K983746

DEC - 9 1999

DADE BEHRING

DADE MICROSCAN INC.
1584 Enterprise Boulevard
West Sacramento, CA 95691
Tel: +1 (916) 372-1900

510(k) Summary Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Sharolyn Lentsch, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	October 22, 1998
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® MICroSTREP *plus*™ Panel - **Amoxicillin**
Intended Use:	To determine bacterial antimicrobial agent susceptibility
Indication for Use	For use with aerobic non-enterococcal streptococci including *S. pneumoniae*
Predicate device:	NCCLS Frozen Reference Panels

510(k) Summary:

The proposed MicroScan® MICroSTREP *plus*™ Panel demonstrated substantially equivalent performance with streptococcal isolates when compared with an NCCLS frozen Reference Panel, as defined in the FDA DRAFT document "Review Criteria for Assessment of Antimicrobial Susceptibility Devices" (dated May 31, 1991).

The Premarket Notification (510[k]) presents data in support of the new MICroSTREP *plus*™ Panel with various antimicrobial agents.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The MICroSTREP *plus*™ Panel demonstrated acceptable Essential Agreement performance when compared with the frozen Reference panel.

Reproducibility testing demonstrated acceptable reproducibility and precision with each of the antimicrobial agents tested.

Quality Control testing demonstrated acceptable results for each of the antimicrobial agents tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 9 1999

Mr. Trevor Wall
Regulatory Affairs Manager
Dade MicroScan, Inc.
1584 Enterprise Boulevard
West Sacramento, California 95691

Re: K983746
Trade Name: MicroScan® MICroSTREP plus™ Panel (AMOXICILLIN)
Regulatory Class: II
Product Code: JWY
Dated: October 1, 1999
Received: October 4, 1999

Dear Mr. Wall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): K983746

Device Name: MICroSTREP plus™ panel - AMOXICILLIN

Indications For Use:

The MicroScan® MICroSTREP plus™ Panel is used to determine antimicrobial susceptibility of aerobic non-enterococcal streptococci, including *Streptococcus pneumoniae.* After inoculation, panels are incubated for 20 – 24 hours at 35°C +/- 1°C in a non-CO2 incubator, and read visually according to the Package Insert.

This particular submission is for the addition of the antimicrobial AMOXICILLIN at concentrations of 0.008 – 16 mcg/ML to the test panel

The organisms which may be used for AMOXICILLIN susceptibility testing in this panel are;

Streptococcus pneumoniae

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woodie Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983746

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use___