Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.
% Sandra Jiang
Shanghai Sungo Management Consulting Company Limited
Room 1401, Dongfang Building, 1500# Century Avenue
Shanghai, 200122
China

Re: K230741
Trade/Device Name: Macro & Micro-Test HCG 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: August 31, 2023
Received: August 31, 2023

Dear Sandra Jiang:

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,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2023.10.13 13:59:57 -04'00'

Joseph Kotarek
Branch Chief
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230741

Device Name
Macro & Micro-Test HCG Pregnancy Test Midstream

Indications for Use *(Describe)*
Macro & Micro-Test HCG Pregnancy Test Midstream is intended for over-the-counter use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.

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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Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.
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510(K) Summary

K230741

(As requirement by 21 CFR 807.92)

Date prepared: 17th, Aug 2023

A. Applicant:

Name: Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.
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B. Device:

Trade Name:
Macro & Micro-Test HCG Pregnancy Test Midstream

Regulatory Information
Classification Name: Kit, Test, Pregnancy, Hcg, Over The Counter
Classification: Class II
Product code: LCX
Regulation Number: 21 CFR 862.1155
Review Panel: Clinical Chemistry

C. Predicate device:

K150063

ACCU NEWS One Step hCG Pregnancy Test Strip

ACCU NEWS One Step hCG Pregnancy Test Cassette

D. Indications for use of the device:

Macro & Micro-Test HCG Pregnancy Test Midstream is intended for over-the-counter use for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.

E. Device Description:

Macro & Micro-Test HCG Pregnancy Test Midstream is a qualitative lateral flow test for the detection of hCG (human chorionic gonadotropin) hormone, which is present in urine during the early stage of pregnancy.

The Macro & Micro-Test HCG Pregnancy Test Midstream will be sold in one format: midstream. The midstream kits consist of one test device and a package insert. The test device contains mouse monoclonal anti- β hCG antibody coated membrane and a pad containing mouse monoclonal anti- α -hCG antibody colloidal gold conjugate. The control antibodies are goat anti-rabbit IgG.

F. Principle of Operation

The product uses the reaction principle of double antibody sandwich method and is developed in combination with immunochromatography technology. The goat anti-mouse polyclonal antibody is coated at the quality control line (C) on the nitrocellulose membrane, and the HCG monoclonal antibody is coated at the test line (T) on the nitrocellulose membrane. The HCG monoclonal antibody labeled with red tracers is coated on the glass cellulose membrane. During detection, the sample flows upward under the action of chromatography, and when the HCG concentration in the sample is higher than the LoD of this test strips, HCG will specifically bind to the anti-HCG and be captured by the HCG monoclonal antibody at the test line, thus a red band appears at the test line. When the HCG concentration in the sample is lower than the LoD of this test strip or there is no HCG in the sample, then no red band appears at the test line. Regardless of the content of HCG in the samples, anti-HCG can be captured by the goat anti-mouse polyclonal antibody at the quality control line to form an immune complex, thus a red band appears at the quality control line.

G. Summary of Technological Characteristics

Device	**Proposed Device**	**Predicate Device**	**Result**
510K #	K230741	K150063	-
Basic Information Comparison			
Manufacturer	Jiangsu Macro & Micro-Test Med-Tech Co., Ltd.	Coretests Inc.	-
Intended use	It is intended for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.	It is intended for qualitative detection of hCG hormone in urine to aid early detection of pregnancy.	Same
Intended use environment	Over the Counter (OTC)	Over the Counter (OTC) and professional	Different

Specimen Type	Urine	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
Storage Temperature	4-30℃	4-30℃	Same
Shelf life	24 months when stored at 4-30℃	24 months when stored at 4-30℃	Same
Format	Midstream	Strip, Cassette, Midstream	Same
Read Time	At 5 minutes	At 5 minutes	Same
Result	Qualitative	Qualitative	Same
Analytical Performance Comparison			
Detection Limit	25 mIU/mL	25 mIU/mL	Same
High Dosage Hook Effect	No high dosage hook effect for hCG up to 1,000,000 mIU/mL	No high dosage hook effect for hCG up to 500,000 mIU/mL	Similar
Specificity	LH at 500mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 μIU/mL	LH at 1000mIU/mL, FSH at 1000 mIU/mL, and TSH at 1000 μIU/mL	Similar
pH Interference	No interference for urine with pH 4-9	No interference for urine with pH 2-9	Similar
Specific Gravity Interference	No interference for urine with Specific Gravity 1.000-1.035	No interference for urine with Specific Gravity 1.000-1.030	Similar
Beta hCG Core Fragment Reactivity	No interference when the concentration of HCG β-core fragment reaches 1μmol/L.	no interference when the concentration of HCG β-core fragment reaches 1μmol/L.	Same

Analysis:

The proposed device is substantially equivalent to the predicate device (midstream version), in terms of intended use, format, test principle, shelf life, read time and LoD.

