March 28, 2018

Runbio BioTech Co.,Ltd
Chandler Chen
QA Manager
Rongsheng Technology Garden, Shantou University Road
Shantou, Guangdong 515063, China

Re: K172627
Trade/Device Name: David Home Pregnancy Test Cassette
David Professional Pregnancy Test Cassette
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX, JHI
Dated: February 9, 2018
Received: February 12, 2018

Dear Chandler Chen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K172627

Device Name
David Home Pregnancy Test Cassette

Indications for Use *(Describe)*

David Home Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in the urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for the Over-the-Counter Use only.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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)*
K172627

Device Name

David Professional Pregnancy Test Cassette

Indications for Use *(Describe)*

David Professional Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in the urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for prescription use only.

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)

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510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is K172627.
DATE of Summary: March 01, 2018

A. Applicant Information

1. Company Name: RUNBIO BIOTECH CO.,LTD
2. Address: RONGSHENG TECHNOLOGICAL ZONE, UNIVERSITY ROAD SHANTOU, GUANGDONG,CHINA 515063
3. Telephone No.: 86-754-82528311
4. Fax: 86-754-82537111

B. Contact Information

1. Contact Person : Chandler Chen
2. Company Name: RUNBIO BIOTECH CO.,LTD
3. Address: RONGSHENG TECHNOLOGICAL ZONE, UNIVERSITY ROAD SHANTOU , GUANGDONG,CHINA 515063
4. Telephone No.: 86-754-82537812
5. Fax No.: 86-754-82537111
6. E-mail Address:runiroad@126.com

C. Proprietary and Established Names

David Home Pregnancy Test Cassette

David Professional Pregnancy Test Cassette

D.Regulatory Information

1.Regulation section:

21 CFR 862.1155 Human Chorionic Gonadotropin (HCG) test system

2.Classification:

Class II

3.Product Code:

LCX, kit, test, pregnancy, hCG, over the counter

JHI, visual, pregnancy hCG, prescription use

4. Classification Panel:

Clinical Chemistry (75)

Intended Use/Indication(s) for use Indications for use:

David Home Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in the urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for the Over-the-Counter Use only.

David Professional Pregnancy Test Cassette is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (HCG) in the urine to aid in early detection of pregnancy, based on lateral flow immunoassay. It is intended for prescription use only.

2.**Special conditions for use statement(s):**

David Home Pregnancy Test Cassette is for the Over-the-Counter only.

David Professional Pregnancy Test Cassette is for the prescription use only.

E. Device Description:

David Pregnancy Test Cassette will be designed in one format:Cassette.The Cassette kit consists of one test device, a disposable plastic dropper, and a package insert. Each test strip contains mouse monoclonal anti-α-hCG antibody coated

membrane and a pad containing mouse monoclonal anti-β-hCG antibody colloidal gold conjugate. The control antibodies are goat anti-mouse IgG polyclonal antibody.

F. Substantial Equivalence Information

1.Predicate Device Name(s):

Wondfo One Step HCG Urine Pregnancy Test

2.**Predicate 510（K）Number(s):**

k043443

3.**Comparison with predicate**

Similarities and Differences			
Item	Predicate device	Candidate device	
Device	Wondfo One Step HCG Urine Pregnancy Test	David Home Pregnancy Test	David Professional Pregnancy Test
Format	Strip,Cassette and midstream	Cassette	Cassette
Intended Use	Qualitative detection of Human Chorionic Gonadotrophine（hCG） in urine to aid in the detection of pregnancy hormone	Same	Same
Test Principle	Sandwich Immunochromatographic Assay	Same	Same
Methodology	Colloidal Gold Immunoassay（Membrane particle assay）	same	same
Test Line	Mouse monoclonal anti-α hCG antibodies	Same	Same
Detection Antibody	Mouse monoclonal anti-β hCG antibodies	Same	Same
Intended User	Prescription use (strip and cassette) and OTC use (strip, cassette and midstream)	OTC use (cassette)	Prescription use (cassette)
Device format	strip, cassette and midstream	cassette	cassette
Sample Matrix	Human urine	same	same
Target Population	Pregnant women	Same	Same
Sterility	Non-sterile	Same	Same
Sensitivity	25mIU/mL	Same	Same
Specificity	LH at 300 mIU/mL, FSH at 300 mIU/mL, and TSH at 1000 mIU/mL	LH at 500 mIU/mL, FSH at	LH at 500 mIU/mL, FSH at
		1000 mIU/mL, and TSH at 1000 μIU/mL	1000 mIU/mL, and TSH at 1000 μIU/mL
pH Interference	No interference for urine with pH 4-9	No interference for urine with pH 3-10	No interference for urine with pH 3-10
Specific Gravity Interference	No interference for urine with Specific Gravity 1.000-1.050	Same	Same

