510(K) SUMMARY

K023677

JAN 2 9 2003

SUBMITTED BY: Osmetech plc
Electra House
Electra Way
Crewe, CW1 6WZ
United Kingdom

CONTACT NAME: Andrew Tummon, Healthcare Project Manager

DATE PREPARED: January 23, 2003

DEVICE TRADE NAME: Osmetech Microbial Analyser™- Bacterial Vaginosis (OMA™-BV)

COMMON NAME: Microorganism Differentiation and Identification Device

CLASSIFICATION NAME AND PRODUCT CODE: 21 CFR 866.2660, Microscopic Differentiation and Identification, LIB or LRH

DEVICE CLASSIFICATION: Class I

DEVICE PANEL: Microbiology Branch

PREDICATE DEVICE: Osmetech Microbial Analyser™ - Urinary Tract Infection (OMA™-UTI, Osmetech plc, K011043, 21 CFR 866.2660)

DEVICE DESCRIPTION:

The OMA™-BV uses "electronic nose" technology for the detection of volatile compounds released from microorganisms in human specimens. The principle is based on the release of volatile compounds from bacteria into the headspace [the volume above the High Vaginal Swab (HVS) samples] of clinical samples. The volatile compounds are detected by an array of gas sensors based on patented conducting polymer technology.

STATEMENT OF INTENDED USE:

The Osmetech Microbial Analyzer-Bacterial Vaginosis (OMA™-BV) is an automated in vitro diagnostic device intended for use to indirectly measure bacterial presence by semi-quantitative analysis of volatile compounds released into the headspace above a high vaginal swab. The OMA™-BV is indicated for use as an adjunct for the diagnosis of Bacterial vaginosis (BV). The device may be used together with other clinical and patient information when diagnosing BV including pH, vaginal discharge characteristics, amine odor and clue cells or gram stain procedures that are currently commonly used to diagnose infection.

SUBSTANTIAL EQUIVALENCE COMPARISON:

The technology used for the OMA™-BV in the detection of BV relies on the same principles and device design as that of the OMA™-UTI (K011043):

(1) The OMA™-BV and the OMA™-UTI both provide a negative or positive result for the condition under study (BV or UTI);
(2) The OMA™-BV and OMA™-UTI devices utilize the same technology to measure the same analytes, albeit in different types of sample media; and
(3) No new issues of safety or effectiveness are raised by the difference in intended use between the OMA™-BV and the predicate. The detection threshold of the BV device has been set to detect levels of volatile metabolites found in specimens associated with BV, as demonstrated in a multi-center clinical trial of subjects with suspected BV.

INTENDED USE OF THE OMA™-BV AND PREDICATE DEVICES:

The intended use of the OMA™-BV and the predicate device (OMA™-UTI) are essentially the same in that they are both automated *in vitro* diagnostic devices that indirectly measure bacterial presence by qualitative analysis of volatile compounds released into the headspace above the clinical sample.

The main difference in intended use between the OMA™-BV and the predicate is in the nature of the clinical samples being analyzed. To ensure that this change to detection of BV does not impact on device safety or effectiveness, a multi-center clinical trial was conducted in the U.S. and the U.K. Since there is no "gold standard" for diagnosis of BV, agreement between current clinical procedures and the OMA™-BV device results was used to compare BV diagnostic methods.

TECHNOLOGICAL CHARACTERISTICS OF THE OMA™-BV AND PREDICATE DEVICES:

The OMA™-BV and the OMA™-UTI utilize identical technology.

CLINICAL PERFORMANCE DATA

A multi-center clinical trial was conducted to compare the performance and results of the OMA™-BV to the combination of three clinical procedures commonly used to diagnose BV (the Nugent scoring system, Amsel criteria, and clinical diagnosis) in a statistically designed study.

Results of this clinical trial showed that the percent agreement between Amsel and OMA™-BV was 82.0% (95%CI: 78.9% to 85.0%), the percent agreement between Nugent-positive and OMA™-BV was 82.0% with 95% CI: (76.0%; 87.1%), the percent agreement between Nugent-negative and OMA™-BV was 88.9% with 95% CI: (85.0%;

92.1%), and the percent agreement between clinical diagnosis and OMA™-BV was 75.2% (95%CI: 71.7% to 78.6%).

Reproducibility

As part of the clinical laboratory study in support of this 510(k) premarket notification, two reproducibility studies were included to test for the Inter-site and Inter-run reproducibility (repeatability). The inter-site reproducibility study demonstrated good inter-site reproducibility, with a kappa statistic of 0.7688. The inter-run reproducibility (repeatability) study also demonstrated good inter-run reproducibility, with a kappa statistic of 0.7464.

Interference Studies

Data on interfering substances was obtained from two studies: bench testing and the pivotal clinical study. Bench testing revealed that only one vaginal douche product tested (in quantities equal to that of the average total patient sample) was found to interfere with the OMA™-BV result. No other substances were found to interfere with the OMA™-BV result. Therefore, vaginal douches should not be used 48 hours prior to sample collection for OMA™-BV analysis to ensure a representative microbial flora, as per the vaginal douche label and the OMA™-BV label.

In the pivotal clinical trial there was some evidence that blood was a confounding factor. Hence, specimens containing blood should not be analyzed using the OMA™-BV. This is included as a warning in the OMA™-BV label.

Other Clinical Data

The clinical procedures Amsel criteria and the Gram stain Nugent scoring system for the diagnosis of BV were evaluated against each other to determine the performance of the two systems. Results of this comparison demonstrated that, for each way of reporting the Nugent intermediate results (*i.e.*, reported as positive, negative or excluded), the Amsel / Nugent agreements were comparable to or worse than the OMA™-BV / Amsel and the OMA™-BV / Nugent agreement.

CONCLUSIONS

It is concluded that the clinical performance and the technology of the OMA™-BV is substantially equivalent to the OMA™-UTI. The results of the multi-center pivotal clinical trial provide additional evidence that any differences between the devices do not impact on the safety or effectiveness of the OMA™-BV.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 9 2003

Mr. James White
Chief Executive Officer
Osmetech plc
Electra House, Electra Way
Crew, CW1 6WZ
United Kingdom

Re: k023677
Trade/Device Name: Osmetech Microbial Analyser™ – Bacterial Vaginosis (OMA™ – BV)
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: Class I
Product Code: LIB, LRH
Dated: November 1, 2002
Received: November 1, 2002

Dear Mr. White:

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). Other general information on your responsibilities under the Act may be obtained 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

3.0 INDICATIONS FOR USE/INTENDED USE STATEMENT

510(k) Number (if known): K023677

Device Name: Osmetech Microbial Analyser™ - Bacterial Vaginosis (OMA™-BV)

Indications for Use/Intended Use:

The Osmetech Microbial Analyzer-Bacterial Vaginosis (OMA™-BV) is an automated in vitro diagnostic device intended for use to indirectly measure bacterial presence by semi-quantitative analysis of volatile compounds released into the headspace above a high vaginal swab. The OMA™-BV is indicated for use as an adjunct for the diagnosis of Bacterial vaginosis (BV). The device may be used together with other clinical and patient information when diagnosing BV including pH, vaginal discharge characteristics, amine odor and clue cells or gram stain procedures that are currently commonly used to diagnose infection.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PRESCRIPTION USE ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Freddie Tu-Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K02-3677