August 4, 2021

Atlas Link Technology Co., Ltd.
Shuzhi Zang
Regulatory Affairs Consultant
Gu'an South Industry Zone
Langfang, Hebei 065500
China

Re: K203246
Trade/Device 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)
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: October 30, 2020
Received: November 9, 2020

Dear Shuzhi Zang:

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: 06/30/2023
See PRA Statement below.

510(k) Number:k203246

Device 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)

Indications for Use *(Describe)*

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.

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 K203246

August 02, 2021

A. 510(k) Submitter:

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B. Submitter Contact:

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C. 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)

Device Classification:

Class II, Human chorionic gonadotropin (HCG) test system (21 CFR 862.1155)

Product Code:

LCX

D. Predicate:

BLUECROSS BIO-MEDICAL CO., LTD.
One Step HCG Urine Pregnancy Test (Strip) (K071930)
One Step HCG Urine Pregnancy Test (Cassette) (K071930)
One Step HCG Urine Pregnancy Test (Midstream) (K071930).

E. Intended Use/Indications 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 Kit (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 Kit (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.

F. 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-beta-hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti-alpha-hCG antibodies (on test region) and goat anti-mouse IgG (on control region) are coated and immobilized on a membrane.

G. 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. Other absorbent pads at the end of the assay absorb excess sample fluid. As the urine sample contacts the membrane, it dissolves the lyophilized conjugate. In a reactive sample, the hCG antigen will attach to the anit-βhCG monoclonal antibodies in the colloidal solution. As the conjugate moves forward on the membrane, anti- αhCG monoclonal antibody affixed on the test zone ("T") will bind the HCG-gold conjugate complex, forming 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.

H. Technological Characteristics:

Atlas One Step hCG Urine Pregnancy Test Kit (Strip, Cassette, Midstream) are compared with the predicate device BLUECROSS BIO-MEDICAL CO., LTD.'s One Step HCG Urine Pregnancy Test (Strip, Cassette, Midstream) (K071930). The product characteristics are shown below in the Comparison Tables:

Table 1: General Comparison Table

Item(s)	Subject Device (K203246)	Predicate Device (K071930)	Comparison
Intended Use/Indications for Use	It 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 by visual. 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.	It 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 by visual. The device is designed for over-the-counter use as well as professional use. Additional clinical examination should be performed to confirm the pregnancy.	Similar
Specimen	Urine	Urine	Same
Technology	Lateral Flow Immunoassay	Lateral Flow Immunoassay	Same
Detection Limit	25 mIU/mL	25 mIU/mL	Same
Format	Strip, Cassette, Midstream	Strip, Cassette, Midstream	Same
Read Time	5-10 minutes	Not available from the 510(k) Summary document	Different
High Dosage Hook Effect	No hook effect up to 500,000 mIU/mL	No hook effect up to 250,000 mIU/mL	Same
Specificity	No interference for urine with specific gravity from 1.003-1.050	Not available from the public information	Different
pH Interference	No interference for urine with pH 3-10	No interference for urine with pH 4-9	Different
Specific Gravity Interference	No interference for urine with specific gravity from 1.003-1.050	Not available from the 510(k) Summary document	Different

I. Standards/Guidance Documents Referenced:

FDA Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s, dated July 22, 2000.

J. Performance Characteristics (if/when applicable):

a. Analytical Performance:

1. Precision/Reproducibility:

Precision studies were performed for 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)(stimulated midstream method only) using 40 urine samples

collected from non-pregnant females spiked with hCG traceable to the WHO 5th International Standard (IS) for each batch. Samples created had concentrations of 0mIU/mL, 12.5mIU/mL, 16mIU/mL, 25mIU/mL, 30mIU/mL, 40mIU/mL. Samples were masked and randomized prior to testing. The study was conducted over 5 days by more than three operators. Three batches of each of the three device formats were tested. The midstream format was tested with the simulated midstream method.

