510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K203246

B Applicant

Atlas Link Technology Co., Ltd.

C Proprietary and Established Names

Atlas One Step hCG Urine Pregnancy Test (Strip), Atlas One Step hCG Urine Pregnancy Test (Cassette), Atlas One Step hCG Urine Pregnancy Test (Midstream)

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 devices

B Measurand:
Human chorionic gonadotropin (hCG)

C Type of Test:
Lateral flow immunoassay for qualitative detection of hCG (three formats: strip, cassette, and midstream)

III Intended Use/Indications for Use:

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

B Indication(s) for Use:

Atlas One Step hCG Urine Pregnancy Test (Strip) is a visually-read , lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in the urine to help in the early detection of pregnancy. The device is designed for over-the-counter use only. Additional clinical examination should be performed to confirm the pregnancy. The device is single use.

Atlas One Step hCG Urine Pregnancy Test (Cassette) is a visually-read, lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in the urine to help in the early detection of pregnancy. The device is designed for over-the-counter use only. Additional clinical examination should be performed to confirm the pregnancy. The device is single use.

Atlas One Step hCG Urine Pregnancy Test (Midstream) is a visually-read , lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in the urine to help in the early detection of pregnancy. The device is designed for over-the-counter use only. Additional clinical examination should be performed to confirm the pregnancy. The device is single use.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Additional clinical examination should be performed to confirm the pregnancy.

D Special Instrument Requirements:

None

IV Device/System Characteristics:

A Device Description:

Atlas Link Technology Co., Ltd.'s One Step hCG Urine Pregnancy Test will be sold in three formats: Strip, Cassette, and Midstream. Each format of the device contains mouse monoclonal anti- β hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti α hCG antibodies (on test region) and goat anti-mouse IgG (on control region) are coated and immobilized on a membrane.

B Principle of Operation:

Atlas One Step Urine Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in early detection of pregnancy. The assay is based on an immunochromatographic technology. Each test device contains monoclonal anti-β hCG antibody colloidal gold conjugate pre-dried on a pad. Monoclonal anti-α hCG antibodies (on the test region) and goat anti mouse IgG (on the control region) are coated and immobilized on a membrane. As the urine sample contacts the membrane, it dissolves the lyophilized conjugate. In a reactive sample, the hCG antigen will attach to the anit-β hCG monoclonal antibodies in the colloidal solution. If hCG is present in the sample, it will reach the test zone ("T") of the membrane and form a pink line. In addition, all samples will cause a pink colored line to appear in the control zone ("C"). This line is formed by the binding of the polyclonal antibodies (Anti-mouse IgG) affixed onto the control zone to the sample-colloidal gold conjugate. Presence of this line indicates sufficient sample volume was added.

V Substantial Equivalence Information:

A Predicate Device Name(s):
One Step Hcg Urine Pregnancy Test (strip), One Step Hcg Urine Pregnancy Test (cassette)

B Predicate 510(k) Number(s):
K071930

C Comparison with Predicate(s):

Device & Predicate Device(s):	K203246	K071930
Device Trade Name	Atlas One Step hCG Urine Pregnancy Test (Strip) Atlas One Step hCG Urine Pregnancy Test (Cassette) Atlas One Step hCG Urine Pregnancy Test (Midstream)	One Step HCG Urine Pregnancy Test (Strip) One Step HCG Urine Pregnancy Test (Cassette) One Step HCG Urine Pregnancy Test (Midstream)
General Device Characteristic Similarities		
Intended Use/Indications For Use	Same	For the qualitative determination of human chorionic gonadotropin (hCG) in urine to help in the early detection of pregnancy.
General Device Characteristic Differences		
Specificity	No interference for FSH at 1000 mIU/mL	No interference for FSH at 2000 mIU/mL

VI Standards/Guidance Documents Referenced:
FDA Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s, dated July 22, 2000.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   The sponsor performed a study to evaluate the imprecision of the device with trained operators using all three test formats (strip, cassette, and midstream using a stimulated midstream method). Forty negative urine samples were collected and spiked with WHO 5th International hCG standard to the following concentrations: 0, 12.5, 16, 25, 30, and 40

mIU/mL. The spiked samples were measured in replicates using 3 lots for each format over five days by eight operators. Results are summarized below:

Strip format

Conc. of hCG	Lot 1		Lot 2		Lot 3		Total result		% Positive	% Negative
	+	-	+	-	+	-	+	-		
40 mIU/mL	40	0	40	0	40	0	120	0	100	0
30 mIU/mL	40	0	40	0	40	0	120	0	100	0
25 mIU/mL	40	0	40	0	40	0	120	0	100	0
20 mIU/mL	23	17	25	15	23	17	71	49	59	41
16 mIU/mL	0	40	0	40	3	37	3	117	2.5	97.5
12.5mIU/mL	0	40	0	40	0	40	0	120	0	100
0 mIU/mL	0	40	0	40	0	40	0	120	0	100

