JUL 27 2001

K010159

DADE BEHRING

DADE MICROSCAN INC.
1584 Enterprise Boulevard
West Sacramento, CA 95691
Tel: +1 (916) 372-1900

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Cynthia Van Duker, Sr. Regulatory Affairs Specialist
Fax:	916-374-3144
Date prepared:	January 15, 2001
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 - Gatifloxacin
Predicate device:	MicroScan Dried Gram Negative and Gram Positive MIC/Combo Panels

510(k) Summary:

MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative Gram-Negative and Gram-Positive cocci.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water, after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panel demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000. The Premarket Notification (510[k]) presents data in support of the MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panel with Gatifloxacin.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Negative and Gram-Positive Panel by comparing its performance with an NCCLS frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The Dried Gram-Negative and Gram-Positive Panel demonstrated acceptable performance with an overall Essential Agreement of >98% for Gatifloxacin when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Gatifloxacin, regardless of which inoculum method (i.e., Turbidity and Prompt), or instrument (autoScan-4® and WalkAway®) was used.

Quality Control testing demonstrated acceptable results for Gatifloxacin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 27 2001

Ms. Cynthia Van Duker
Senior Regulatory Affairs Specialist
Dade MicroScan Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: 510(k) Number: K010159
Trade/Device Name: MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels with Gatifloxacin (0.004-32mcg/ml)
Regulation Number: 866.1640
Regulatory Class: II
Product Code: LTT
Dated: May 18, 2001
Received: May 22, 2001

Dear Ms. Van Duker:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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" (21CFR 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 (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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K010159

Device Name: MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels with Gatifloxacin (0.004 - 32 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative Gram-Negative and Gram-Positive cocci. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Gatifloxacin at concentrations of 0.004 to 32 mcg/ml to the test panel.

The Gram-Negative organisms which may be used for Gatifloxacin susceptibility testing in this panel are:

Escherichia coli	Citrobacter freundii
Klebsiella pneumoniae	Enterobacter aerogenes
Proteus mirabilis	Enterobacter cloacae
Acinetobacter lwoffii	Klebsiella oxytoca
Citrobacter koseri	Morganella morganii
Proteus vulgaris	

The Gram-Positive organisms which may be used for Gatifloxacin susceptibility testing in this panel are:

Staphylococcus aureus *(methicillin susceptible strains only)*
Staphylococcus saprophyticus

The MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels with Gatifloxacin are not intended for use with *Streptococcus pneumoniae* and *viridans streptococci.*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Julie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010159

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____.

(Optional Format 1-2-96)