Results for the One Step hCG Urine Pregnancy Test Strip

Conc. of hCG	Batch 20190501		Batch D0501		Batch 2019-05-07		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
25mIU/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

Results for the One Step hCG Urine Pregnancy Test Cassette

Conc. of hCG	Batch A0501		Batch BCP190301		Batch 20190301HC		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
25mIU/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

Results for the One Step hCG Urine Pregnancy Test Midstream (Stimulated method only)

Conc. of hCG	Batch HCG190501		Batch HCG190401		Batch 190403		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
25mIU/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:

   Cross-relativity:

   To evaluate cross-reactivity for 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, urine samples with hCG level (12.5mIU/mL) and urine samples with hCG level (25mIU/mL) were spiked with various concentrations of glycoprotein hormones, Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), and Thyroid Stimulating Hormone (TSH). These samples were tested 3 batches of each format of the device.

   The results demonstrated there is no interference from the tested glycoprotein hormones up to 500 mIU/mL LH, 1000mIU/mL FSH, and 1000 mIU/mL TSH in either 12.5mIU/mL hCG urine samples or in 25mIU/mL hCG urine samples.

   Interference:
   To evaluate the potential for interference by certain exogenous compounds and potentially interfering clinical conditions, the substances listed were prepared by diluting stock interference material to the desired concentration. Normal, nonpregnant female urine specimens containing 0 and 25 mIU/mL hCG were spiked with the interferences to obtain the desired test concentration. Three lots of each format were tested.

   The results showed that no interferences were observed from substance at the following concentrations for both negative and positive hCG urine samples.

Interfering substances	Substances concentration
Acetaminophen	20 mg/dl
Aspirin	20 mg/dl
Ascorbic acid	20 mg/dl
Caffeine	20 mg/dl
Gentisic acid	20 mg/dl
Glucose	200 mg/dl
Phenylpropanolamine	20 mg/dl
Hemoglobin	1mg mg/dl
Salicylic acid	20 mg/dl

Thiophene	20 mg/dl
Tetracycline	20 mg/dl
Ampicillin	200mg/dl
Albumin	2000 mg/dl
Bilirubin	2 mg/ml
Erythrocytes	250 /µl
Leukocyte	500/ µl
Uric acid	450 mmol/l
Ketone	80 mg/dl
Ethanol	1%
Atropine	20 mg/dl
Benzoylecgonine	10 mg/dl
Cannabinol	10 mg/dl
EDTA	80 mg/dl
Methanol	1%

Effect of hCG beta-core fragment:

To evaluate potential interference by hCG β-core fragment for the Atlas One Step hCG Urine Pregnancy Test Strip, Atlas One Step hCG Urine Pregnancy Test Cassette, Atlas One Step hCG Urine Pregnancy Test Midstream devices, one group urine samples with 12.5mIU/mL hCG (below the 25mIU/mL cut-off level) and another group urine samples with 30mIU/mL (above the 25mIU/mL cut-off level) hCG were spiked with the hCG β -core fragment (traceable to WHO reference reagent 99/708) to yield samples with concentrations of 50,000 pmol/mL, 125,000 pmol/mL, 250,000 pmol/mL, 500,000 pmol/mL, 1,000,000 pmol/mL. These samples were tested with 3 batches of each format of the 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 for the Atlas One Step hCG Urine Pregnancy Test Strip, Atlas One Step hCG Urine Pregnancy Test Cassette, Atlas One Step hCG Urine Pregnancy Test Midstream devices, urine samples containing 0mIU/mL and 25mIU/mL hCG were tested with 3 batches of each device using samples at pH values of 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:

Negative urine specimen containing 0 mIU/mL hCG and urine specimen with hCG 25mIU/mL were adjusted to specific gravities from 1.003-1.050. Three lots of each

format of the devices were test. The results showed that no interference in samples with specific gravity ranging from 1.003-1.050.

Hook effect study:
To evaluate high dose hook effect, hCG-free urine specimens spiked with hCG at 1,000mIU/mL, 10,000mIU/mL, 100,000mIU/mL, 500,000mIU/mL, 1,000,000mIU/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 and Stability
   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 material.

