August 13, 2020

Safecare Biotech (Hangzhou) Co., Ltd.
Selina Zhang
Regulatory Affair
18 Haishu Road, Yuhang District
Hangzhou, China

Re: K200133
Trade/Device Name: hCG Urine Test Strip, hCG Urine Test Cassette, hCG Urine Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: June 29, 2020
Received: June 29, 2020

Dear Selina Zhang:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200133

Device Name
hCG Urine Test Strip
hCG Urine Test Cassette
hCG Urine Test Midstream

Indications for Use *(Describe)*
The hCG Urine Test Strip is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.
The hCG Urine Test Cassette is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.
The hCG Urine Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for 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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Section 5:

510(K) Summary

Date of Preparation: August 12, 2020

A. Applicant

Name: Safecare Biotech (Hangzhou) Co., Ltd.
Address: 18 Haishu Road, Yuhang District, Hangzhou, China
Official Contact Person Information
Name: Selina Zhang
Tel: 0086-571-89712897
Mail: selinazhang@safecare.com.cn

B. Device

Trade name:	hCG Urine Test Strip hCG Urine Test Cassette hCG Urine Test Midstream
Common name:	KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER
Classification name:	KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER
Regulation Medical Specialty	Clinical Chemistry
Regulation Number	862.1155
Product Code	LCX
Classification	Class II

C. Predicate device

510 (K) Number: k043443
One Step HCG Urine Pregnancy Test
Produced by Guangzhou Wondfo Biotech Co., Ltd.

D. Intended use of the device

Intended use(s):
The hCG Urine Test Strip is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.
The hCG Urine Test Cassette is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.
The hCG Urine Test Midstream is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

E. Device Description

The hCG Urine Test will be sold in three formats: cassette, test strip, and midstream. The test strip and midstream kits consist of one test device and a package insert. The cassette kit consists of one test device and a disposable plastic dropper, and a package insert. Each test device contains mouse monoclonal anti-βhCG 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. Comparison with predicate

A summary comparison of features of the HCG Urine Test and the predicate devices is provided in the following Table:

Device	New Device	Predicate Device (K043443)	Comparison
Manufacturer	Safecare Biotech (Hangzhou) Co., Ltd.	Guangzhou Wondfo Biotech Co., Ltd.	NA
Intended use	early detection of pregnancy	early detection of pregnancy	Same
Specimen	Urine	Urine	Same
Sensitivity	25mIU/mL	25mIU/mL	Same
Indications	Over the Counter (OTC)	Over the Counter (OTC)	Same
Read time	3-5 minutes	5 minutes	Similar
Test Principle	Immunochromatographic assay	Immunochromatographic assay	Same
Format	Strip, cassette, midstream	Strip, cassette, midstream	Same
Result	Qualitative	Qualitative	Same

There are no differences identified between new device and the predicate device for intended use, clinical cut-off, test principle, test format, etc. There is a minor difference in the reading time, the new device has a 3-5 minutes reading time while the predicate device has 5 minutes of reading time. However, this minor difference will not impact the safety or performance of the device. The HCG Urine Test Strip/cassette/midstream, and the predicate device use the same chemistry with essentially the same test design, thus they are substantial equivalent.

G. Standard/Guidance Document Referenced (if applicable)

Guidance for Over-the Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s

H. Test Principle

This device operates by detecting human chorionic gonadotropin (hCG), the hormone produced during pregnancy in urine, using a lateral flow sandwich immunochromatographic assay.

