K021111

JUN 6 2002

510(k) Summary Information:

Device Manufacturer:	Dade MicroScan Inc.
Contact name:	Cynthia Van Duker, Regulatory Affairs Manager
Fax:	916-374-3144
Date prepared:	April 3, 2002
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® MICroSTREP *plus*™ Panel
Intended Use:	To determine bacterial susceptibility to Cefotaxime
Indication for Use	For determining antimicrobic susceptibility with aerobic streptococci, including *Streptococcus pneumoniae*
Predicate device:	MicroScan® Streptococcus MIC Panel (K963641).

510(k) Summary:

The MicroScan® MICroSTREP *plus*™ Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic 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.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test. Various antimicrobial agents are diluted in water, buffer or minute concentrations of broth to concentrations bridging the range of clinical interest. Panels are rehydrated with 115 µl Mueller-Hinton broth supplemented with 2-5% lysed horse blood (LHB) and buffered with 50 mM HEPES, after inoculation of the broth with a standardized suspension of the organism in saline. After incubation in a non-CO_2 incubator for 20-24 hours, the minimum inhibitory concentration (MIC) for the test organism is manually read by observing the lowest antimicrobial concentration showing inhibition of growth.

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 "Guidance on Review Criteria for Assessment of Antimicrobial Susceptibility Devices", dated March 8, 2000.

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

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 MICroSTREP *plus*™ Panel by comparing its performance with an NCCLS frozen Reference panel. The MICroSTREP *plus*™ Panel demonstrated acceptable performance with an overall Essential Agreement of 98.6% for Cefotaxime when compared with the frozen Reference panel.

Reproducibility testing demonstrated acceptable reproducibility and precision with Cefotaxime.

Quality Control testing demonstrated acceptable results for Cefotaxime.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 6 2002

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

Re: k021111
Trade/Device Name: MicroScan® MICroSTREP *plus*™ Panels
Microbial agent: Cefotaxime 0.15-8µg/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test System
Regulatory Class: Class II
Product Code: LTT
Dated: April 3, 2002
Received: April 5, 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

Indication for Use Statement

510(k) No.: K021111
(To be assigned by FDA)

Device Name: MicroScan® MICroSTREP *plus*™ Panel

Intended Use To determine bacterial antimicrobial agent susceptibility

Indications for Use: The MicroScan® MICroSTREP *plus*™ Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic 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 Cefotaxime at concentrations of 0.015 to 8 mcg/ml to the test panel

The organisms which may be used for Cefotaxime susceptibility testing in this panel are:

Streptococcus pyogenes (Group A beta-hemolytic streptococci)
Streptococcus agalactiae (Group B streptococci)
Streptococcus pneumoniae (formerly *Diplococcus pneumoniae*)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021111

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)