K091949

JAN 26 2010

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Siemens Healthcare Diagnostics
Contact name:	Shannon Popson, Regulatory Affairs Senior Technical Specialist
Fax:	916-374-3330
Date prepared:	June 16, 2009
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® MICroSTREP *plus*® Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	Device Modification – Evaluation of Penicillin (K062773) versus *Streptococcus pneumoniae* interpretive criteria (meningitis S ≤ 0.06, R ≥ 0.12 and non-meningitis S ≤ 2, I = 4, R ≥ 8).
Predicate device:	MicroScan® MICroSTREP *plus*® Panels

510(k) Summary:

MicroScan MICroSTREP *plus*® Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing 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 or with the MicroScan WalkAway instrument according to the Package Insert.

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 water, buffer, or minute concentrations of broth to concentrations bridging the range of clinical interest. Panels are rehydrated with 115µl Mueller-Hinton broth supplemented with 2-5% lysed horse blood (LHB) and buffered with 50 mM HEPES, after inoculation 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 read by determining the lowest antimicrobial concentration showing inhibition of growth.

The proposed MicroScan MICroSTREP *plus*® Panel demonstrated substantially equivalent performance when compared with an 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 March 5, 2007.

This Special 510(k) presents data and information in support of updating the penicillin labeling for the updated *Streptococcus pneumoniae* interpretive criteria (meningitis S ≤ 0.06, R ≥ 0.12 and non-meningitis S ≤ 2, I = 4, R ≥ 8).

The *Streptococcus pneumoniae* data from the previously cleared Penicillin external evaluations (K062773 and K020626) were compared to the performance of a CLSI frozen Reference panel utilizing the revised interpretative criteria (meningitis S ≤ 0.06, R ≥ 0.12 and non-meningitis S ≤ 2, I = 4, R ≥ 8). Challenge strains were compared to Expected Results determined prior to the evaluations. The MICroSTREP *plus*® Panel demonstrated acceptable performance versus the with an overall Essential Agreement of 92.5% for Penicillin when compared with the frozen Reference panel.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993

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Shannon Popson
Senior Technical Specialist,
Regulatory Affairs
Siemens Healthcare Diagnostics, Inc.
2040 Enterprise Blvd.
West Sacramento, CA 95691

Re: K091949
Trade/Device Name: MicroScan® MICroSTREP *plus*® Panel
Regulation Number: 21 CFR 1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: LTT, LRG
Dated: January 14, 2010
Received: January 19, 2010

Dear Ms. Popson:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K091949

Device Name: MicroScan® MICroSTREP plus® Panels with Penicillin (0.015 – 16 µg/ml)

Indication 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 either visually or with MicroScan® WalkAway instrument.

This particular submission is for the evaluation of antimicrobial agent penicillin on the MicroScan® MICroSTREP *plus*® Panel utilizing the updated *Streptococcus pneumoniae* meningitis interpretative criteria ($S \leq 0.06$, $R \geq 0.12$) and non-meningitis interpretative criteria ($S \leq 2$, $I = 4$, $R \geq 8$).

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

Streptococcus pneumoniae
Streptococci (Groups A, C, G, H, L and M)
Streptococcus agalactiae
Viridans *Streptococci*

Prescription Use ___√___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K091949