Although the indications of the predicate device and the proposed device are different, i.e. OTC and professional for predicate device and OTC for proposed device, the indication of the proposed device is covered by that of the predicate device. Such difference will not give any impact on the safety and effectiveness of the proposed deice.

The minor difference of analytical performance between the predicate device (midstream version) and the proposed device will not influence the effectiveness of the proposed device.

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

H. Summary of Non-Clinical Testing

a. Comparison Studies

- Consistency of Proposed device and the Predicate Device (midstream version)

Urine samples were selected from 250 women aged from 18-55 years old. About half of the selected women were suspected to be pregnant (less than 5 weeks pregnant, including women who tested as early as the day of their missed period). The samples were tested by three different health professionals at each of three sites for a total of three operators with the candidate device and the midstream version of predicate device. Test results were compared. The data show that the agreement of hCG pregnancy test midstream with the predicate device was 100%.

Table 1. Test Results of 250 samples of Test Midstream

		Predicate Device		
		Positive (+)	Negative (-)	Total
Candidate Device	Positive	127	0	127
	Negative	0	123	123
	Total	127	123	250
Evaluation Index	Kappa Value	Positive Percent Agreement	Negative Percent Agreement	Total Percent Agreement
	1	100%	100%	100%

- OTC Layer User Test Results

Urine samples were selected from 250 women aged from 18-55 years old. About half of the selected women were suspected to be pregnant (less than 5 weeks pregnant, including women who tested as early as the day of their missed period). Those women were given Macro & Micro-Test HCG Pregnancy Test Midstream to test the collected urine samples. The same urine samples were tested by professionals in parallel using the proposed device. The recorded test results from the lay users were compared with those from professionals. In parallel, after testing, each participant was given a questionnaire to assess the readability of the instructions for use. The result showed that the lay users found the product instructions were easy to understand and the devices were easy to use.

Table 2.Test Results of 250 samples of Test Midstream

		Professionals Test Results		
		Positive (+)	Negative (-)	Total
Lay User Test Results	Positive	127	0	127
	Negative	0	123	123
	Total	127	123	250
	% Agreement	100%		

The test result showed that 100% agreement between lay user results and professional results.

b. Read Time

To determine the optimal time to interpret the test results of the hCG pregnancy test midstream, 10 non-pregnant samples were selected. Add HCG standard to 3 samples to obtain the HCG positive samples with concentration of 25mIU/mL, 50mIU/mL, 100mIU/mL. After the test is completed, interpret the results after 5 minutes, 10 minutes, 15 minutes, 20 minutes, and 30 minutes. Data indicated that test result was most accurate when it was interpreted within 5-10 minutes.

c. Precision/Reproducibility

Three batches of device were used to test urine samples containing 0, 12.5, 18.75, 25, 50, and 100mIU/mL of hCG. The Urine samples were prepared by using hCG free urine samples spiked with hCG to achieve the following concentrations: 0, 12.5, 18.75, 25, 50, and 100 mIU/mL. All urine samples were traceable to the hCG standard WHO 6th IS. The study was carried out at 3 sites (one internal site and two external sites representative of the intended use setting). Each site tested a unique lot of test device. Each sample was tested in 10 replicates per day. Repeat the test for 5 non-consecutive days for each device lot, 150 Urine samples were tested for each concentration (3sites(lots) ×5days ×10 replicates). Totally, 900 urine samples (150 urine samples × 6 concentrations) were tested.

Table 3 Precision Study Data for Midtream

hCG Concentration (mIU/mL)	2105MY19001 (Location 1)		2105MY24001 (Location 2)		2105MY27001 (Location 3)		% Positive	% Negative
	+	-	+	-	+	-		
0	0	50	0	50	0	50	100%	0%
12.5	0	50	0	50	0	50	100%	0%
18.75	26	24	26	24	28	22	53.33%	46.67%
25	50	0	50	0	50	0	0%	100%
50	50	0	50	0	50	0	0%	100%
100	50	0	50	0	50	0	0%	100%

Test result demonstrated that hCG pregnancy test midstream was able to produce consistent and precise test results.

d. Specificity

To determine if the hCG pregnancy test midstream was affected (i.e., cross reacted) by a relevant challenge dose of closely related human luteinizing hormone (hLH), human follicle stimulating hormone (hFSH) or human thyroid stimulating hormone (hTSH). The results demonstrated no cross reaction with hLH at 500mIU/ml, hFSH at 1000 mIU/mL, and hTSH at 1000 μIU/mL.

e. Interfering Substances

To determine if the hCG pregnancy test midstream was affected by potentially interfering substances which may be found in human urine, positive urine samples (hCG 25mIU/mL) and negative urine samples were spiked with the interference substance to obtain the specific concentrations. Each spiked urine sample was tested with the results show that no interference was observed from exogenous compounds at the different concentrations for both negative and positive HCG urine samples.