High Dosage Hook effect	No high dosage hook effect for hCG up to 100,000 mIU/mL	No high dosage hook effect for hCG up to 2000,000 mIU/mL	No high dosage hook effect for hCG up to 2000,000 mIU/mL
Storage Temperature	4 to 30℃	2 to 30℃	2 to 30℃
Read time	3 to 5 Minutes	5 to 15 Minutes	5 to 15 Minutes
Traceability	WHO 3rd International Standard	WHO International Standard5th WHO Chorionic Gonadotrophin （NIBSC code: 07/364）	WHO International Standard5th WHO Chorionic Gonadotrophin （NIBSC code: 07/364）

G. Test Principle:

The test is a qualitative, solid phase, double antibodies sandwich immunochromatographic assay. Each test device contains mouse monoclonal anti-β-hCG antibody colloidal gold conjugate pre-dried on a pad. Mouse monoclonal anti-α-hCG antibody (on the Test Line) and goat anti-mouse IgG polyclonal antibody (on the Control Line) are coated and immobilized on a nitrocellulose membrane.

For the cassette device, the sample is pipette onto the sample well.

During the test, hCG in the urine specimen reacts with the dye conjugate (mouse anti-β-hCG antibody- colloidal gold conjugate specific to the beta subunit of hCG) and forms a complex. The complex migrates along the membrane to the mouse anti-α-hCG antibody test region (T), and remains captured in the T line.

J． Performance Characteristics:

1. **Analytical performance**

a. Precision/Reproducibility

The study was conducted in three（3） sites by a total of 9 operators with 3 lots of proposed device over 5 non-consecutive days. The samples were used with hCG spiked at the concentrations of 0, 16, 18.75, 20, 25, 27.5 and 100mIU/mL in urine. The result demonstrated that all the test results of samples with the HCG concentration higher than 25 mIU/mL are positive, and 98% of the test results of samples with the HCG concentration lower than 20 mIU/mL are negative. The colour of test line should keep consistant for each concentration sample.

According to the consistency of test results of the same sample, it can also be determined that the reagent has good repeatability between lots and within lot.

Statistical table of repeatability test results of different lots

Test Concentration	Lot No.:1		Lot No.:2		Lot No.:3	
	Positive	Negative	Positive	Negative	Positive	Negative
HCG0mIU/mL	+/+(0/150)	-/-(150/150)	+/+(0/150)	-/-(150/150)	+/+(0/150)	-/-(150/150)
HCG16mIU/mL	+/+(0/150)	-/-(150/150)	+/+(0/150)	-/-(150/150)	+/+(0/150)	-/-(150/150)
HCG18.75mIU/mL	+/+(1/150)	-/-(149/150)	+/+(1/150)	-/-(149/150)	+/+(1/150)	-/-(149/150)
HCG 20mIU/mL	+/+(5/150)	-/-(145/150)	+/+(3/150)	-/-(147/150)	+/+(2/150)	-/-(148/150)
HCG 25mIU/mL	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)
HCG 27.5mIU/mL	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)
HCG 100mIU/mL	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)	+/+(150/150)	-/-(0/150)

b. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

The test is calibrated against the WHO International Standard 5th WHO Chorionic Gonadotrophin （NIBSC code: 07/364）

Stability:

The applicant claims a 24-month shelf life for the test when stored at 36-86℉ (2-30℃).

Expected values :

1. Negative results are expected in healthy non-pregnant women
2. The amount of hCG will vary greatly with gestational age and between individuals.

c. Detection limit:

The study was conducted in three（3） sites by a total of 3 operators and by 30 volunteers with 3 lots of proposed device over 5 non-consecutive days. The samples were used with hCG spiked at the concentrations of 0, 12.5, 16, 18.75, 20, 22.5, 25, 27.5, 50 and 100mIU/mL in urine.

Each concentration was detected for 90 times totally in each test sites, 60 times by professionals using professional test kit and Home use test kit for either 30 times respectively, and 30 times by lay users in total. The comprehensive test result statistics demonstrated that the positive ratio of samples containing more than 25 mIU/mL HCG are more than 95%, so the minimum detection limit of the reagent is HCG 25 mIU/mL; about 50% of the test results of samples containing 22.5 mIU/mL HCG are positive.

