DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 30 2004

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

Re: k031601
Trade/Device Name: MicroScan® Synergies Plus Gram Negative MIC/Combo Panels with Cephalothin (0.5 – 32 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, LRG, JWY, LTT, LTW
Dated: July 30, 2004
Received: August 3, 2004

Dear Mr. Eusebio:

This letter corrects our substantially equivalent letter of April 2, 2004, 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,

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): K031601

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

Indications For Use:

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. 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 Cephalothin, at concentrations of 0.5 to 32 µg/ml, to the test panel.

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

Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis

The MicroScan® Gram rapID/S *plus* Gram-Negative Panels with Cephalothin 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) 031601