K020185

FEB 0 6 2002

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Dade Behring Inc.
Contact name:	Maureen Mende, Group Manager Regulatory Affairs
Fax:	916-374-3144
Date prepared:	January 17, 2002
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	Antimicrobials: Gentamicin
Predicate device:	MicroScan Dried Gram Negative MIC/Combo Panels

510(k) Summary:

MicroScan® rapID/S *plus*™ Gram-Negative 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 anaerobic gram-negative bacilli. The MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels are read on the WalkAway® *SI* System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in Mueller-Hinton Broth to concentrations bridging the range of clinical interest and are presented in micro-titer wells in dried form. rapID/S *plus*™ panels are inoculated and rehydrated with a standardized suspension of the organism and incubated at 35°C in the WalkAway® *SI* System or equivalent for 4.5 – 18 hours. The minimum inhibitory concentration (MIC) for the test organism is determined by the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan® rapID/S plus™ Gram-Negative 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® rapID/S *plus*™ Gram-Negative MIC/Combo Panel with Gentamicin.

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 rapID/S *plus*™ Gram-Negative Panel by comparing its performance with an NCCLS frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The rapID/S *plus*™ Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of greater than 96% for Gentamicin when compared with the frozen Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Gentamicin with Turbidity inoculum preparation method and the WalkAway® *SI* System or equivalent (upgraded WalkAway® 40 or WalkAway® 96 instruments).

Quality Control testing demonstrated acceptable results for Gentamicin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Maureen Mende
Group Manager Regulatory Affairs
Dade Behring Inc.
2040 Enterprise Boulevard
West Sacramento, CA 95691

FEB 0 6 2002

Re: k020185
Trade/Device Name: MicroScan® RapID/S *plus*™ Gram-Negative MIC/Combo Panels with Gentamicin (0.12-32 μg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: January 17, 2002
Received: January 18, 2002

Dear Ms. Mende:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 International and Consumer 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

Page 1 of 1.

510(k) Number (if known): K 020185

Device Name: MicroScan® rapID/S *plus*™ Gram-Negative MIC/Combo Panels with Gentamicin (0.12 – 32 µg/ml)

Indications For Use:

The MicroScan® rapID/S *plus*™ Gram-Negative 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 anaerobic Gram-Negative bacilli (Enterobacteriaceae, glucose non-fermenters, and non-Enterobacteriaceae glucose fermenters. After inoculation, panels are read on the WalkAway® *SI* System or equivalent (upgraded WalkAway® 40 or WalkAway® 96) according to the Package Insert.

This particular submission is for the antimicrobial Gentamicin on the rapID/S *plus*™ Gram-Negative MIC/Combo Panels.

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

Citrobacter amalonaticus
Citrobacter koseri (diversus)
Citrobacter freundii
Citrobacter spp
Escherichia coli
Enterobacter aerogenes
Enterobacter agglomerans
Enterobacter cloacae
Enterobacter sakazakii
Enterobacter spp
Klebsiella oxytoca
Klebsiella ozaenae
Klebsiella pneumoniae
Klebsiella rhinoscleromatis
Klebsiella spp
Proteus mirabilis
Proteus vulgaris
Proteus spp
Pseudomonas aeruginosa
Serratia spp
Serratia marcescens
Shigella flexneri
Shigella sonnei
Shigella spp
Salmonella spp

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020185

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)