Table: Summary of Test Results

Test Concentration	Professional User				Lay User	
	David Professional Pregnancy Test Cassette		David Home Pregnancy Test Cassette		David Home Pregnancy Test Cassette	
	Positive	Positive Ratio	Positive	Positive Ratio	Positive	Positive Ratio
HCG0mIU/mL	+/+(0/90)	0%	+/+(0/90)	0%	+/+(0/90)	0%
HCG 12.5mIU/mL	+/+(0/90)	0%	+/+(0/90)	0%	+/+(0/90)	0%
HCG 16mIU/mL	+/+(0/90)	0%	+/+(0/90)	0%	+/+(0/90)	0%
HCG 18.75mIU/mL	+/+(1/90)	1.1%	+/+(2/90)	2.2%	+/+(1/90)	1.1%
HCG 20mIU/mL	+/+(6/90)	6%	+/+(7/90)	7%	+/+(3/90)	6%
HCG 22.5mIU/mL	+/+(45/90)	50%	+/+(51/90)	56%	+/+(40/90)	45%
HCG 25mIU/mL	+/+(90/90)	100%	+/+(90/90)	100%	+/+(90/90)	100%
HCG 27.5mIU/mL	+/+(90/90)	100%	+/+(90/90)	100%	+/+(90/90)	100%
HCG 50mIU/mL	+/+(90/90)	100%	+/+(90/90)	100%	+/+(90/90)	100%
HCG 100mIU/mL	+/+(90/90)	100%	+/+(90/90)	100%	+/+(90/90)	100%

d. Analytical specificity:

Cross reactivity:

To evaluate cross-reactivity, 20 fresh urine specimens obtained from 10 healthy non-pregnant women and 10 healthy men were spiked with different

concentrations of Lutenizing Hormone (LH), Follicle stimulating Hormone (FSH), and thyroid stimulating hormone (TSH) into negative (0 mIU/mL) and positive (25mIU/ml) samples. The results demonstrated no cross reaction with LH at 500mIU/ml, FSH at 1000 mIU/mL, and TSH at 1000μIU/mL. Results are tabulated below.

Table: test results of Specificity

HCG concentration	Homologous hormone concentration	LOT NO.		
		20120901	20120902	20120903
HCG 0mIU/mL	LH 500mIU/mL	-/-（20/20）	-/-（20/20）	-/-（20/20）
	FSH 1000mIU/mL	-/-（20/20）	-/-（20/20）	-/-（20/20）
	TSH 1000μIU/mL	-/-（20/20）	-/-（20/20）	-/-（20/20）
HCG 25mIU/mL	LH 500mIU/mL	+/+（20/20）	+/+（20/20）	+/+（20/20）
	FSH 1000mIU/mL	+/+（20/20）	+/+（20/20）	+/+（20/20）
	TSH 1000μIU/mL	+/+（20/20）	+/+（20/20）	+/+（20/20）

Interference:

A study was conducted to evaluate interference of specific exogenous compounds. Negative and positive hCG urine samples (25 mIU/mL) were individually spiked with the substances listed in the table below. Three devices of each format were tested. No interference was observed from the compounds at the concentrations listed below.

Table: Interfering Substance

Substance	Concentration	Substance	Concentration
Glucose	2g/dL	Acetaminophen	20 mg/dL
Albumin	2g/dL	Atropine	20 mg/dL
protein	2g/dL	Aspirin	20 mg/dL
Bilirubin	2mg/dL	Ascorbic Acid	20 mg/dL
Hemoglobin	1mg/dL	Ampicillin	20mg/dL
Vitamins C	20 mg/dL	Salicyclic Acid	20 mg/dL
Caffeine	20 mg/dL	Phenothiazine	20 mg/dL
Gentisate	20 mg/dL	Thiophene	20 mg/dL
Gentisic Acid	20 mg/dL	Ephedrine	20mg/dL
Tetracycline	20mg/dl	Ethanol	1%
Acetylsalicylic Acid	20 mg/dL	Phenylpropanolamine	20 mg/dL

Effects of urine pH：

A study was conducted to evaluate the effect of pH. Negative and positive hCG urine samples (25 mIU/mL) were tested across a pH range of 3-10. The results demonstrate that pH ranging from 3 to 10 in urine samples does not interfere with the performance of the test.

Specific Gravity:

A study was performed to evaluate the effects of urine specific gravity on the device. The device was challenged with negative urine and positive urine with specific gravity from 1.000 to 1.050. The results demonstrate that specific gravity ranging from 1.000 to 1.050in urine samples does not interfere with the performance of the test.

High dose hook effect study:

The test was evaluated for high dose hook effect. Negative urine specimens were spiked with high hCG concentration of of ranging from 50 mIU/mL to 2000,000 mIU/mL.All samples yielded the expected positive results. This study demonstrates that this device shows no hook effect up to 2,000,000 mIU/mL hCG.