I. Performance characteristic

1. Analytical performance

a. Precision/Reproducibility:

Fresh urine samples were took from normal, nonpregnant females spiked with the HCG (traceable to WHO 5th IS） at different concentration 0mIU/ml, 12.5mIU/ml, 18.75mIU/ml, 25mIU/ml, 50mIU/ml, 100mIU/ml. The study was conducted 3 runs / day and lasted 10 days and was conducted by 3 operators. There are 3 batches HCG Urine Test of three formats and each operator should conduct one batch separately. The midstream format was performed with both of these midstream test sample application methods (simulated midstream and dip). the result was recorded as the following:

The results of precision (strip)

HCG concentration	LOT 1		LOT 2		LOT 3	
	positive	negative	positive	negative	positive	negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (cassette)

HCG concentration	LOT 1		LOT 2		LOT 3	
	positive	negative	positive	negative	positive	negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (midstream, using the dip method)

HCG concentration	LOT 1		LOT 2		LOT 3	
	positive	negative	positive	negative	positive	negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results of precision (midstream, using the simulated midstream method)

HCG concentration	LOT 1		LOT 2		LOT 3	
	positive	negative	positive	negative	positive	negative
0mIU/ml	0	30	0	30	0	30
12.5mIU/ml	0	30	0	30	0	30
18.75mIU/ml	0	30	0	30	0	30
25mIU/ml	30	0	30	0	30	0
50mIU/ml	30	0	30	0	30	0
100mIU/ml	30	0	30	0	30	0

The results show that the precision of HCG Urine Test in 3 batches of different formats are good. HCG Urine Test exhibited reproducibility of results.
Based on the above results, the sensitivity is demonstrated to be 25 mIU/mL.

b. Linearity/assay reportable range:
Not applicable. This is a qualitative assay.

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

Traceability:

The 510(k) describes traceability of the assay to the WHO 5th IS material. Stability testing was provided to support the claimed shelf life (30months).

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

d. Detection limit/Sensitivity study*:*
See Precision section above. According to the results of precision data above, the sensitivity of HCG Urine Test is 25mIU/ml.

e. Analytical specificity:
e.1) To determine if the hCG Test Strip/cassette/midstream was affected (i.e. cross- reacted) by a relevant challenge dose of closely-related human lutieinzing hormone (hLH), human follicle stimulating hormone (hFSH) or human thyroid stimulating hormone (hTSH). The results demonstrated no cross reaction with LH at 500mIU/ml, FSH at 1000 mIU/mL, and TSH at 1000 µIU/mL.

e.2) To evaluate the potential for interference by certain exogenous compounds and potentially interfering clinical conditions. Each substance was prepared by diluting stock interference material to the desired concentration. Normal, nonpregnant female's urine specimens containing 0 and 25mIU/ml HCG were spiked with the interferents to obtain the desired test concentration. Three batches of each format were tested. The results show that no interferences were observed from substance at the following concentrations for both negative and positive HCG urine samples.

Interfering substances	Substances concentration
Acetaminophen	20mg/mL
Aspirin	20mg/dL
Ascorbic acid	20mg/mL
Caffeine	20mg/dL
Glucose	200mg/dL
Hemoglobin	1mg/mL
Tetracycline	20mg/dL
Ampicillin	20mg/dL
Albumin	2000mg/dL
Bilirubin	2mg/mL
Erythrocytes	>250/uL
Leukocyte	>500/ul
Uric acid	450mMol/L
Ketone	> 80mg/dL
Ethanol	1%

e.3) To evaluate the effects of the HCG β-core fragment normal nonpregnant female urine specimens containing 0 and 25mIU/ml HCG were spiked with the HCG β-core fragment (traceable to WHO reference reagent 99/708) at the concentration of 125000, 250000, 500000 and 1000000 pmol/mL. Three batches of each format were tested. The data shows that there's no interference in the test result when the HCG β-core fragment at the highest levels at which it is likely to be found on patient samples.

e.4) PH study
The PH of an aliquot negative urine pool is adjusted to a PH range of 3 to 9 in 1 PH unit increments and spiked with HCG at 25mIU/ml and 0mIU/ml and 3 batches of HCG Urine Test were tested repeatedly. The result demonstrates that varying ranged of PH do not interfere with the performance of the test.

