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

A. 510(k) Number:
k040866

B. Purpose for Submission:
New device

C. Analyte:
Human chorionic gonadotropin

D. Type of Test:
Qualitative

E. Applicant:
Armkel, LLC

F. Proprietary and Established Names:
FIRST RESPONSE® One-Step Digital Pregnancy Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155 Human chorionic gonadotropin (HCG) test system
2. Classification:
   II
3. Product Code:
   LCX
4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   FIRST RESPONSE® One-Step Digital Pregnancy Test is an *in vitro* diagnostic test device that incorporates a digital read out of the test result for the early detection of pregnancy (hCG in urine) by the lay user prior to the expected menses.
2. Indication(s) for use:
   FIRST RESPONSE® One-Step Digital Pregnancy Test is an *in vitro* diagnostic test device that incorporates a digital read out of the test result for the early detection of pregnancy (hCG in urine) by the lay user prior to the expected menses.
3. Special condition for use statement(s):
   This device is intended for over-the-counter use.

4. Special instrument Requirements:
   This device is a single use device containing a micro chip and digital readout. The device was developed under adequate software life cycle processes, and the sponsor provided all the documentation necessary to support a moderate level of concern review. The documentation was reviewed and found to be sufficient for making a substantial equivalent decision.

I. Device Description:

The FIRST RESPONSE® One-Step Digital Pregnancy Test is a chromatographic strip contained within a plastic housing, which is integral with a digital component that reads and displays the result of the immunochemical reaction on the Display Screen of the device housing. The immunochemical reagents are the same as those in the predicate FIRST RESPONSE® One-Step Pregnancy Test, k992232.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   FIRST RESPONSE® One-Step Pregnancy Test, CLEARBLUE® Easy Digital Pregnancy Test
2. Predicate K number(s):
   k992232, k030659
3. Comparison with predicate:

Similarities			
Item	**Device**	**Predicate**	
		k992232	k030659
Intended Use/Indications	Qualitative detection of hCG in urine for early detection of pregnancy	Same	Same
Principle	Immunochromatography	Same	Same
Differences			
Item	**Device**	**Predicate**	
Readout	Digital/LCD	Manual/visual interpretation of colored line(s)	Digital/LCD
Detection Limit	25 mIU/mL	25 mIU/mL	50 mIU/mL
Standardization	WHO 3rd I.S.	WHO 3rd I.S.	WHO 4th I.S.

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

WHO Third International Reference Standard

L. Test Principle:

The test is an immunochromatographic assay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    Not applicable
    b. *Linearity/assay reportable range:*
    Not applicable
    c. *Traceability (controls, calibrators, or method):*
    WHO Third International Reference Standard
    d. *Detection limit:*
    The analytical sensitivity of the FIRST RESPONSE® One-Step Digital Pregnancy Test is 25 mIU/mL. Five (5) replicate standards each at 50, 37.5, 25, 18.75, 12.5, and 0 mIU/mL were prepared and evaluated with the new test. All replicates of each standard at 18.75 mIU/mL and above yielded the expected results within the specified read time of three minutes. Additionally, all of the 0 mIU/mL samples produced negative results.
    e. *Analytical specificity:*
    Homologous hormones (LH, FSH, and TSH), various prescription and OTC drugs, and various urine analytes were added to aliquots of a female non-pregnant urine pool with hCG levels of 0 and 50 mIU/mL. All samples, with the exception of one 0 mIU/mL sample and one 50 mIU/mL sample spiked with hemoglobin, produced the expected results. However, additional test replicates of these samples yielded the correct expected results.
    f. *Assay cut-off:*
    See Detection limit above.

2. Comparison studies:
    a. *Method comparison with predicate device:*
    The performance of the FIRST RESPONSE® One-Step Digital Pregnancy Test was compared to that of the predicate non-digital FIRST RESPONSE® One-Step Pregnancy Test and the Clearblue® Easy Digital Pregnancy Test. In this study, 100 urine samples were collected from women who claimed not to be pregnant. These samples were tested using all three tests. All samples were negative with all tests.
    In another phase of the study, 103 urine samples from pregnant women were tested using the three tests. One sample was negative with the FIRST RESPONSE® One-Step Digital Pregnancy Test and the predicate non-digital FIRST RESPONSE® One-Step Pregnancy Test but with positive with Clearblue®. One sample was negative on the subject device but positive on both predicate devices. Therefore, the subject device yielded positive results for 101 out of 103

pregnancy urine samples when compare to Clearblue® and in 102 out of 103 when compared to the non-digital FIRST RESPONSE® One-Step Pregnancy Test.

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):
   One hundred twenty-seven (127) women between the ages of 18 and 45 years, untrained in laboratory testing, participated in a consumer performance study. Each woman was given one digital test device and asked to perform the test according to the package insert instructions. The women were allowed to choose the test format (either mid-stream or dip) according to personal preference. The test result obtained by the consumer was also read and confirmed by the study monitor.
   Excluding results from two defective sticks and twelve invalid results (due to too much/too little sample or digital noise), 113 valid "YES+" or "-NO" results were obtained. Of these, 4 were false positives, resulting in 96.5% correct results.
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   The expected values are based on literature.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.