   Closed Pouch Real Time Stability:
   Closed pouch real time stability studies were performed separately on three lots of each format – test strips, cassette, and midstream. The test kits are stored at 2-8°C, and 25-30°C after production. Test kits are from those products that were manufactured between January 2017 and May 2017. The first testing was at late May, 2017. Urine samples will be tested every 6 month for the subject devices in all three formats in the first 30 months at 2-8°C, and 25-30°C environment; then more subject devices are tested every 3 months for the remaining 9-month period for hCG at 4 concentrations around the cutoff. Based on these studies, closed pouch stability is 36 months when stored at 2-30°C .

   Open Box Stability:
   Open box studies were performed over 5 days at 25-30°C and $\geqslant$ 85% relative humidity for various concentrations of hCG. Based on these studies, the device was stable for up to 4 hours once opened, however, labeling recommends that testing take place immediately after opening the box.

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 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.

K. Comparison Studies

1. Method Comparison with Predicate Devices:

Urine samples were collected from 300 women at two different hospitals. These samples were collected from women between the ages of 18 to 45 who were nonpregnant, were pregnant, experienced later periods or were ready to be pregnant. 100 samples were tested per each format of the devices. Samples were randomly collected at various times throughout the day and were masked and randomized prior to testing. 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:

The results of professional method comparison (Strip format)

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	22 (a)	0 (b)
	Negative	0 (c)	28 (d)
Hospital B	Positive	19 (a)	0 (b)
	Negative	0 (c)	31 (d)

The results of professional method comparison (Cassette format)

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	14 (a)	0 (b)
	Negative	0 (c)	36 (d)
Hospital B	Positive	18 (a)	0 (b)
	Negative	0 (c)	32 (d)

The results of professional method comparison (Midstream format, stimulated method only)

Candidate Device		Predicate device Positive	Predicate device Negative
Hospital A	Positive	19 (a)	0 (b)
	Negative	0 (c)	31 (d)
Hospital B	Positive	18 (a)	0 (b)
	Negative	0 (c)	32 (d)

2. Matrix Comparison

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

L. Clinical Studies

1. Clinical Sensitivity:
   Not Applicable.

2. Clinical Specificity:
   Not Applicable.

3. Lay-user Studies:
   A lay-user study was conducted with 300 lay users. Each subject tested their own urine with only one test method on the candidate device following the instructions on the package insert. Then the results of their test were compared to results reported by a laboratory professional at the hospital. The same sample was tested by a healthcare professional using the predicate device. 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. All samples were masked and randomized prior to professional testing. Summary of results is presented in the table below:

Results of the lay user method comparison for the One Step hCG Urine Pregnancy Test (Strip)

Candidate Device Lay User		Candidate Device Professional Positive	Candidate Device Professional Negative	Total
Hospital A	Positive	22 (a)	0 (b)	22
	Negative	0 (c)	28 (d)	28
Hospital B	Positive	19 (a)	0 (b)	19
	Negative	0 (c)	31 (d)	31
Total		41	59	100

Results of the lay user method comparison for the One Step hCG Urine Pregnancy Test (Cassette)

Candidate Device Lay User		Candidate Device Professional Positive	Candidate Device Professional Negative	Total
Hospital A	Positive	14 (a)	0 (b)	14
	Negative	0 (c)	36 (d)	36
Hospital B	Positive	18 (a)	0 (b)	18
	Negative	0 (c)	32 (d)	32
Total		32	68	100

Results of the lay user method comparison for the One Step hCG Urine Pregnancy Test (Midstream)

Candidate Device Lay User		Candidate Device Professional Positive	Candidate Device Professional Negative	Total
Hospital A	Positive	19 (a)	0 (b)	19
	Negative	0 (c)	31 (d)	31
Hospital B	Positive	18 (a)	0 (b)	18
	Negative	0 (c)	32 (d)	32
Total		37	63	100

M. Conclusion

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