K091287

Section 5. 510(k) Summary

AUG 31 2009

5.1. 510(k) summary information:

5.1.1.

5.1.1.1. **Submitter's name:** Common Sense Ltd

5.1.1.2. **Address:** 7 Haeshel St, Caesarea 38900, POB 3567, Israel

5.1.1.3. **Telephone:** 972-4-6277101, Fax: 972-4-6277103

5.1.1.4. **Contact person:** Ms. Natasha Leskovsek, US Regulation Consultant

5.1.1.5. **Date:** August 21, 2009

5.1.2.

5.1.2.1. **Name of the device:** VS-SENSE™

5.1.2.2. **Classification name:** Paper, Obstetric pH

5.1.3. **Identification of the legally marketed predicate device:**
PHEM-CHEK™, 510(k) no: K960648

A description of the device: The VS-SENSE™ comprises a regular vaginal swab with its tip coated by an indicating polymer. When the indicating tip has been in contact with vaginal secretion, with elevated pH level, the user will observe a blue or green stain on the yellow background of the tip. The stains on the tip are caused by the sensitivity of a proprietary polymer, which coats the tip and contains the traditional indicator – Nitrazine Yellow. The VS-SENSE™ polymer matrix has a specific composition of ingredients that changes color when the pH of the vaginal discharge is greater than 4.7 +0.3/-0.2.

The intended use of the device: The VS-SENSE™ TEST is a qualitative, visually-read swab for clinicians who wish to evaluate women with vaginal symptoms. The device is a vaginal pH indicator swab intended to be used in conjunction with other clinical examinations, such as the Amsel criteria or the Nugent Gram stain, to aid in determining conditions characterized by elevated vaginal pH, such as bacterial vaginosis.

5.1.4. Technological characteristics comparison of VS-SENSE™ vs. Predicate Device:

Characteristic	VS-SENSE™	PHEM-CHEK™
Sample collecting device	Swab	Swab
Sample collecting Method	Insert into vagina and come in contact with vaginal secretion	Insert into vagina and come in contact with vaginal secretion
Duration of test	10 seconds	10 seconds + comparing to color scale
Chemical parameters	pH	pH
Other parameters that affect the assay	Buffer capacity	NA
Result reading	Blue or green stain on yellow background	Comparing to a color scale
Sensitivity	Stand-alone 86.3% As 2nd test of the Amsel Criteria procedure 97% Based on pivotal study results	Stand-alone 91% As 2nd test of the Amsel Criteria procedure 99% Based on pivotal study results
Specificity	Stand-alone 93.9% As 2nd test of the Amsel Criteria procedure 43.5% Based on pivotal study results	Stand-alone 84.2% As 2nd test of the Amsel Criteria procedure 43.42% Based on pivotal study results

(*) PHEM-CHEK™ reads pH levels in the same manner as pH paper does, thus pH readings in our study were used to simulate the results of using PHEM-CHEK.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Common Sense Ltd.
c/o Natasha Leskovsek
Cooley Godward Kronish LLP
777 6th Street NW Suite 1100
Washington, District of Columbia 20001

AUG 31 2009

Re: k091287
Trade Name: VS-SENSE™
Regulation Number: 21 CFR §862.1550
Regulation Name: Urinary pH (non-quantitative) test system
Regulatory Class: Class I, meets limitation of exemption 862.9(b)(6)
Product Codes: CEN
Dated: July 17, 2009
Received: July 21, 2009

Dear Ms. Leskovsek:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K091287

Device Name: VS-SENSE™

Indications For Use: The VS-SENSE™ TEST is a qualitative, visually-read swab for clinicians who wish to evaluate women with vaginal symptoms. The device is a vaginal pH indicator swab intended to be used in conjunction with other clinical examinations, such as the Amsel criteria or the Nugent Gram stain, to aid in determining conditions characterized by elevated vaginal pH, such as bacterial vaginosis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091287