e.5) Specific gravity
Negative specimen 0 mIU/ml and specimen with HCG 25mIU/ml were formulated into the solution with specific gravity at 1.001, 1.020, 1.031, 1.039separately. Three lots of HCG Urine Test were tested. The data show that there's no interference in the test result when the specific gravity is between 1.001-1.039.

e.6) HOOK effect study
The test was evaluated for high dose hook effect. 30 HCG free specimens spiked with the HCG at different concentration containing 5,000mIU/ml, 10,000mIU/ml, 100,000mIU/ml, 500,000mIU/ml, 650,000mIU/ml, 850,000mIU/ml， 950,000mIU/ml. Three lot of tests for each format were tested. The result show that HCG Urine Test can get the positive result when the HCG concentration is range from 5,000 to 850,000 mIU/ml.

2. Comparison studies:
a. Professional method comparison
Urine samples were collected from 120 women at hospital laboratory to test for pregnancy. The data show that the agreement of hCG Test Strip/cassette/midstream with the predicate device was 100%.

The results of professional method comparison (strip)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (cassette)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (midstream, using dip method)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

The results of professional method comparison (midstream, using the simulated method)

Candidate device		Predicate device professional	
		Positive	Negative
Professional A	Positive	53	0
	Negative	0	67
Professional B	Positive	53	0
	Negative	0	67

b. The lay user method comparison:

Urine samples were collected from 360 women at hospital laboratory to test for pregnancy. Ages were from 18 to 45 years. Out of the 360 women, 84 have an education background of middle school, 103 have an education background of high school, 84 have an education background of college degree, 59 have an education background of bachelor degree, 30 have an education background of Master & PhD degree. The conformity between the user interpretation of the and the professional interpretation of the hCG Test Strip/cassette/midstream is 100%.

The results of the lay user method comparison (strip)

Safecare device	Safecare device professional		Total
	Positive	Negative	

Lay users	Positive	33	0	33
	Negative	0	57	57
Total		33	57	90

The results of the lay user method comparison (cassette)

Safecare device		Safecare device professional		Total
		Positive	Negative	
Lay users	Positive	29	0	29
	Negative	0	61	61
Total		29	61	90

The results of the lay user method comparison (midstream, using dip method)

Safecare device		Safecare device professional		Total
		Positive	Negative	
Lay users	Positive	23	0	23
	Negative	0	67	67
Total		23	67	90

The results of the lay user method comparison (midstream, using the actual midstream method)

Safecare device		Safecare device professional		Total
		Positive	Negative	
Lay users	Positive	26	0	26
	Negative	0	64	64
Total		26	64	90

c. The performance tested by OTC user:

To evaluate its suitability to be used by the home use consumers (lay persons), spiked urine samples were tested by the lay persons and the results were compared with professional laboratory results. The results show that hCG Test Strip/cassette/midstream can be used by the untrained operator and get the correct results.

Results of performance tested by OTC user

Formats	Masked spiked sample	Masked spiked sample Professional users

			+(31.25mIU/ml)	-(18.75mIU/ml)
strip	Lay users	+(31.25mIU/ml)	30	0
		-(18.75mIU/ml)	0	30
Cassette	Lay users	+(31.25mIU/ml)	30	0
		-(18.75mIU/ml)	0	30
Midstream, using dip method	Lay users	+(31.25mIU/ml)	30	0
		-(18.75mIU/ml)	0	30
Midstream, using the simulated midstream method	Lay users	+(31.25mIU/ml)	30	0
		-(18.75mIU/ml)	0	30

After recording their results, participants were asked to evaluate the test. All participants thought the test was either “very easy” or “easy” to read and interpret (on a scale ranging from very difficult to very easy).

d. Matrix comparison:
Not applicable.

3. Clinical studies:
a. Clinical Sensitivity:
Not applicable.
b. Clinical specificity:
Not applicable.
c. *Other clinical supportive data (when a. and b. are not applicable):*
4. Clinical cut-off**:**
2SmIU/mL
5. Expected values/Reference range:
Not applicable

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

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