K983922

JUN 17 1999

Attachment G

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:	November 3, 1998
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 - Cefdinir
Predicate device:	NCCLS Frozen Cefdinir Reference Panels

510(k) Summary:

The proposed MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panel with Cefdinir demonstrated substantially equivalent performance when compared with an NCCLS frozen Cefdinir 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, Cefdinir, 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 Cefdinir panels by comparing their performance with an NCCLS frozen Cefdinir Reference panel.

The Dried gram-negative Cefdinir panel demonstrated acceptable performance with an overall Essential Agreement of 97.9% when compared with the frozen Cefdinir Reference panel. The Dried gram-positive Cefdinir panel demonstrated acceptable performance with an overall Essential Agreement of 94.0% when compared with the frozen Cefdinir Reference panel.

Inoculum and instrument reproducibility testing was conducted; both the gram-negative and the gram-positive Dried Cefdinir panels 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 both the gram-negative and the gram-positive Dried Cefdinir panels.

The following limitations will be added to the labeling for Cefdinir:

"Do Not Report" with *S. pneumoniae* and viridans streptococci (MIC and Breakpoint dilutions).
"Do Not Report" with methicillin-resistant, coagulase-negative staphylococci (MIC and Breakpoint dilutions).
"Use Alternate Method" with *Providencia* spp. (MIC and Breakpoint dilutions).
"The performance of Cefdinir has not been established with Stationary and Log Inoculum methods."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1999

Ms. Sharon K. Cullen
Director RA/Compliance
Dade MicroScan, Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: K983922
Trade Name: MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels/Cefdinir
Regulatory Class: II
Product Code: JWY
Dated: May 21, 1999
Received: May 24, 1999

Dear Ms. Cullen:

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 legally marketed predicate 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 requirements, 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

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

Attachment F

Indications for Use Statement

510(k) No.: K983922

Device Name: MicroScan® Dried Gram-Negative and Gram-Positive MIC/Combo Panels with Cefdinir (0.015 - 8 mcg/ml on the gram-negative and gram-positive panels)

Indications for Use: To determine gram-negative and gram-positive bacterial .. susceptibility against the antimicrobial agent Cefdinir.

Organisms with indications for testing* include:

Gram-Negative Bacteria	Gram-Positive Bacteria
None**	*Staphylococcus aureus**** (Including methicillin-susceptible, β-lactamase producing strains)
	Streptococcus pyogenes

*As taken from the indications and Usage section of the manufacturer's package insert (Issued: March 1998).

**No gram-negative organisms for which Microscan is seeking clearance are indicated for testing in the Indications and Usage section of the manufacturer's package insert.

***Cefdinir is inactive against methicillin-resistant Staphylococci.

The following secondary organisms included for the testing of MicroScan® panels with Cefdinir have *in vitro* data but the safety and effectiveness in treating clinical infections have not been established: *Citrobacter* (diversus) *koseri, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Staphylococcus epidermidis* (methicillin-susceptible), *Streptococcus agalactiae*

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

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983922

PRESCRIPTION USE X