Effects of hCG β-core fragment:

Interference testing was performed to evaluate whether high levels of beta core fragment interfere with the device. Negative urine hCG （containing 0 mIU/mL hCG,16mIU/mL HCG）and positive urine samples (containing 27.5 mIU/mL hCG) were spiked with hCG beta core fragment standard (traceable to WHO reference reagent 99/708) at several different concentrations up to 1,000,000 pmol/L. The samples were tested using 3 different lots. Samples of each concentration were tested 10 times with the professional and lay-user respectively. However, the results demonstrated that no hook effect was observed at an hCG β-core fragment concentration up to 100,000 pmol/L.

2. **Comparison Study:**

a. **Method comparison with predicate device:**

Totally 360 fresh women urine samples were tested at 3 sites. According to synchronous test results by the predicate device and candidate device by professionals, there were153 positive samples and 207 negative samples and all the test

results were the same as expected. The test results obtained by the lay-users and by the professionals with predicate device were exactly the same, which means the total agreement rate was 100%.

All lay users tested their own urine by themselves with David Home Pregnancy Test Cassette according to the instructions for use in English.

Table: statistic analysis of data (professionals)

		Predicate Device Wondfo One Step HCG Urine Test		
		Positive	Negative	total
Proposed Device David Professional Pregnancy Test Cassette	Positive	(a)153	(b)0	(a+b)153
	Negative	(c)0	(d)207	(c+d)207
	total	(a+c)153	(b+d)207	(a+b+c+d)360

Positive coincidence rate=[a/(a+c)]×100%=[153/(153+0)]×100%=100%;

Negative coincidence rate=[d/(b+d)]×100%=[207/(207+0)]×100%=100%;

Totalcoincidencerate=[(a+d)/(a+b+c+d)]×100%=[(153+207)/(360)]×100%=100%.

Table: statistic analysis of data (professionals)

		Predicate Device Wondfo One Step HCG Urine Test		
		Positive	Negative	total
Proposed Device David Home Pregnancy Test Cassette	Positive	(a)153	(b)0	(a+b)153
	Negative	(c)0	(d)207	(c+d)207
	total	(a+c)153	(b+d)207	(a+b+c+d)360

Positive coincidence rate=[a/(a+c)]×100%=[153/(153+0)]×100%=100%;

Negative coincidence rate=[d/(b+d)]×100%=[207/(207+0)]×100%=100%;

Totalcoincidencerate=[(a+d)/(a+b+c+d)]×100%=[(153+207)/(360)]×100%=100%.

Table: statistic analysis of data （David Home Pregnancy Test Cassette）

		Results of Professionals		
		Positive	Negative	total
Results of non-Professionals	Positive	(a)153	(b)0	(a+b)153
	Negative	(c)0	(d)207	(c+d)207
	total	(a+c)153	(b+d)207	(a+b+c+d)360

Positive coincidence rate=[a/(a+c)]×100%=[153/(153+0)]×100%=100%;

Negative coincidence rate=[d/(b+d)]×100%=[207/(207+0)]×100%=100%

Total coincidence rate=[(a+d)/(a+b+c+d)]×100%=[(153+207)/(360)]×100%=100%.

b.Lay-user study:

After finishing the comparison study, 40 female volunteers aged from 18-45 and of different occupation and education were selected from each of the three sites, for a total of 120 volunteers to participate in the lay-user study and and fill-out questionnaires to evaluate the users comprehension of the instructions for use. Lay users conducted the test according to the English instructions for use for the David Home Pregnancy Test Cassette without any assistance. After finishing the test on their own samples, all the 120 volunteers were asked to test 3 other samples spiked with HCG of different concentrations, (HCG 0mIU/mL, HCG20mIU/mL, and HCG27.5mIU/mL). Every volunteer randomly selected one set of double-blind numbered samples to test. The results showed that all the test results of samples containing 27.5mIU/mL of HCG are positive and 99% of the test results of samples containing 20mIU/mL of HCG are negative.

Every lay-user participant was asked to answer the Likert scale style questions in the questionnaire after finishing the above test. The respondents specified their level of agreement or disagreement to a statement on a scale of 1 to 5,for example, 1-strongly disagree, 2-disagree, 3-neither agree or disagree, 4-agree, and 5-strongly agree. The results of the questionnaire reflected that the lay-users found the test to be easy to use and that they did not have trouble understanding the labeling or interpreting results. The Flesch-Kincaid software was used to assess the readability of the packaging labels for lay-user use and the results show that the labels can be understood by people with no more than 8th grade education.

M.CONCLUSION:

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