June 30, 2022

Healstone Biotech Inc.
% Guang Gao
Principal Consultant
Axteria Biomed Consulting
8040 Cobble Creek Circle
Potomac, Maryland 20854

Re: K212418
Trade/Device Name: hCG One Step Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test System
Regulatory Class: Class II
Product Code: LCX
Dated: May 5, 2022
Received: May 5, 2022

Dear Guang Gao:

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
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k212418

Device Name
hCG One Step Pregnancy Test

Indications for Use *(Describe)*
The hCG One Step Pregnancy Test is an in vitro diagnostic test for the qualitative determination of human chorionic gonadotropin hormone in human urine samples. It is used as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

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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K212418

510(K) SUMMARY

Submitter's Identification:
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Date: June 29, 2022

Contact Person:
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Proprietary Name of the Device: hCG One Step Pregnancy Test

Common Name: hCG One Step Pregnancy Test

Classification Name: 21 CFR § 862.1155 Human chorionic gonadotropin (HCG) test system

Product Code: LCX

1.0 Device Description

The hCG One Step Pregnancy Test is a lateral flow sandwich immunochromatographic assay for the qualitative determination of human chorionic gonadotropin (hCG) in human urine samples.

2.0 Intended Use

The hCG One Step Pregnancy Test is an in vitro diagnostic test for the qualitative determination of human chorionic gonadotropin hormone in human urine samples. It is used as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

3.0 Test Principle

The hCG One Step Pregnancy Test is a lateral flow sandwich immunochromatographic assay that utilizes a combination of monoclonal antibodies for qualitative detection of hCG in human urine samples. The test uses two lines to show the results. When the urine sample is added into the absorbent tip, the sample migrates via capillary action along the membrane. If present in the sample, hCG will react with the specific monoclonal hCG antibody and form a colored line at the test line region of the membrane, indicating a positive result (pregnant). Absence of a colored line at the test line region suggests a negative result (not pregnant). To serve as a procedural control, a colored line will always appear in the control line region. If the control line does not appear (no color appears at the control line region 3 minutes after application of the sample), the test is invalid and the specimen should be retested with a new device.

4.0 Comparison of the Predicate Device

Similarities and Differences		
	Proposed device	**Predicate device**
Name	hCG One Step Pregnancy Test	First Response Early Result Pregnancy Test (K123436)
Device Type	In vitro diagnostic	Same
Classification	Class II	Same
Regulatory Number	21 CFR §862.1155 Human Chorionic Gonadotropin	Same
Product Usage	OTC	Same
Principle of Operation	Lateral flow sandwich immunochromatographic assay	Same
Specimen Collection Method	Mid-stream or dip mode	Same
Intended Use	A chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.	Same

Type of Specimen	Human urine	Same
Sensitivity	10 mIU/mL	Same
Time to Result	3 minutes	Same
Result	Qualitative	Same
Shelf Life	24 months shelf life when stored in a dry place at 2–30°C.	Same
hCG Isoforms Detected	Intact hCG	Intact hCG, hyperglycosylated hCG, hCG β-subunit, hCG β-core fragment

5.0 Test Performance

5.1 Analytical Performance

5.1.1 Limit of Detection

The Limit of Detection (LOD) was determined by testing serial dilutions of the hCG standard substance that is commercially available and traceable to the 5th WHO international Standard. Three internal sites used 3 lots of the proposed device with a simulated stream method and dip method. The panel was created by spiking 30 negative urine samples (from males and non-pregnant females) with the hCG standard substance at eight different hCG concentrations (below, at and above the initial assigned LOD). These panel members were randomized, blind coded and tested with the 3 lots of the proposed device by three different lab technicians on different days. Each operator performed the test with one lot of the proposed device and interpreted the results independently.

The results showed that the LOD (the lowest concentration that yields ≥ 95% positive results) is 10 mIU/mL for urine obtained by both the simulated stream method and the dip method.

5.1.2 Precision/Reproducibility

Panels were prepared from 100% pooled human urine containing no analyte. The hCG human urine samples were spiked with hCG positive specimen that is traceable to the 5th WHO international standard to obtain the hCG at concentrations 0, 5, 7.5, 8.75, 10, 12.5, and 25 mIU/mL.

Repeatability testing was conducted with twenty replicates of each urine sample in one day with one lot of the hCG One Step Pregnancy Test. For intermediate precision testing, each panel member was tested by three operators with 10 replicates and 3 lots of device for 5 non-consecutive days. A total of 450 replicates of each urine sample was tested over multiple days by multiple operators. When testing hCG at 10 mIU/mL and above, a 100% positive rate was

obtained for all operators with all device lots, at both the simulated stream method and the dip method.

The results show that the proposed device can produce consistent results when detecting hCG in urine samples.

5.1.3 Analytical Specificity

5.1.3.1 Potential Interfering Substances Study

The interference substance study was performed with urine containing prescription/OTC drugs, elevated levels of chemical analytes (e.g., caffeine, ascorbic acid), and elevated levels of biological analytes (e.g., glucose, protein, albumin, bilirubin, hemoglobin).

For the potential interfering substances study, negative female urine samples containing 0 and 10 mIU/mL of hCG were individually spiked with the potential interfering substances. Five devices were used for the testing. Based on the five replicates results, no interference was observed from the potential interfering substances at the level evaluated.

5.1.3.2 Cross Reactivity Study

The hCG One Step Pregnancy Test was evaluated for cross-reactivity with other substances that are similar in structure to hCG. Human urine specimens with hCG concentrations of approximately 0 and 10 mIU/mL were supplemented with potentially cross-reacting compounds. The compounds were tested and found to have no cross-reactivity.

5.2 Comparison Study

The performance the hCG One Step Pregnancy Test was evaluated by professional users at 2 sites with 2 lots of the proposed device. A total of 158 urine samples were collected from 158 subjects with ages ranging between 18 to 45 who were in need of determining their pregnancy status. The urine samples were collected at various times of day in a random fashion. The urine specimens were tested with the proposed device and with the predicate device (First Response Early Result Pregnancy Test) by independent operators. The urine samples were masked with a code and randomized by individuals who were not conducting the test. The test results of the hCG One Step Pregnancy Test and the First Response Early Result Pregnancy Test were compared to evaluate the clinical test performance.

The test performance of the hCG One Step Pregnancy Test is with 100% concordance when compared to the predicate.

6.0 Conclusion

Based on the test principle and acceptable performance characteristics including interfering substances, cross reactivity, method comparison, clinical specificity, and lay-user studies of the devices, it is concluded that the hCG One Step Pregnancy Test is substantially equivalent to the predicate.