concentrations of <0.5, 25, 250,000, 500,000, or 1,000,000 mIU/mL and tested in five replicates per each of three lots. No hook effect was observed at concentrations of up to 1,000,000 mIU/mL hCG.

4. Assay Reportable Range:
Not applicable. This is a qualitative test.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Traceability:
The One Step Pregnancy Test is traceable to the WHO 4th International Standard for human Chorionic Gonadotropin (hCG) (NIBSC code 75/589).

6. Detection Limit:
The device cut-off is 25 mIU/mL. See Precision/Reproducibility section (Section VII.A.1.) above.

7. Assay Cut-Off:
The device cut-off is 25 mIU/mL. See Precision/Reproducibility (Section VII.A.1.) section above.

B. Comparison Studies:

1. Method Comparison with Predicate Device:
A total of 150 urine samples from pregnant women and 150 urine samples from non-pregnant women were tested by trained technicians using devices across three lots of the One Step Pregnancy Test and the predicate device. The results are summarized below.

One Step Pregnancy Test	Predicate device		
	Negative	Positive	Total
Negative	150	0	150
Positive	0	150	150
Total	150	150	300

The data show that the agreement of the One Step Pregnancy Test with the predicate device was 100%.

2. Matrix Comparison:
Not Applicable. The device is intended for urine samples only.

C. Clinical Studies:

1. Clinical Sensitivity:

Not Applicable

2. Clinical Specificity:
   Not Applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
   a. Detection of hCG in Early Pregnancy Clinical Samples:
   A total of 1197 One Step Pregnancy Test devices were tested across 3 lots with urine samples collected from days -9 to 0 relative to the day of the expected menstrual period from 272 different women aged 18 to 55 years who planned to become pregnant. The early pregnancy detection results are summarized in table below:

Days Relative to expected menstrual period	Total (n)	Positive (n)	% Positive
-9	51	0	0
-8	66	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

   b. Lay User Study:
   A lay user study was performed with a total of 120 lay users from the intended use population. The lay users were in two age groups: 18 to 45, and 46 and older women with diverse educational and professional backgrounds. The lay users tested their own urine sample, provided a sample for professional testing, and took a questionnaire regarding their experience with the candidate device. The data show that the agreement between lay user results and professional results was 100%.

Lay user versus Clinical status

Lay user Result	Clinical status		
	Pregnant	Not Pregnant	Total
Positive	21	0	21
Negative	0	99	99
Total	21	99	120

Lay user versus Professional user

Lay user	Professional user		
	Positive	Negative	Total
Positive	21	0	21
Negative	0	99	99
Total	21	99	120

The questionnaire results indicated that lay users found the test easy to use, the results clear and easy to read, and the instructions for use easy to understand.

c. Lay user spiked sample study
A total of 120 lay users tested negative and positive urine samples. Samples were blinded and the order of testing was randomized. Professionals also conducted testing with the spiked urine samples. A comparison of lay user and professional results for the samples demonstrated >99% agreement.

d. Specificity study to determine false-positive result rate:
The incidence of positive test results from One Step Pregnancy Test among non-pregnant women was determined in three age groups: 18–40 years of age (pre-menopausal), 41–55 years of age (peri-menopausal) and >56 year of age (post-menopausal). A total of 433 subjects provided urine samples including 133 from pre-menopausal patients (also included in the method comparison study), 150 from peri-menopausal patients, and 150 from post-menopausal patients. All 433 urine samples were tested with three lots of One Step Pregnancy Test devices. No positive results were observed in any of the age groups.

D. Clinical Cut-Off:
Not applicable.

E. Expected Values/Reference Range:
Not applicable.

VIII Proposed Labeling:

The proposed labeling support substantial equivalence for this device.

IX Conclusion:

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