K041150

JUL 2 2 2004

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Dade Behring Inc.
Contact name:	Robert Eusebio, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	May 19, 2003
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	New antimicrobial - Cefazolin
Predicate device:	MicroScan® Synergies plus™ Gram Negative MIC/Combo Panels

510(k) Summary:

MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels, utilizing both the MicroScan® Rapid Fluorogenic Identification and Dried Overnight Antimicrobial Susceptibility Testing (AST) technologies, 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 Mueller-Hinton 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 the WalkAway® *SI* System or equivalent for 4.5 - 18 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® Synergies plus™ 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® Synergies plus Gram-Negative MIC/Combo Panel with Cefazolin.

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 Synergies 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 Synergies plus Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of >97% for Cefazolin when compared with the frozen NCCLS Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Cefazolin, with Turbidity inoculum preparation method and the WalkAway® *SI* System or equivalent. An additional reproducibility study was performed to obtain additional rapid (<16 hour) results (**Attachment 3**) per the request of FDA.

Quality Control testing demonstrated acceptable results for Cefazolin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 2004

Mr. Robert Eusebio
Regulatory Affairs Manager
Dade Behring
Dade MicroScan Inc.
1584 Enterprise Boulevard
West Sacramento, CA 95691

Re: k041150
Trade/Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels Cefazolin (0.5 – 32 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully automated short-term incubation cycle antimicrobial susceptibility system.
Regulatory Class: Class II
Product Code: LRG, LON
Dated: April 26, 2004
Received: May 11, 2004

Dear Mr. Eusebio:

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 Statement

510(k) Number (if known): K 041150

Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels with Cefazolin (0.5 - 32 µg/ml,)

Indications For Use:

The MicroScan® Synergies 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. After inoculation, panels are incubated for 4.5 – 18 hours at 35°C +/- 1°C, in a WalkAway *SI* or equivalent, and read by the MicroScan® Instrumentation. Additionally, the panels may be incubated in a non-CO_2 incubator and the AST portions can be read visually, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Cefazolin, at concentrations of 0.5 to 32 µg/ml, to the test panel.

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

Escherichia coli
Klebsiella spp.
Proteus mirabilis

The MicroScan® Synergies plus™ Gram-Negative Panels with Cefazolin is not intended for use with:

Klebsiella oxytoca
Enterobacter spp.
Citrobacter freundii
Morganella morganii
Proteus vulgaris
Proteus penneri
Providencia spp
Serratia spp
Yersinia enterolitica

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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) K041150