K032161

SEP 3 0 2003

510(k) SUMMARY
pHEM-ALERT
July 11, 2003

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in this 510(k) premarket notification was in accordance with 21 CFR 807.87.

1. Sponsor/Submitter

Sponsor
FemTek, LLC
50 Bellefontaine Street
Pasadena, CA 91105-3181
Attention: James C. Caillouette, M.D., President
Telephone: (626) 796-3200
Facsimile: (626) 793-1651

Submitted by:
Consultant
Joel S. Faden, Ph.D., Inc.
11605 Hitching Post Lane
Rockville, MD 20852
Contact person: Joel Faden
Telephone: (301) 881-9139
Facsimile: (301) 881-9249

2. Name of Device

Trade Name: pHEM-ALERT
Common/Usual Name: pH paper
Classification Name: "Obstetric pH Paper", 85LNW, unclassified

3. Legally Marketed Predicate Devices

pHEM-ALERT 510(k) K012230

4. Indications for Use / Intended Use

The indications and intended uses for the pHEM-ALERT device are:

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.

5. Device Description

The pHEM-ALERT provides a method for the lay user to measure her vaginal pH. The pHEM-ALERT test is comprised of a plastic probe with pH paper on one end, a color chart and a package insert. The plastic probe is in the shape of small flat key. pHEM-ALERT is indicated for measuring vaginal pH for the purpose of differentiating normal and abnormal conditions in symptomatic women. The device is inserted into the vagina and the measurement taken.

6. Substantial Equivalence

This Premarket Notification [510(k)] was submitted because FemTek wishes to make two changes to the package insert for the pHEM-ALERT Over-The-Counter (OTC) device, which was cleared on October 9, 2001 (K012230).

Specifically, the package insert has been modified in the following manner:

- Modify the warning to read:
  "This is NOT a test for diseases such as HIV, chlamydia, herpes, gonorrhea or syphilis."
- Remove the exclusionary language in the current package insert pertaining to pregnant women. and revise the labeling to allow symptomatic pregnant women to use the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 0 2003

FEMTEK, LLC
c/o Joel S. Faden, Ph.D.
President/CEO
Joel S. Faden, Ph.D., Inc.
Regulatory Consultants
11605 Hitching Post Lane
Rockville, MD 20852

Re: k032161
Trade/Device Name: pHEM-ALERT
Regulation Number: 21 CFR 862.1550
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: Class I
Product Code: LNW
Dated: July 11, 2003
Received: July 28, 2003

Dear Dr. Faden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

K032161

Device Name: pHEM-ALERT

Indications For Use:

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Sean Cooper
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032161

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: (Per 21 CFR 801.109) OR Over-The-Counter: ✓

(Optional Format 1-2-96)