Attachment G

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

DADE BEHRING

K981199

510(k) Submission Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Sharolyn Lentsch, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	October 7, 1998
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram Negative MIC/Combo Panels with Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone
510(k) Notification:	New Indication for Use
Reference method:	Molecular Characterization Tests

510(k) Summary:

MicroScan® Dried Gram Negative MIC/Combo Panels with Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone were cleared for susceptibility testing via Premarket Notification submissions. This Premarket Notification (510[k]) presents data in support of a request for a new indication for use (detection of suspected *Escherichia coli*, *Klebsiella oxytoca*, and *K. pneumoniae* extended spectrum beta-lactamases), similar to that described in the NCCLS documents M7-A4 and M100-S9.

Efficacy testing with MicroScan® Dried Gram Negative Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone antimicrobial agents was conducted with ESBL and non-ESBL producing strains and AmpC-type strains. The Efficacy study was designed to confirm the acceptability of the MicroScan® Dried Gram Negative Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone antimicrobial agents for detection of suspected ESBLs (*E. coli*, *K. oxytoca*, and *K. pneumoniae*) by comparing the panel susceptibility results against previously generated molecular characterization data.

Inoculum and instrument reproducibility testing with the MicroScan® Dried Gram Negative Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone antimicrobial agents demonstrated acceptable reproducibility with >95% of the results in agreement with the comparative system, regardless of which inoculum method (i.e., Turbidity, Log, and Prompt), or instrument (autoScan®-4 and WalkAway® System) was used.

The MicroScan® Dried Gram Negative Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, Ceftriaxone antimicrobial agents demonstrated acceptable Quality Control throughout each phase of the ESBL evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1998

Ms. Sharolyn J. Lentsch
Regulatory Affairs Manager
Dade Microscan, Inc./Dade Behring
1584 Enterprise Boulevard
West Sacramento, California 95691

Re: K981199/S1
Trade Name: MicroScan® Dried Gram Negative MIC/Combo Panels
Regulatory Class: II Product Code: LRG
II JWY
Dated: October 7, 1998
Received: October 8, 1998

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 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 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"(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 (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

Attachment E

Indications for Use Statement

510(k) No.: To be assigned by FDA

Device Name: MicroScan® Dried Gram Negative MIC/Combo Panels
Cefpodoxime (0.015-64 µg/ml)
Ceftazidime (0.5-64 µg/ml)
Aztreonam (0.5-64 µg/ml)
Cefotaxime (1*-64 µg/ml)
Ceftriaxone (1-128 µg/ml)

*1 ug/ml will be for ESBL screening only. Performance characteristics with isolates other than *E. coli* and *Klebsiella* spp., have not been established.

Intended Use: For use in determining antimicrobial agent susceptibility and/or identification to the species level of aerobic and facultatively anaerobic gram-negative bacilli.

Indications for Use: This submission requests clearance of the following new Indication for Use:

Panels containing Cefpodoxime, Ceftazidime, Aztreonam, Cefotaxime, or Ceftriaxone at 1 ug/ml can be used to screen for *Escherichia coli, Klebsiella oxytoca*, or *K. pneumoniae* strains suspected of producing extended-spectrum beta-lactamases (ESBLs).

An alternate method is required for confirmation testing.

Woody Derbes
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981199

PRESCRIPTION USE X