

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

A. 510(k) Number:

K032161

B. Analyte:

Vaginal pH

C. Type of Test:

Qualitative

D. Applicant:

FemTek, LLC

E. Proprietary and Established Names:

pHEM-ALERT®

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1550
2. Classification:
Class I
3. Product Code:
LNW
4. Panel:
75

G. Intended Use:

1. Intended use(s):

The pHEM-ALERT® test measures vaginal pH and is intended for use by women who have any of the following vaginal symptoms:
Itching – burning – unpleasant odor – unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding) or who may currently be pregnant. If you are pregnant, always discuss your symptoms and the result of this test with your healthcare provider and NEVER treat yourself.

2. Indication(s) for use:

The pHEM-ALERT® test measures vaginal pH and is intended for use by women who have any of the following vaginal symptoms:
Itching – burning – unpleasant odor – unusual discharge

This test may help decide if these symptoms are caused by an infection that may require follow-up by your healthcare provider. This test is only intended for women who have normal menstrual periods (periodic vaginal bleeding) or who may currently be pregnant. If you are pregnant, always discuss your

symptoms and the result of this test with your healthcare provider and NEVER treat yourself.

3. Special condition for use statement(s):
This device is intended for over-the-counter (OTC) use.
4. Special instrument Requirements:
Not applicable

H. Device Description:

See K012230.

I. Substantial Equivalence Information:

1. Predicate device name(s):
pHEM-ALERT®
2. Predicate K number(s):
K012230
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Differences		
Item	Device	Predicate
Indications for Use	Symptomatic nonpregnant and pregnant women	Symptomatic nonpregnant women only
Limitation	Removed statement/ remained silent	Not a test for Group B Streptococcus
Physical Dimensions	Thinner with a round probe end and round pH paper mounted on the end	Rectangular probe end and rectangular pH paper mounted on the end

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

Not applicable

K. Test Principle:

See K012230.

L. 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):*
Not applicable
 - d. *Detection limit:*
Not applicable
 - e. *Analytical specificity:*
Not applicable

- f. Assay cut-off:
Not applicable
2. Comparison studies:
 - a. Method comparison with predicate device:
Not applicable
 - b. Matrix comparison:
Not applicable
3. Clinical studies:
 - a. Clinical sensitivity:
See K012230.
 - b. Clinical specificity:
See K012230.
 - c. Other clinical supportive data (when a and b are not applicable):
See K012230.
4. Clinical cut-off:
Not applicable
5. Expected values/Reference range:
See K012230.

M. Conclusion:

The minor physical changes made to the device and labeling revisions do not raise any issues of safety and effectiveness. Therefore, it is recommended that the pHEM-ALERT® device be found substantially equivalent.