



AUG 30 2004

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

Re: k031602
Trade/Device Name: MicroScan[®] Synergies Plus Gram Negative MIC/Combo Panels
with Nitrofurantoin (1 – 256 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial
Susceptibility System
Regulatory Class: II
Product Code: LON, JWY
Dated: July 30, 2004
Received: August 3, 2004

Dear Mr. Eusebio:

This letter corrects our substantially equivalent letter of July 31, 2003, regarding the trade name which was changed to MicroScan[®] Synergies Plus to better reflect the intended use of the device.

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 (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 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 continue 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for *in vitro* diagnostic devices), please contact the Office of Compliance at (301) 594-3084. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Sally A. Hojvat" with a small "for" written below it.

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): K031602

Device Name: MicroScan® Synergies plus™ Gram-Negative MIC/Combo Panels with Nitrofurantoin (1 – 256 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-CO2 incubator and the AST portions can be read visually, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Nitrofurantoin, at concentrations of 1 to 256 µg/ml, to the test panel.

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

Escherichia coli
Citrobacter amalonaticus
Citrobacter freundii
Citrobacter koseri (diversus)
Klebsiella oxytoca
Klebsiella ozaenae
*Klebsiella spp.**
*Enterobacter spp.**

* Some strains of *Klebsiella* species and *Enterobacter* species are resistant to Nitrofurantoin.

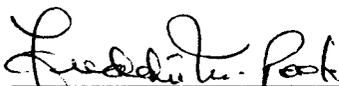
Prescription Use X
(Part 21 CFR 801 Subpart D)

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

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K 031602

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 15, 2003
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: New antimicrobial - Nitrofurantoin
Predicate device: MicroScan® rapID/S *plus*™ 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 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® 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 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® rapID/S *plus*™ Gram-Negative MIC/Combo Panel with Nitrofurantoin.

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 >99% for Nitrofurantoin when compared with the frozen NCCLS Reference panel.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Nitrofurantoin.

Quality Control testing demonstrated acceptable results for Nitrofurantoin.