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

A. 510(k) Number:
k043231

B. Purpose for Submission:
New Device

C. Measurand:
Human chorionic gonadotropin

D. Type of Test:
Qualitative

E. Applicant:
Mizuho USA, Inc.

F. Proprietary and Established Names:
Proof Positive Electronic Pregnancy Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155

2. Classification:
   Class II

3. Product code:
   LCX

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   Proof Positive Electronic Pregnancy Test is an over-the-counter test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the early detection of pregnancy.

2. Indication(s) for use:
   Proof Positive Electronic Pregnancy Test is an in-vitro diagnostic test for the qualitative determination of human chorionic gonadotropin (hCG) in urine, for the

early detection of pregnancy. The test has a sensitivity of 50 mIU/mL hCG in urine.

The test will be marketed for the retail or "over-the-counter" (OTC) market use.

3. Special conditions for use statement(s):
   This device is for OTC use.

4. Special instrument requirements:
   None

I. Device Description:

The Proof Positive Electronic Pregnancy Test is composed of two dye conjugates consisting of latex and colloidal gold particles, each labeled to a mouse anti-hCG monoclonal antibody, and onboard electronics. The test kit contains 1 test device and 1 instruction pamphlet.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Absolute hCG Pregnancy Test

2. Predicate 510(k) number(s):
   k000844

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Qualitative detection of hCG for early detection of pregnancy	Same
Specimen	Urine	Same
Assay Format	Lateral flow immunoassay	Same
Result Read Time	3 minutes for urine	Same
Analytical Sensitivity	50 mIU/mL (urine)	Same

Differences		
Item	Device	Predicate
Result Readout	LCD shows "Positive," "Negative," or "Positive Negative" with a clock symbol	Presence of one or two colored bars

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

None referenced

L. Test Principle:

The Proof Positive Electronic Pregnancy Test is a solid phase dye-conjugate lateral flow immunoassay that utilizes an antibody conjugated to latex particles and an antibody labeled with colloidal gold particles. The urine specimen is absorbed through an absorbent strip and flows up to the reactive area where the conjugate dyed particles are located. When the urine enters the reactive area, the hCG antigen present in the urine binds to the labeled antibody dye conjugate, which forms an antibody-antigen-antibody complex. This results in the production of a red or green band, depending on the level of hCG.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

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

WHO 3rd I.S.

d. Detection limit:

To determine the sensitivity/detection limit, a total of 280 samples were run on the new device. The samples consisted of urine pool in 5 mIU/mL increments ranging from 20 mIU/mL to 80 mIU/mL hCG. Twenty (20) tests per level were run. The results were all negative for the 0 mIU/mL level and were all positive for the levels ≥ 20 mIU/mL.

e. Analytical specificity:

Specificity was evaluated by dipping two tests in negative urine pool spiked with the following: luteinizing hormone (1000 mIU/mL), follicle stimulating hormone (1000 mIU/mL), and thyroid stimulating hormone (1000 mIU/mL). All the results were negative.

Interference was evaluated by dipping one test in 50 mIU/mL hCG pooled

urine spiked with various prescription and over-the-counter drugs and urine metabolites. pH levels of 5 and 9 were also tested for interference. All the results were positive as expected.
The same interfering substances and pH levels were spiked into negative pooled urine and evaluated for potential interference. All the results were negative as expected.

f. Assay cut-off:
See "Detection limit" above.

2. Comparison studies:
   a. Method comparison with predicate device:
   A consumer study was conducted using 100 consumers. Participants were each provided a Consumer Study/Performance Report, the subject device, a midstream pregnancy test, and package inserts. They were instructed to perform the tests at separate times and to complete and return the report.
   The study resulted in 9 positive results and 91 negative results, with complete agreement between the subject device and the midstream pregnancy test. The participants ranged from 14 to 57 years of age, with education levels ranging from high school through doctorate degrees. English was the second language of some of the participants.
   At the request of FDA, the sponsor provided additional data to support performance relative to positive results. An additional 55 tests were performed by participants, 16 to 46 years of age, who were either pregnant or expected to be pregnant. The same protocol as described above was followed for this study. This study resulted in 29 positives and 26 negatives, with 100% correlation between the two devices.

   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):
   Not applicable

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   The expected values were based on literature.

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.