Cassette format

Conc. of hCG	Lot 1		Lot 2		Lot 3		Total result		% Positive	% Negative
	+	-	+	-	+	-	+	-		
40 mIU/mL	40	0	40	0	40	0	120	0	100	0
30 mIU/mL	40	0	40	0	40	0	120	0	100	0
25 mIU/mL	40	0	40	0	40	0	120	0	100	0
20 mIU/mL	23	17	22	18	22	18	67	53	56	44
16 mIU/mL	2	38	2	38	3	37	7	113	5.8	94.2
12.5mIU/mL	0	40	0	40	0	40	0	120	0	100
0 mIU/mL	0	40	0	40	0	40	0	120	0	100

Midstream format

Conc. of hCG	Lot 1		Lot 2		Lot 3		Total result		% Positive	% Negative
	+	-	+	-	+	-	+	-		
40 mIU/mL	40	0	40	0	40	0	120	0	100	0
30 mIU/mL	40	0	40	0	40	0	120	0	100	0
25 mIU/mL	40	0	40	0	40	0	120	0	100	0
20 mIU/mL	20	20	20	20	21	19	61	53	50.8	49.2
16 mIU/mL	2	38	1	39	3	37	6	114	5	95
12.5mIU/mL	0	40	0	40	0	40	0	120	0	100
0 mIU/mL	0	40	0	40	0	40	0	120	0	100

2. Linearity:
Linearity is not applicable since this is a qualitative test.

3. Analytical Specificity/Interference:
For all analytical specificity testing, the Atlas One Step hCG Urine Pregnancy Test Strip, Atlas One Step hCG Urine Pregnancy Test Cassette, and Atlas One Step hCG Urine Pregnancy Test Midstream devices were evaluated. Three lots of each device format were used in all studies.

Cross-reactivity:
The sponsor performed a study to evaluate potential cross-reactivity from LH, FSH and TSH. Normal, nonpregnant female urine samples containing 12.5 mIU/mL and 25 mIU/mL hCG were spiked with various concentrations of glycoprotein hormones, Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and Thyroid Stimulating Hormone (TSH). No interference was observed from the tested glycoprotein hormones at up to 500 mIU/mL LH, 1000 mIU/mL FSH, and 1000 mIU/mL TSH.

Interference:
The sponsor performed a study to evaluate potential interference from certain exogenous compounds. Each interfering substance was prepared by diluting stock interfering material to the desired concentration. Normal, nonpregnant female urine samples containing 0 mIU/mL and 25 mIU/mL hCG were spiked with the interfering substance to obtain the desired test concentration listed in the table below. No interferences were observed from exogenous compounds at the following concentrations for both negative and positive hCG urine samples.
No interferences were observed from these exogenous compounds at the following concentrations for both negative and positive hCG urine samples.

Interfering substances	**Concentration**	**Interfering substances**	**Concentration**
Acetaminophen	20 mg/dL	Albumin	2000 mg/dL
Aspirin	20 mg/dL	Bilirubin	2 mg/mL
Ascorbic acid	20 mg/dL	Erythrocytes	250 /µL
Caffeine	20 mg/dL	Leukocyte	500/ µL
Gentisic acid	20 mg/dL	Uric acid	450 mmol/L
Glucose	200 mg/dL	Ketone	80 mg/dL
Phenylpropanolamine	20 mg/dL	Ethanol	1%
Hemoglobin	1mg mg/dL	Atropine	20 mg/dL
Salicylic acid	20 mg/dL	Benzoylecgonine	10 mg/dL
Thiophene	20 mg/dL	Cannabinol	10 mg/dL
Tetracycline	20 mg/dL	EDTA	80 mg/dL
Ampicillin	200mg/dL	Methanol	1%

Effect of hCG beta-core fragment:
To evaluate potential interference by hCG β-core fragment, urine samples containing 12.5 mIU/mL hCG (below the 25 mIU/mL cut-off level) and 30 mIU/mL (above the 25mIU/mL cut-off level) hCG were spiked with the hCG β-core fragment to yield samples with concentrations of 50,000 pmol/mL, 125,000, 250,000, 500,000, and 1,000,000 pmol/mL.

These samples were tested with 3 lots of each device. The data obtained demonstrated that there is no interference by hCG β -core fragment at the concentrations tested.

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 with 3 lots of each device using samples at pH 3.0, 3.5, 4.0, 5.0, 6.0, 7.0, 8.0, 8.5, 9.0, 9.5, 10.0. The results demonstrated that samples within the pH range of 3.0-10.0 do not interfere with either positive or negative results from the device.

