MAR 2 2 2002

K 020037

510(k) Submission Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Cynthia Van Duker, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	January 2, 2002
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram Negative MIC/Combo Panels with Ceftazidime, Cefotaxime, Ceftazidime/Clavulanic Acid and Cefotaxime/Clavulanic Acid
510(k) Notification:	New antimicrobials - Ceftazidime/Clavulanic Acid and Ceftriaxone/Clavulanic Acid New Intended Use – Ceftazidime and Ceftriaxone
Predicate device:	MicroScan Dried Gram-Negative MIC/Combo Panels

510(k) Summary:

The MicroScan® ESBL plus ESBL Confirmation Panel is designed for use in the determination of antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing gram negative bacilli and for the detection of ESBL production in *Escherichia coli*, *Klebsiella oxytoca* and *Klebsiella pneumoniae*.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobials 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 at 35 °C for a minimum of 16 hours, the minimum inhibitory concentration (MIC) for the test organism is determined by observing the lowest antimicrobial concentration showing inhibition of growth.

Ceftazidime and Ceftriaxone have been cleared for susceptibility testing via Premarket Notification submissions. This Premarket Notification (510[k]) presents data in support of a request for a new intended use (confirmation of suspected *E. coli, K. oxytoca*, and *K. pneumoniae* extended spectrum beta-lactamases) similar to that described in the NCCLS document M100-S9 for Ceftazidime, and Ceftriaxone alone and in combination with Clavulanic Acid.

Efficacy and Challenge testing with MicroScan® Dried Gram Negative panel with Ceftazidime, Ceftazidime/Clavulanic Acid, Ceftriaxone and Ceftriaxone/Clavulanic Acid was conducted with both ESBL and non-ESBL producing strains including AmpC and HiK1 type strains. The Efficacy and Challenge studies were designed to confirm the acceptability of these antimicrobial agents for confirmation of ESBLs (*E. coli, K. oxytoca*, and *K. pneumoniae*) by comparing the panel susceptibility results against previously generated molecular characterization data. The Dried panel antimicrobial agents demonstrated an overall Agreement of > 90% with the ESBL and non-ESBL producing strains.

Inoculum reproducibility testing with the MicroScan® Dried Gram Negative panel with Ceftazidime, Ceftazidime/Clavulanic Acid, Ceftriaxone and Ceftriaxone/Clavulanic Acid demonstrated acceptable reproducibility regardless of which inoculum method (i.e., Turbidity and Prompt) was used.

The MicroScan® Dried Gram Negative panel with Ceftazidime, Ceftazidime/Clavulanic Acid, Ceftriaxone and Ceftriaxone/Clavulanic Acid antimicrobial agents demonstrated acceptable Quality Control throughout each phase of the ESBL evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 2 2 2002

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

Re: k020037
Trade/Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Ceftazidime, (0.5-128 µg/ml), Cefotaxime (0.5-128 µg/ml), Ceftazidime/Clavulanic Acid (0.12/4-32/4 µg/ml), and Cefotaxime/Clavulanic Acid (0.12/4-32/4 µg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: January 2, 2002
Received: January 4, 2002

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 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

510(k) Number (if known): K 02 0037

Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Ceftazidime (0.5-128 µg/ml), Cefotaxime (0.5-128 µg/ml), Ceftazidime/Clavulanic Acid (0.12/4-32/4 µg/ml) and Cefotaxime/Clavulanic Acid (0.12/4-32/4 µg/ml)

Indications For Use:

The MicroScan® ESBL *plus* ESBL Confirmation Panel is designed for use in the determination of antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing gram negative bacilli and for the detection of ESBL production in *Escherichia coli*, *Klebsiella oxytoca* and *Klebsiella pneumoniae*. After inoculation, panels are incubated for a minimum of 16 hours at 35°C in a non-CO_2 incubator, and read visually, according to the Package Insert.

This particular submission is for the addition of the antimicrobials Ceftazidime (0.5-128 µg/ml), Cefotaxime (0.5-128 µg/ml), Ceftazidime/Clavulanic Acid (0.12/4-32/4 µg/ml) and Cefotaxime/Clavulanic Acid (0.12/4-32/4 µg/ml) to the test panel.

The Gram-Negative organisms which may be used for detection of ESBL production in this panel are:

Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K020037

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use ____.

(Optional Format 1-2-96)