

MicroScan Inc
1584 Enterprise Boulevard
West Sacramento, CA 95691
916.372.1900

510(k) Submission Information:

Device Manufacturer: Dade MicroScan Inc.
Contact name: Sharolyn Lentsch, Sr. Regulatory Affairs Administrator
Fax: 916-374-3144
Date prepared: May 31, 1996
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan[®] Dried Gram-Negative and Gram-Positive MIC/Combo Panels
Intended Use: To determine antimicrobial agent susceptibility
510(k) Notification: New antimicrobial - Cefepime
Predicate device: NCCLS Frozen Cefepime Reference Panels

510(k) Summary:

The proposed MicroScan[®] Dried Gram-Negative and Gram-Positive MIC/Combo Panel with Cefepime demonstrated substantially equivalent performance when compared with an NCCLS frozen Cefepime Reference Panel, as defined in the FDA DRAFT document "Review Criteria for Assessment of Antimicrobial Susceptibility Devices" (dated May 31, 1991).

The Premarket Notification (510[k]) presents data in support of the new antimicrobial, Cefepime, for the MicroScan[®] Dried Gram-negative and Gram-positive MIC/Combo Panels.

Both the gram-negative and gram-positive external evaluations were conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Cefepime panels by comparing their performance with an NCCLS frozen Cefepime Reference panel.

The Dried gram-negative Cefepime panel demonstrated acceptable performance with an overall Essential Agreement of 98.6% when compared with the frozen Cefepime Reference panel. The Dried gram-positive Cefepime panel demonstrated acceptable performance with an overall Essential Agreement of 95.9% when compared with the frozen Cefepime Reference panel.

Inoculum and instrument reproducibility testing was conducted; both the gram-negative and the gram-positive Dried Cefepime panels demonstrated acceptable reproducibility and precision, regardless of which inoculum method (i.e., Turbidity, Log, Stationary, and Prompt), or instrument (autoScan-4[®] and WalkAway[®]) was used.

Quality Control performance was acceptable for both the gram-negative and the gram-positive Dried Cefepime panels.