K061872

AUG 2 3 2006

510(k) Summary Information:

Device Manufacturer:	Dade Behring Inc.
Contact name:	Maureen Mende, Regulatory Affairs Group Manager
Phone/Fax:	916-374-3174/916-374-3144
Date prepared:	June 26, 2006
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan MICroSTREP *plus*® Panel
Intended Use:	To determine bacterial susceptibility to Trimethoprim/Sulfamethoxazole
Indication for Use:	For determining antimicrobic susceptibility with *Streptococcus pneumoniae*
Predicate device:	MicroScan® MICroSTREP *plus*® Panel

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 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-CO2 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. Additionally, the panels may be incubated in and read by a MicroScan® WalkAway instrument.

The proposed instrument read method for the MicroScan MICroSTREP *plus*® Panel demonstrated substantially equivalent performance with streptococcal isolates when compared with an expected result generated on a CLSI frozen Reference Panel, as defined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", dated February 5, 2003.

This Premarket Notification (510[k]) presents data in support of reading the MICroSTREP *plus*® Panel with Trimethoprim/Sulfamethoxazole on the MicroScan® WalkAway instrument.

The external evaluation was conducted with stock and CDC Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed instrument read method

for the MICroSTREP *plus*® Panel by comparing its performance with Expected Results determined before the evaluation. The MICroSTREP *plus*® Panel demonstrated acceptable performance with an overall Essential Agreement of 100% for Trimethoprim/Sulfamethoxazole instrument read results compared with the Expected Result.

Instrument reproducibility testing demonstrated acceptable reproducibility and precision with Trimethoprim/ Sulfamethoxazole and the WalkAway® instrument.

Quality Control testing demonstrated acceptable results for Trimethoprim/Sulfamethoxazole.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 3 2006

Ms. Maureen Mende
Regulatory Affairs Group Manager
Dade Behring, Inc.
2040 Enterprise Boulevard
West Scaramento, California 95691

Re: k061872
Trade/Device Name: MicroScan MICroSTREP *plus*® Panel
Trimethoprim/Sulfamethoxazole (0.06/1.15 – 8/152 mcg/ml)
Regulation Number: 21 CFR § 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: LRG, LTT
Dated: June 28, 2006
Received: July 19, 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.

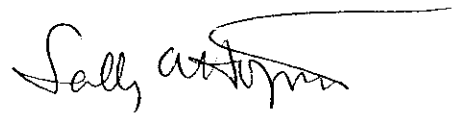
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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

Indication for Use Statement

510(k) No.: K061872
(To be assigned by FDA)

Device Name: MicroScan MICroSTREP *plus*® Panel
Trimethoprim/Sulfamethoxazole (0.06/1.15 - 8/152 mcg/ml)

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. Additionally, the panels may be incubated in and read by a MicroScan® WalkAway instrument.

This particular submission is for the addition of instrument read capability of the antimicrobial Trimethoprim/Sulfamethoxazole, at concentrations of 0.06/1.15 to 8/152 mcg/ml on the MicroScan MICroSTREP *plus*® Panel.

The organisms which may be used for Trimethoprim/ Sulfamethoxazole susceptibility testing on this panel are:

Streptococcus pneumoniae

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

(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

510(k) K061872