April 5, 2022

Co-Innovation Biotech Co., Ltd.
Hong Feng
Product Manager
No. 9 Baihe 3 Street, Economic And Technological Development East Zone
Guangzhou, Guangdong 510507
China

Re: K213808
Trade/Device Name: Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Strip, Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Cassette ,Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Midstream
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: December 6, 2021
Received: December 6, 2021

Dear Hong Feng:

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 *(if known)*
K213808

Device Name
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Strip
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Cassette
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Midstream

Indications for Use *(Describe)*
The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) 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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Co-Innovation Biotech Co.,Ltd.

Section 5 - 510(k) Summary

Date of Summary Preparation: 31/03/2022

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.
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2. Correspondent's Identifications

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Contact Person: Hong Feng
Contact Email Address: fenghongfda@126.com
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3. Name of the Device

Recommended classification regulation: 21 CFR 862.1155
Device class: Class Ⅱ
Panel: Clinical Chemistry (75)
Product code: LCX
Common Name:Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test
Proprietary names:
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Strip
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Cassette
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Midstream

4. The Predicate Devices

K132085 One Step Human Chorionic Gonadotropin (HCG) Test

5. Device Description

The subject device One Step Human Chorionic Gonadotropin (HCG) Test is identical to the previous cleared version of the device with the same name (K132085). The purpose of this special 510(k) submission is to expand shelf-life from 2 years to 3 years, the device itself has not changed.
Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test is a rapid sandwich

immunoassay device designed for the qualitative determination of human chorionic gonadotropin (hCG) concentration in human urine samples, as an aid in the early detection of pregnancy. The test devices are in three different formats: Strip,Cassette and Midstream . Three test formats use identical strips and each test strip in the device consists of:

1. A conjugate pad contains colloidal gold conjugated with mouse monoclonal anti-β-HCG antibody specific to the beta subunit of hCG.
2. A nitrocellulose membrane which is striped with the mouse monoclonal anti-α-HCG antibody in the test line (T line) and goat anti-mouse IgG polyclonal antibody in the control line (C line).

The Cassette format has the same performance specifications as the Test Strip format. The difference is that the urine sample is dispensed by dropper onto the sample well on the cassette.

The Midstream format has the same performance specifications as the Test Strip format. The difference is that the device is placed into the urine stream or dipped into the urine collection cup for 5 seconds.

6. Intended Use of Device

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Strip is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Cassette is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

The Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. It is intended for over-the-counter (OTC) use.

7. Comparison to Predicate Devices:

A summary comparison of features of the Co-Innovation One Step Human Chorionic Gonadotropin (HCG) Test and the predicate devices is provided in the following Table：

Item	Subject device	Predicate (K132085)	Remark
Indication for use	Qualitative detection of human chorionic gonadotropin (“HCG”) in urine	Qualitative detection of human chorionic gonadotropin (“HCG”) in urine	Same
Intended Users	Over the Counter (OTC)	Over the Counter (OTC)	Same
Component	Nitrocellulose Membrane,	Nitrocellulose Membrane,	Same

	Gold Spray Fiber, Glass fiber	Gold Spray Fiber, Glass fiber	
Specimen	Urine	Urine	Same
Clinical cut-off	25mIU/mL	25mIU/mL	Same
Read time	5 minutes	5 minutes	Same
Storage	4 ~ 30 ºC	4 ~ 30 ºC	Same
Test Principle	Colloidal Gold Immunoassay	Colloidal Gold Immunoassay	Same
Traceability	WHO 3rd IS	WHO 3rd IS	Same
Format	Strip,cassette,midstream	Strip,cassette,midstrea m	Same
Antibodies	Monoclonal anti-β-HCG antibody , monoclonal anti-α-HCG antibody, goat anti mouse IgG polyclonal antibody	Monoclonal anti-β-HCG antibody , monoclonal anti-α-HCG antibody, goat anti mouse IgG polyclonal antibody	Same
Shelf-life	3 Years	2Years	Differences

Remark:

1、 The subject devices have all features of the predicate device except the Shelf-life. The subject device have performed the Stability Study.This differences do not affect the performance characteristics of the subject devices.

8. Standard/Guidance Document Referenced (if applicable):

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

9. Test principles:

The assay tests the human chorionic gonadotropin (HCG) qualitatively in the urine specimen, using the double antibody sandwich method. 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. During the test procedures, the intact 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 form Ag-Abβ-Au complexes. Because of capillary and chromatographic effects of the Nitrocellulose membrane, the complexes migrate along the membrane to the α-HCG antibody line (T), form Abα-Ag-Abβ-Au complexes and remain captured in the T line. As a result a red colored band develops in T and the result is positive. If there is no HCG in the urine, there is no red band in the Test zone, indicating negative result. No matter if there's HCG in the urine specimen, when the complexes migrate along the Control zone, a red band must be developed in the C zone.

10.Antibody Information

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

11. Stability Study Data:

11.1 The methods of the testing:

Take 9 lots HCG tests, with the lot numbers 101180301,101180302,101180303, 101180301C, 101180302C,101180303C101180301M,101180302M,101180303M, place them at 4℃ and 30℃ for 42 months, then make the study of the physical testing, positive reference conformity rate, negative reference conformity rate, sensitivity, and precision based on the manufacturer inner Reference Panel.

11.2 Conclusion

The information provided supports that the devices are substantially equivalent to the predicate.

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