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

A. 510(k) Number:
K040575

B. Purpose for Submission:
New device

C. Analyte:
Follicle stimulating hormone

D. Type of Test:
Qualitative

E. Applicant:
Phamatech, Inc.

F. Proprietary and Established Names:
Moments Menopause Check (Models 9111 and 9112)

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1300
2. Classification:
   I
3. Product Code:
   CGJ
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   This Moments Menopause Check is a rapid, qualitative immunoassay for the detection of the FSH in urine. This test is intended for use at home by women who have symptoms of "pre-menopause" or "menopause" and want to confirm their hormone status.
2. Indication(s) for use:
   The Moments Menopause Check is an in-vitro diagnostic screen for the detection of FSH (follicle stimulating hormone) in urine. Change in FSH levels may be associated with stages in menopause. This kit provides a preliminary result for the detection/presence of FSH in urine. It is intended for over-the-counter sales.
3. Special condition for use statement(s):
   This device is for over-the-counter use.
4. Special instrument Requirements:
   None

I. Device Description:
The Moments Menopause Check is supplied in two test formats: cassette and cup. The cassette model (9111) includes a sealed foil pouch containing the test device and a plastic dropper, and a collection cup. The cup model (9112) contains one sealed

collection container with an embedded test strip. The test strip in both models contains goat anti-FSH on the test band region and goat anti-mouse on the control band region.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Genua Menopause Monitor, SureStep FSH Menopause Test
2. Predicate K number(s):
   K002450, K010556
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicates**
Intended Use	Qualitative detection of FSH to assist in the detection of menopause	Qualitative detection of FSH to assist in the detection of menopause
Specimen	Urine	Urine
Methodology	Lateral flow immunoassay	Lateral flow immunoassay
Antibodies	Monoclonal & polyclonal	Monoclonal & polyclonal
Sensitivity	25 mIU/mL	25 mIU/mL
Differences		
Item	**Device**	**Predicate**
End User	Lay Person	Professional (SureStep test)

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

L. Test Principle:
The test is a two-site immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. *Precision/Reproducibility:*
   To determine lot-to-lot consistency, three normal male urine pools were spiked with intact FSH to concentrations of 0, 44, and 71 mIU/mL. Three device lots were used for this study. Ten replicates of each FSH level were assayed, and the time of the appearance of the control line or test line was recorded in each case and used for precision comparison. The test and control line development times resulted in low standard deviations. Also, low variability among lots, for each FSH level tested, was observed.
   b. *Linearity/assay reportable range:*
   Not applicable
   c. *Traceability (controls, calibrators, or method):*
   Not applicable

d. Detection limit:
To determine the detection limit, ten normal female urine samples with FSH concentrations ranging from 5 to 71 mIU/mL and five control materials with FSH concentrations ranging from 0 to 1000 mIU/mL were used. Aliquots (10) of each sample were randomized, coded, and run on the subject device. The results showed 100% correct identification (10/10 positive results) for all samples ≥25 mIU/mL.

Additionally, a blind study using coded test samples was conducted as part of the consumer survey. In this survey one hundred (100) respondents correctly interpreted 95 of 98 (97%) of the coded urine samples.

e. Analytical specificity:
To determine the immunological specificity, various concentrations of hLH (300 mIU/mL), hTSH (1000 μIU/mL), and hCG (1000 mIU/mL) were spiked into a normal male urine pool, which was previously spiked with 0, 10, 30, and 100 mIU/mL FSH. Each sample was tested in triplicate using the subject device. The results demonstrate that the subject device has no cross reactivity with structurally similar glycoprotein hormones.

To test for possible interference with a variety of common biological and chemical analytes that may be found in urine, each analyte was spiked into aliquots of a normal urine pool previously spiked with 0, 10, 30, and 100 mIU/mL FSH. The pools were tested in triplicate for possible interference in the assay. None of the compounds tested showed any sign of interference in the test.

f. Assay cut-off:
See Detection limit.

2. Comparison studies:
   a. Method comparison with predicate device:
   One hundred three (103) female urine samples were obtained from clinical sites and run on the subject device and the two predicate devices (at Phamatech). All samples were collected from normal females who exhibited perimenopausal-type symptoms. The Phamatech device produced 64 positive results and 39 negative results, yielding 98% correlation when compared to the predicate 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):*
A study was conducted at five geographically distinct locations using a panel of coded specimens to demonstrate that lay people could perform the Moments Menopause Check reproducibly and obtain accurate results. The proficiency panel contained negative (0 mIU/mL) and low positive (30 mIU/mL FSH – WHO 1st IRP) specimens. Trial participants were each sent one test device, one coded sample, and a questionnaire to complete. Results were obtained from one hundred (100) consumers. The Moments Menopause Check correctly detected 52 of 54 positive samples (96.3%) and 45 of 46 negative samples (97.8%). Therefore, the overall accuracy in the hands of lay users was 97%.

4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
The expected values are based on literature and are supported with performance data obtained by the sponsor. Forty-two (42) samples with known concentrations from women age 30 to 60 (35 in between the ages of 41 to 60) were run on the subject device. The results showed positive results for samples with FSH between 25 and 120 mIU/mL.

N. Conclusion:

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