

JAN 14 2000

510(k) Summary Information:

Device Manufacturer: Dade MicroScan Inc.
Contact name: Trevor Wall, Regulatory Affairs Manager
Fax: 916-374-3144
Phone: 916-374-3332
Date prepared: October 20, 1999
Product Name: Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name: MicroScan® MICroSTREP *plus*™ Panel – **Ampicillin**
Intended Use: To determine bacterial susceptibility to AMPICILLIN
Indication for Use: For use with *Haemophilus* spp.
Predicate device: MicroScan® Streptococcus MIC Panel (K963641).

510(k) Summary:

The proposed MicroScan® MICroSTREP *plus*™ : AMPICILLIN, demonstrated substantially equivalent performance with *Haemophilus* isolates when compared with an NCCLS frozen Reference, 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 AMPICILLIN (0.015 to 16 mcg/ml)**.

The external evaluation was conducted with fresh and stock Efficacy isolates and stock Challenge strains of *Haemophilus* spp. The external evaluations were designed to confirm the acceptability of the proposed **MICroSTREP *plus*™ Panel – AMPICILLIN**, by comparing its performance with an NCCLS frozen Reference. The **MICroSTREP *plus*™ Panel - AMPICILLIN** demonstrated acceptable performance with an overall Essential Agreement of 91.5% when compared with the frozen Reference Panel.

Reproducibility testing demonstrated acceptable results with **AMPICILLIN**.

Quality Control testing demonstrated acceptable results with **AMPICILLIN**.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JAN 14 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K993679
Trade Name: MicroScan® MICroSTREP *plus*™ Panel (Haemophilus/Ampicillin)
Regulatory Class: II
Product Code: JWY
Dated: October 29, 1999
Received: November 1, 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 (Pre-market 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.

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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 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): K993679

Device Name: MICROScan MICROSTREP plusTM panel - Ampicillin

Indications For Use:

The intended use of this panel is for determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of *Haemophilus* spp.

After incubation in a non-CO₂ incubator for 20 – 24 hours, the minimum inhibitory concentration (MIC) for the test organism is determined by observing the lowest antimicrobial concentration showing inhibition of growth.

The two-fold dilutions of AMPICILLIN in the panel range from 0.015 to 16 mcg/ml for testing *Haemophilus* spp.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K993679

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)