K032706

FEB 1 0 2004

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Dade Behring, Inc.
Contact name:	Cynthia Van Duker, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	August 26, 2003
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram-Negative MIC/Combo Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	New antimicrobial - Ertapenem
Predicate device:	MicroScan Dried Gram-Negative and Gram-Positive MIC/Combo Panels

510(k) Summary:

MicroScan® Dried 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 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 MIC/Combo Panel demonstrated substantially equivalent performance when compared with an NCCLS frozen Reference Panel, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated February 5, 2003. The Premarket Notification (510[k]) presents data in support of the MicroScan® Dried Gram-Negative MIC/Combo Panel with Ertapenem.

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 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 Panel demonstrated acceptable performance with an overall Essential Agreement of >97% for Ertapenem when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Ertapenem, 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 Ertapenem.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 0 2004

Ms. Cynthia Van Duker
Regulatory Affairs Manager
Dade MicroScan, Inc.
1584 Enterprise Blvd.
West Sacramento, CA 95691

Re: k032706
Trade/Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Ertapenem (0.002 – 32 mcq/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: JWY; LTT; LTW
Dated: December 4, 2003
Received: December 5, 2003

Dear Ms. Van Duker:

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.

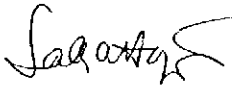
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032706

Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Ertapenem (0.002 – 32 mcg/ml)

Indications For Use:

The MicroScan® Dried 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. 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 Ertapenem at concentrations of 0.002 to 32 mcg/ml to the test panel.

The gram-negative organisms which may be used for Ertapenem susceptibility testing in this panel are:

Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca (excluding ESBL producing strains)
Klebsiella pneumoniae
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Serratia marcescens

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032706