K061687

510(k) Summary

JUL 21 2006

510(k) Submission Information:

Device Manufacturer:	Dade Behring Inc.
Contact name:	Maureen Mende, Regulatory Affairs Group Manager
Fax:	916-374-3144
Date prepared:	June 14, 2006
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram Negative MIC/Combo Panels
Intended Use:	To be used in the confirmation of Extended-Spectrum Beta-Lactamase production in *Escherichia coli, Klebsiella* spp. and *Proteus mirabilis*.
510(k) Notification:	Modification to k020037- ESBL Confirmation
Predicate device:	MicroScan® Dried ESBL plus ESBL Confirmation Panel

510(k) Summary:

MicroScan® Dried Gram Negative MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility for Gram Negative organisms and screening for suspected ESBL production in *E. coli, Klebsiella* spp. and *P. mirabilis.*

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 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.

The antimicrobics: cefotaxime, cefotaxime/clavulanic acid, ceftazidime and ceftazidime/clavulanic acid have been cleared for confirmation of suspected extended-spectrum beta-lactamases with *E. coli, K. oxytoca* and *K. pneumoniae* via Premarket Notification submission (k020037). Confirmation of suspected ESBL with *P. mirabilis* was submitted to the FDA and is pending clearance.

This Premarket Notification 510(k) presents data in support of a request for confirmatory testing of suspected extended-spectrum beta-lactamase producing *E. coli, K. oxytoca, K. pneumoniae* and *P. mirabilis* using streamlined dilutions of the antimicrobial agents recommended for confirmation testing described in the CLSI document M100-S16 for cefotaxime and ceftazidime, alone and in combination with clavulanic acid. In addition, this Premarket Notification 510(k) presents data for automated (WalkAway® and autoSCAN®-4 instruments) reads of the MicroScan® Dried Gram Negative panel with streamlined dilutions.

Challenge studies with the MicroScan® Dried Gram Negative panel with cefotaxime (2, 16 μg/ml), cefotaxime/clavulanic acid (0.5/4, 4/4 μg/ml), ceftazidime (1, 8 μg/ml) and ceftazidime/clavulanic acid (0.25/4, 2/4 μg/ml) were conducted using stock challenge strains. The Design Validation studies were designed to confirm the acceptability of streamlined dilutions of these antimicrobial agents for confirmation of suspected ESBL-producing organisms by comparing the panel confirmation result against the molecular characterization result. The dried Test panel with streamlined dilutions of the antimicrobial agents demonstrated an overall Agreement of > 93% with ESBL and non-ESBL-producing strains.

Inoculation method and instrument reproducibility testing demonstrated acceptable reproducibility with cefotaxime (2, 16 μg/ml), cefotaxime/clavulanic acid (0.5/4, 4/4 μg/ml), ceftazidime (1, 8 μg/ml) and ceftazidime/clavulanic acid (0.25/4, 2/4 μg/ml) regardless of which inoculation method (i.e. Turbidity and Prompt) and read method (Manual, WalkAway® and autoSCAN®-4 instruments) used.

The MicroScan® Dried Gram Negative panel with cefotaxime, cefotaxime/clavulanic acid, ceftazidime and ceftazidime/clavulanic acid antimicrobial agents demonstrated acceptable Quality Control throughout each phase of the ESBL evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Maureen Mende
Regulatory Affairs Group Manager
Dade Behring Inc.
2040 Enterprise Blvd.
West Sacramento, CA 95691

JUL 21 2006

Re: k061687
Trade/Device Name: MicroScan® Dried Gram Negative MIC/Combo Panels with cefotaxime (2, 16 µg/ml), cefotaxime/clavulanic acid (0.5/4, 4/4 µg/ml), ceftazidime (1, 8 µg/ml) and ceftazidime/clavulanic acid (0.25/4, 2/4 µg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: JWY, LRG
Dated: June 14, 2006
Received: June 15, 2006

Dear Ms. Mende:

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.

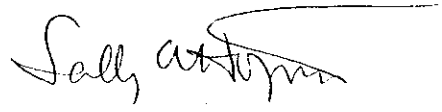
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,



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): K061687

Device Name:

MicroScan® Dried Gram Negative MIC/Combo Panels with cefotaxime (2, 16 µg/ml), cefotaxime/clavulanic acid (0.5/4, 4/4 µg/ml), ceftazidime (1, 8 µg/ml) and ceftazidime/clavulanic acid (0.25/4, 2/4 µg/ml)

Indications For Use:

The MicroScan® Dried Gram Negative Panel is designed for use in the Confirmation of Extended-Spectrum Beta-Lactamase (ESBL) production in *Escherichia coli, Klebsiella* spp. and *Proteus mirabilis.*

After inoculation, panels are incubated for 16-20 hours at 35°C +/- 1°C in a non-CO_2 incubator and read either visually or with MicroScan® instrumentation, according to the Package Insert.

This particular submission is for the use of cefotaxime (2, 16 µg/ml), cefotaxime/clavulanic acid (0.5/4, 4/4 µg/ml), ceftazidime (1, 8 µg/ml) and ceftazidime/clavulanic acid (0.25/4, 2/4 µg/ml) for ESBL confirmatory testing on MicroScan® Dried Gram Negative MIC/Combo Panels and the addition of automated read methods.

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

Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061687

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Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis

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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