

K970676 MAY -2 1997

DADE

DADE INTERNATIONAL

MicroScan Inc
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510(k) Submission Information:

Device Manufacturer: Dade MicroScan Inc.
Contact name: Sharolyn Lentsch, Sr. Regulatory Affairs Administrator
Fax: 916-374-3144
Date prepared: February 21, 1997
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan[®] Dried Gram-Negative MIC/Combo Panels
Intended Use: To determine antimicrobial agent susceptibility
510(k) Notification: New antimicrobial - Levofloxacin
Predicate device: NCCLS Frozen Levofloxacin Reference Panels

510(k) Summary:

The proposed MicroScan[®] Dried Gram-Negative MIC/Combo Panel with Levofloxacin demonstrated substantially equivalent performance when compared with an NCCLS frozen Levofloxacin 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, Levofloxacin, for the MicroScan[®] Dried Gram-Negative MIC/Combo Panels

The 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 MicroScan[®] Dried Gram-Negative Levofloxacin Panel by comparing their performance with an NCCLS frozen Levofloxacin Reference panel.

The MicroScan[®] Dried Gram-Negative Levofloxacin Panel demonstrated acceptable efficacy performance with an overall Essential Agreement of 100% when compared with the frozen Levofloxacin Reference panel.

Inoculum and instrument reproducibility testing was conducted; the MicroScan[®] Dried Gram-Negative Levofloxacin Panel demonstrated acceptable reproducibility and precision, regardless of which inoculum method (i.e., Turbidity and Prompt), or instrument (autoScan-4[®] and WalkAway[®]) was used.

Quality Control performance was acceptable for the MicroScan[®] Dried Gram-Negative Levofloxacin Panel.