K960648

510(k) SUMMARY
pHEM-CHEK™
February 12, 1996

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

1. **Submitter of 510(k)**

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2. **Name of Device:**

A. Trade/Proprietary Name:

pHEM-CHEK™

B. Common/Usual Name:

pH paper

C. Classification Name:

In accordance with FDA's manual, "Classification Names for Medical Devices and *In Vitro* Diagnostic Products" and FDA's listing of prior 510(k) clearances, predicate devices were assigned to classification 21 CFR 884.1550 "Amniotic fluid sampler".

3. **Sponsor/Manufacturer:**

Name/Address: FEMTEK Inc.
50 Bellefontaine Street
Pasadena, CA 91105-3181

Attention: James C. Caillouette, M.D., President

Telephone: 818-796-7145
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4. Reason for Submitting the 510(k)

This document is being submitted on behalf of Femtek, Inc. (Femtek). Femtek wishes to commercially distribute its new pHEM-CHEK™ device for the general application of testing the pH level of the vagina.

5. Device Description

The pHEM-CHEK is comprised of a flat probe on which a strip of phenaphthazine pH paper is mounted. One end of the probe will be textured for better gripping and a strip of phenaphthazine pH paper will be mounted on the flat surface of the opposing end. A color chart, provided by the manufacturer of the pH paper, will be enclosed in each box of probes.

6. Intended Use

The pHEM-CHEK is intended for checking the pH level of a woman's vagina.

7. Substantial Equivalence

PH paper, phenaphthazine, has been prescribed in medical textbooks published as early as 1950 to test the pH level of the vagina. In fact, Nitrazine®, a phenaphthazine pH paper distributed by Apothecon®, A Bristol-Myers Squibb Company, was cited and recommended in such publications. PH paper for measuring vaginal pH has also been the subject of prior 510(k) clearances, K850858 and K850305. It is currently the practice of physicians to press a strip pH paper against the vaginal wall while holding it with either the fingers or a hemostat. Femtek has merely made it more convenient for the physician by mounting phenaphthazine paper on the end of a probe, thus allowing for a less cumbersome procedure. The placement of the pH paper on a probe, for purposes of convenience, does not alter the intended use, safety or the effectiveness of the application of the pH paper and its measure of pH. New issues of safety and effectiveness are not raised by mounting the predicate pH paper on a probe.

Copies of the pHEM-CHEK package insert and outer package labels and an engineering drawing of the device were provided. Further, biocompatibility testing was conducted and the findings presented.

Since, the pHEM-CHEK has the same intended use, safety and effectiveness as the legally marketed predicate devices, the pHEM-CHEK is substantially equivalent.