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

A. 510(k) Number:
K032661

B. Analyte:
Human Chorionic Gonadotropin (HCG) Test System

C. Type of Test:
Qualitative solid-phase sandwich-format immunochromatographic assay

D. Applicant:
ACON Laboratories, Inc.

E. Proprietary and Established Names:
ACON Quik-Check II Home Pregnancy Test

F. Regulatory Information:

1. Regulation section:
   CFR 862.1155
2. Classification:
   Class II
3. Product Code:
   LCX
4. Panel:
   Clinical Chemistry (75)

G. Intended Use:

1. Indication(s) for use:

The ACON Quik-Check II Home Pregnancy Test Device is intended for non-professional, over-the-counter use for the qualitative identification of the elevated levels of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

2. Special condition for use statement(s):
   Non-professional, over-the-counter use
3. Special instrument Requirements:
   N/A

H. Device Description:
The device consists of a cassette with a sample well at one end and the result and control windows in the middle. The test strip runs under the sample well and result/control windows. The user applies 3 drops of urine which migrate via capillary

action toward the result and control windows. If hCG is present in the urine it reacts with an anti-HCG-colored particle conjugate to form a colored line in the test region of the strip. A colored line in the control region of the device indicates adequate sample volume and capillary action. Absence of a colored line in the control region is an indication of an invalid result.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   ACON Pregnancy Test
2. Predicate K number(s):
   K012215
3. Comparison with predicate:

Similarities		
Item	**Predicate**	**Device**
Intended Use	OTC use for the qualitative identification of HCG to aid in detection of pregnancy	same
Matrix	Urine	same
Endpoint	Colored lines	same
Read Time	3 minutes	same
Antibodies	Rabbit, goat	same
Sensitivity	25 mIU/mL	same
Specificity	No interference when tested with LH, FSH, or TSH	same
Accuracy	>99% at cutoff	same
Standardization	WHO 3rd International Standard	same

	Differences	
Item	**Predicate**	**Device**
Methodology	Membrane EIA	Proprietary membrane ligand-binding EIA
Storage	2-30° C	15-30° C

J. Standard/Guidance Document Referenced (if applicable):
None referenced

K. Test Principle:
Qualitative solid-phase sandwich-format immunochromatographic assay

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
   N/A
   b. Linearity/assay reportable range:

N/A

c. *Traceability (controls, calibrators, or method):*
WHO 3rd International Standard

d. *Detection limit:*
25 mIU/mL

e. *Analytical specificity:*
Cross-reactivity was tested at 0 and 25 mIU/mL with LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000mIU/mL) with no variation from expected results. Also tested were variations in pH (5-9), specific gravity (1.003 – 1.028) and the addition of 22 common compounds, none of which showed any variation from the expected results.

f. *Assay cut-off:*
See detection limit above

2. Comparison studies:
   a. *Method comparison with predicate device:*
   A consumer field study was done which included 113 participants. Urine samples were analyzed using the new device by both consumers and lab professionals and with the predicate device by lab professionals. The study evaluated the participants' ability to understand the package insert and to accurately perform the test. When tested by lab professionals, 77 samples tested positive by both methods and 36 samples tested negative by both methods. When tested by consumers, the same samples tested negative. Of the 77 positive samples, 75 tested positive with one discrepant result and one invalid result.
   b. *Matrix comparison:*
   N/A
3. Clinical studies:
   a. *Clinical sensitivity:*
   N/A

   b. *Clinical specificity:*
   N/A

   c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:

5. Expected values/Reference range:

Human Chorionic Gonadotropin is not found in healthy males or healthy non-pregnant females in concentrations that can be detected by the ACON Quik-Check II Home Pregnancy Test.

M. Conclusion:

Based upon the information provided for the file, I recommend that the ACON Quik-Check II Home Pregnancy Test is substantially equivalent to the predicate device.