

13.0 510(K) SUMMARY

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Name of Device

Trade Name: The Osmetech Microbial Analyser™- Urinary Tract Infection Detector (OMA™-UTI)
Common Name: Urine screening kit
Classification Name: Microorganism Differentiation and Identification Device (Product Code JXA)
Microbiology Branch
Regulation Number: 866.2660
Device Classification: This device is a class I device

Identification of Predicate Devices

1. Uriscreen™, Diatech Diagnostics, Inc.; K981084, Product Code JXA
2. Standard Culture in urine

Device Description

The OMA™-UTI 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 liquid 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 Analyser™ - Urinary Tract Infection Detector (OMA™-UTI) is an automated *in-vitro* diagnostic device intended for use by clinical laboratory healthcare professionals as an aid to diagnosis of urinary tract infection (UTI). The OMA™-UTI indirectly measures bacterial infection by semi-quantitative analysis of volatile compounds released into the headspace above a urine sample.

SUBSTANTIAL EQUIVALENCE COMPARISON

To establish substantial equivalence to an existing device, and thus establish the safety and effectiveness of the OMA™-UTI, the OMA™-UTI has been compared to the Uriscree™ device (Diatech Diagnostics, Inc.; K981084) and Standard Culture in urine.

Intended Use of the OMA™-UTI and Predicate Devices

A review of the intended use of the OMA™-UTI and the Uriscree™ systems shows them to be essentially the same in that they are capable of determining if a urine sample is positive or negative for UTI based on the production of compounds by bacteria in urine.¹⁰ Both devices yield a positive or negative result for bacteriuria (defined as $\geq 1 \times 10^5$ CFU/ml in urine), based on an indirect measure of bacteria in urine.

The difference in the intended use statements of the OMA™-UTI and the Uriscree™ is that the OMA™-UTI is designed for professional use only, while the Uriscree™ may be used by consumers. This difference does not impact on safety or effectiveness of the OMA™-UTI device.

¹⁰ The statement of intended use for the Uriscree™ device is as follows: “Uriscree is a non quantitative rapid screen for the detection of Urinary Tract Infection. Uriscree detects both bacteria and/or white blood cells, common indicators of Urinary Tract Infection.”

Technological Characteristics of the OMA™-UTI and Predicate Devices

The OMA™-UTI and the Uriscreen™ devices monitor compounds released from bacteria in urine. However, the compounds measured are different, and the technology for measurement is different. Hence, a clinical trial was conducted to establish that the technological differences had no adverse effect on safety and effectiveness of the OMA™-UTI.

Clinical Performance Data

Urine test results with the OMA™-UTI were compared to results using the Standard Culture technique (the “gold standard” for measurement of bacteria in urine) in 1038 urine samples from three Clinical Laboratories (two U.S. and one non-U.S. sites) for assessment of UTI. Based on our protocol criteria a positive culture was considered $\geq 1 \times 10^5$ CFU/ml for either single colonies or for mixed colonies containing at least one predominant organism $\geq 1 \times 10^5$ CFU/ml. From this clinical trial the following performance characteristics were calculated:

Sensitivity	81.0% (95% CI 73.7% to 87.0%)
Specificity	83.1% (95% CI 80.4% to 85.5%)
PPV	44.1% (95% CI 38.1% to 50.2%)
NPV	96.4% (95% CI 94.8% to 97.6%)
Accuracy	82.8% (95% CI 80.3% to 85.0%)

These data indicate that the performance values of the OMA™-UTI compare favorably with the predicate device, Uriscreen™ (K981084), which reported a sensitivity of 95%, specificity of 73%, and accuracy of 80%.

Other Clinical Data

An inter-site reproducibility study (two U.S. sites) was conducted using 249 samples to determine reproducibility of OMA™-UTI at two clinical sites. Results of this study showed very good agreement between sites (kappa **0.86, 95%CI** 0.80-0.92).

Interference Studies

In addition, tests of interfering substances were conducted, revealing that there was no effect of blood or specific gravity in clinical samples on the performance of the OMA™-UTI. Laboratory bench testing indicates that sodium nitrite may interfere with OMA™-UTI test results by causing a negative sample to have a positive result.

CONCLUSIONS

When comparing the OMA™-UTI to the predicates, it can be concluded with the results of the pivotal clinical trial and other studies that the OMA™-UTI is substantially equivalent to the **Uriscreen™** and to Standard Culture techniques in urine. Based on the establishment of substantial equivalence, the safety and effectiveness of the OMA™-UTI is confirmed.