510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K123703

B. Purpose for Submission:

Addition of over-the-counter claim

C. Measurand:

Human chorionic gonadotropin (hCG) in human urine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Zhejiang Orient Gene Biotech, Co.,Ltd.

F. Proprietary and Established Names:

Healgen hCG One Step Pregnancy Test Strip

Healgen hCG One Step Pregnancy Test Cassette

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCX	Class II	21 CFR§ 862.1155, Human chorionic gonadotropin (HCG) test system	Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See Indications for Use below

2. Indication(s) for use:

   Healgen hCG One Step Pregnancy Test Strip

   The Healgen HCG One Step Pregnancy 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. Urine sample is collected with cup only. For Over-The-Counter self-testing use.

   Healgen hCG One Step Pregnancy Test Cassette

   Healgen hCG One Step Pregnancy 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.Urine sample is collected with cup only. For Over-The-Counter self-testing use.

3. Special conditions for use statement(s):

   Test strip and cassette formats are for over-the-counter (OTC) use.

4. Special instrument requirements:

   None

I. Device Description:

The Healgen hCG One Step Pregnancy Test (cassette and strip) 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 is available in three formats: strip, cassette, Both configurations have the same membrane format, reagents, and flow characteristics. Devices are packaged one device per pouch with 2 devices per kit

J. Substantial Equivalence Information:

1. Predicate device name(s):

   K043443

2. Predicate 510(k) numbers:

   One Step HCG Urine Pregnancy Test

3. Comparison with predicate:

Comparison with predicate		
Item	Candidate Device	Predicate device
Intended Use	The Healgen hCG One Step Pregnancy Test (cassette and strip) is an in vitro diagnostic visual qualitative immuno-chromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) to aid in the detection of pregnancy. For Over-The-Counter use.	Same
Cut-off	25 mIU/mL	Same
Specimen Type	Urine	Same
Principle	Lateral flow immunochromatographic sandwich assay	Same
Test Format	Test Strip and Cassette	Test Strip, Cassette, Midstream
Read Time	5 minutes	3 to 5 mintues

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

ISO 13485 Medical devices - Quality management systems

ISO 14971 Medical devices - Application of risk management to medical devices

ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice

L. Test Principle:

The test is a qualitative, solid phase, two-site sandwich immunoassay for the detection of human chorionic gonadotropin (hCG) in urine. The membrane is pre-coated with monoclonal anti-hCG antibodies on the test band region and anti-mouse antibodies on the control band region. During testing, the urine sample reacts with the dye conjugate (mouse anti-hCG antibody-colloidal gold conjugate) which has been pre-coated on the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action to react with anti-hCG antibodies on the membrane and generate a red band. Presence of the red band in the test region indicates a positive result, while its absence indicates a negative result. Regardless of the presence of hCG, a red band at the control band region will always appear..

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   The candidate device is identical to the Pregnancy One Step Rapid Test cleared under k103574. The sponsor now seeks an OTC claim for the strip and cassette formats.

   a. Precision/Reproducibility:

   See 510(k) decision summary for k103574

   b. Linearity/assay reportable range:

   See 510(k) decision summary for k103574

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

   See 510(k) decision summary for k103574

   d. Detection limit:

   See 510(k) decision summary for k103574

   e. Analytical specificity:

   See 510(k) decision summary for k103574

   f. Assay cut-off:

   See 510(k) decision summary for k103574

2. Comparison studies:

   a. Method comparison with predicate device:

See 510(k) decision summary for k103574

b. 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):
A lay user study was performed using the test trip and cassette format of the Healgen hCG One Step Pregnancy Test for hCG testing. Urine samples were collected from 100 lay users. Education levels of study participants ranged from middle school level to college educated. Each lay user performed the testing unassisted according to the labeling. The participants collected their sample in a cup for subsequent blinded testing by healthcare professionals. Professionals tested the lay-user samples with the predicate device (k043443).

Equivalent results were obtained with the test strip and cassette. Results are summarized below:

		Predicate		
		Positive	Negative	Total
Candidate (Strip and Cassette)	Positive	24	0	24
	Negative	0	76	76
	Total	24	76	100

After completing the test procedure, the participants answered a questionnaire to evaluate the instructions (package insert) to the strip and cassette separately. All 100 answers from both procedures were collected and summarized.

For strip and cassette:

98% of the participants found the instructions for use for each format very easy to understand and overall 94% of the users thought both tests were easy to administer.

Lay user study to evaluate results at near cut off:

To evaluate the ease at which lay user's can interpret results at concentrations around the cutoff, negative urine samples from normal, non-pregnant females or males were spiked with hCG at concentrations near the cutoff (0, 20, 22.5, 25, 27.5, 30 mIU/mL) and tested with the candidate device and predicate (k043443) by lay users.

Specimens at each concentration (60 samples; 30 samples at or above the cut off and 30 samples below the cut off) were randomly picked by lay users and tested with the Healgen hCG One Step Pregnancy Test (strip and cassette format) and the predicate device. Urine samples were masked before testing. Study participants were instructed to follow the package insert to test and to record their results of the supplied urine samples.
Results are summarized below:

	Predicate		Total
Candidate (strip and cassette)	Positive	Negative	
Positive	29	1	30
Negative	0	30	30
Total	30	30	60

4. Clinical cut-off**:**

   Not applicable

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.