K972688

SEP - 8 1997

DADE

510(k) Summary

DADE INTERNATIONAL

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:	July 3, 1997
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram-Positive 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-Positive 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 a new antimicrobial Levofloxacin, for the MicroScan® Dried Gram-Positive MIC/Combo Panels.

The 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 Levofloxacin panel by comparing its performance with an NCCLS frozen Levofloxacin Reference panel.

The Dried Gram-Positive Levofloxacin panel demonstrated acceptable performance with an overall Essential Agreement of 99.4% when compared with the frozen Levofloxacin Reference panel.

Inoculum and instrument reproducibility testing was conducted; both the Gram-Positive Dried Levofloxacin panels demonstrated acceptable reproducibility and precision, regardless of which inoculum method (i.e., Turbidity and Prompt), or instrument (autoScan-4® and WalkAway® Systems) was used.

Quality Control performance was acceptable for both the Gram-Positive Dried Levofloxacin panels.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Ms. Sharolyn Lentsch
Senior Regulatory Affairs Administrator
Dade International
MicroScan, Inc.
1584 Enterprise Boulevard
West Sacramento, California 95691

Re: K972688
Trade Name: MicroScan® Dried Gram Positive MIC/Combo Panels New Antimicrobial - Levofloxacin
Regulatory Class: II Product Code: JWY
II LRG
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Lentsch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) No.: K972688

Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with Levofloxacin (0.015-32 µg/ml)

Indications for Use: To determine gram-positive bacterial susceptibility against the antimicrobial agent Levofloxacin. Organisms with indications for testing* include:

Levofloxacin
Gram-Positive Bacteria
Enterococcus faecalis
Staphylococcus aureus
Streptococcus pyogenes

* As taken from the Indications and Usage section of the manufacturers' package insert (Ortho-McNeil).

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K972688

✓ For Prescription Use