Specific Gravity:
To evaluate potential interference from changes in specific gravity, testing was performed with negative urine sample containing 0 mIU/mL and urine sample with 25 mIU/mL hCG were adjusted to specific gravities ranging from 1.003 to 1.050 and tested with 3 lots of devices for each format. The results indicated that changes in specific gravity, ranging from 1.003-1.050, do not interfere in the results that were either positive or negative for hCG.

High dose hook effect study:
To evaluate high dose hook effect, hCG-free urine specimens spiked with hCG at 1,000 mIU/mL, 10,000 mIU/mL, 100,000 mIU/mL, 500,000 mIU/mL, 1,000,000 mIU/mL, and 5,000,000 mIU/mL were tested on three lots of devices for each format. The results showed no hook effect up to 500,000 mIU/mL.

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

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

   Traceability:
   The One Step hCG Urine Pregnancy Test Kit (Strip), One Step hCG Urine Pregnancy Test Kit (Cassette), One Step hCG Urine Pregnancy Test Kit (Midstream) are traceable to the WHO 5th IS for human Chorionic Gonadotrophin (hCG).

6. Detection Limit:
   Refer to the Precision and Reproducibility section above for additional information. The sensitivity of the One Step hCG Urine Pregnancy Test Kit (Strip), One Step hCG Urine Pregnancy Test Kit (Cassette), One Step hCG Urine Pregnancy Test Kit (Midstream) are 25 mIU/mL.

7. Assay Cut-Off:
   The sensitivity of One Step hCG Urine Pregnancy Test Strip, One Step hCG Urine Pregnancy Test Cassette, and One Step hCG Urine Pregnancy Test Midstream is 25 mIU/mL. See precision section VII.A.1 above.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   The performance of the three formats- strip, cassette, and midstream (stimulated midstream) of the One Step HCG Urine Pregnancy test was compared to the predicate device. Testing was performed at 2 hospital sites with 150 urine samples in each site of the sites for a total of 300 samples from women between the ages of 18 to 45 who were nonpregnant, were pregnant, experienced later periods or were ready to be pregnant. Samples were randomly collected at various times throughout the day and were masked and randomized prior to testing. One hundred (100) samples were tested per each format of the devices. Results of the professional using the candidate device were compared to results obtained from the predicate device. Summary of results is presented in the table below:

Strip format

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	22	0
	Negative	0	28
Hospital B	Positive	19	0
	Negative	0	31

Cassette format

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	14	0
	Negative	0	36
Hospital B	Positive	18	0
	Negative	0	32

Midstream format

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	19	0
	Negative	0	31
Hospital B	Positive	18	0
	Negative	0	32

The result data shows that the agreement of Atlas One Step hCG Urine Pregnancy Test Strip, Atlas One Step hCG Urine Pregnancy Test Cassette, and Atlas One Step hCG Urine Pregnancy Test Midstream with the predicate device is 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):

Lay-user Studies:
This study was conducted in 2 sites with 300 volunteers with varying educational background. This included 100 lay users using test strip, 100 using test cassette, 100 using test midstream with midstream method. Subject ages ranged from 18 to 45 years. Urine samples from the lay-user testing were split to two groups, one group was for the lay-user testing, and the other was for the professional testing. All samples were masked and randomized prior to professional testing. Each subject tested their own urine specimen with only one test method on the candidate device following the instructions on the package insert. The same sample was tested by a healthcare professional using the predicate device. Then the results of lay-user test were compared to results reported by a laboratory professional.

Summary of results for the comparison between the lay user testing with the candidate device versus the professional testing using the candidate device are presented the table below.

Strip format

Candidate Device - Lay User		Candidate Device - Professional User		Total
		Positive	Negative	
Hospital A	Positive	22	0	22
	Negative	0	28	28
Hospital B	Positive	19	0	19
	Negative	0	31	31
Total		41	59	100

Cassette format

Candidate Device - Lay User		Candidate Device - Professional User		Total
		Positive	Negative	
Hospital A	Positive	14	0	14
	Negative	0	36	36
Hospital B	Positive	18	0	18
	Negative	0	32	32
Total		32	58	100

Midstream format

Candidate Device - Lay User		Candidate Device - Professional User		Total
		Positive	Negative	
Hospital A	Positive	19	0	19
	Negative	0	31	31
Hospital B	Positive	18	0	18
	Negative	0	32	32
Total		37	53	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. Lay users also completed a user survey, and the results supported that lay users believed that the package inserts and box labeling are easy to understand and follow.

The lay person results showed 100% positive and 100% negative agreement with the professional results.

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
Not applicable. This is a qualitative test.

VIII Proposed Labeling:
The labeling supports the finding of substantial equivalence for this device.

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