Interfering Substances	Final Concentration	Interfering Substances	Final Concentration
Acetaminophen	20mg/dL	Hemoglobin	1000mg/dL
β-hydroxybutyrate	2000mg/dL	Pregnanediol	1500μg/dL
Caffeine	20mg/dL	Thiophene	20mg/dL
Phenylpropanolamine	20mg/dL	Ampicillin	20mg/dL
Salicylic acid	20mg/dL	Tetracycline	20mg/dL
Phenothiazine	20mg/dL	Vitamin C	20mg/dL
Aspirin	80mg/dL	(1R,2S)-(-)-Ephedrine	20 mg/dL
Cannabinol	10mg/dL	(1S,2R)-(+)-Ephedrine	20 mg/dL
Ethanol	1.0%	Acetone	20 mg/dL
Methanol	10%	Gentisic Acid	20 mg/dL
Albumin	2000mg/dL	Ibuprofen	40 mg/dL
Glucose	2000mg/dL	Methadone	20 mg/dL
Bilirubin	40mg/dL	Morphine	10 mg/dL
Atropine	20mg/dL	Nicotine	20 mg/dL
Estriol-17-β	1400μg/dL	Uric acid	20 mg/dL
Amoxicillin	20mg/dL	Benzoylecgonine	10 mg/dL
Folic acid	0.03 mg/dL	Vitamin B1	80 mg/dL
EDTA	80 mg/dL	Ketone	20 mg/dL

f. Effects of Urine pH

The PH of an aliquot negative urine pool is adjusted to a PH range of 4 to 9 in 1 PH unit increment and spiked with HCG at 25mIU/ml and 0mIU/ml and 3 batches of hCG pregnancy test midstream were tested repeatedly. The result demonstrated that varying ranged of PH do not interfere with the performance of the test.

g. Effects of Urine Specific Gravity

Urine samples containing 0 and 25 mIU/ml HCG were tested at density values of 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030 and 1.035. 3 batches of hCG pregnancy test midstream were tested. The data show that there's no interference in the test result when the specific gravity is between 1.000-1.035.

h. High Dose Hook Effect

The test was evaluated for high dose hook effect. HCG free specimens spiked with the HCG at different concentration containing 0.5IU/ml, 1IU/ml, 10U/ml, 100IU/ml, 500IU/ml, 1000IU/ml. Three batches of tests were tested.

The result show that hCG pregnancy test midstream can get the positive result when the HCG concentration is range from 0.5IU/ml to 1000IU/ml.

i. Beta hCG Core Fragment Reactivity testing

To evaluate the effects of the HCG β-core fragment normal nonpregnant females' urine specimens containing 0 and 25mIU/ml, HCG were spiked with the HCG β-core fragment at the concentration of 0.5μmol/L and 1μmol/L. The data shows that there's no interference in the test result when the concentration of HCG β-core fragment reaches 1μmol/L.

j. LoD/Sensitivity

To determine the LoD of hCG pregnancy test midstream, 30 negative samples were selected to dilute the WHO International Standard 6th International Standard for Chorionic Gonadotrophin (Batch No.: 6th INTERNATIONAL STANDARD 2820) for human chorionic gonadotropin immunoassay to 0, 12.5, 18.75, 25, 50 and 100 mIU/mL . Use the kit for detection and select the concentration with a positive detection rate of more than 95% as the LoD of the kit.

The results indicate that the positive detection rate is more than 95% when the concentration is not less than 25mIU/mL, so, the LoD of the kit is 25mIU/mL.

k. Expected Value

Not applicable.

l. Calibration

The tests are calibrated against WHO International Standard 6th International Standard.

m. Quality Control

The membrane is pre-coated with anti-mouse antibodies on the control band region. During the testing, the mixture continues to migrate across the membrane to the immobilized goat anti-mouse region, a red band at the control band region will always appear. The presence of this red band

serves as verification for sufficient sample volume and proper flow and as a control for the reagents. The Control line should develop in the control zone regardless of the test result. A red line appearing in the control region (C) is considered an internal positive procedural control. A clear background in the results window in considered an internal negative procedural control. If the Control (C) line does not give the expected reaction on any sample, the test is invalid, and must be repeated.

n. Stability/Shelf Life

The stability data supports that the products have the shelf life of 24 months when stored at 4-30℃.

o. Antibody Information

Antibody	The biological source	The location	Specific targetantigen
Monoclonal anti-β-HCG antibody	Mouse	Conjugate pad	Specific to the beta subunit of hCG
Monoclonal anti-α-H-CG antibody	Mouse	Nitrocellulose membrane	Specific to the alpha subunit of hCG
goat anti mouse lgG polyclonal antibody	Goat	Nitrocellulose membrane	

I. Clinical Test Conclusion

No clinical study is included in this submission.

J. Conclusion

The performance characteristics studies performed demonstrated substantial equivalency between the proposed device and predicate device (K150063 ACCU NEWSTM One Step hCG Pregnancy Test -Midstream version).