SEP - 8 2008

510(k) Summary

K081013

510(k) Submission Information:

Device Manufacturer:	Siemens Healthcare Diagnostics
Contact name:	Libby Warriner, Regulatory Affairs Senior Compliance Specialist
Fax:	916-374-3144
Date prepared:	April 7, 2008
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® Dried Gram-Positive MIC/Combo Panels
Intended Use:	To determine the susceptibility of staphylococci to penicillinase-stable beta-lactams
510(k) Notification:	New antimicrobial test – Cefoxitin Screen
Predicate device:	MicroScan Dried Gram-Positive MIC/Combo Panels

510(k) Summary:

MicroScan Dried Gram-Positive MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive cocci.

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 broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 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 Dried Gram-Positive MIC/Combo Panel with the Cefoxitin Screen demonstrated substantially equivalent performance when compared with the CLSI cefoxitin disk diffusion test and *mec*A PCR, 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, and "Guidance for Industry and FDA Staff—Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests", dated March 13, 2007. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Positive MIC/Combo Panel with the Cefoxitin Screen.

The external design validation (Clinical Trial) was conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Positive Panel by comparing its performance with results of the CLSI cefoxitin disk diffusion test and *mec*A PCR. Challenge strains were compared to Expected Results determined prior to the evaluation.

The Cefoxitin Screen demonstrated acceptable performance with an overall Categorical Agreement of 97.8% when compared with the CLSI cefoxitin disk diffusion test, and 98.7% when compared to *mec*A PCR. Overall sensitivity was 98.6% and specificity was 96.9% compared to cefoxitin disk diffusion results. Overall sensitivity was 99.7% and specificity was 97.7% compared to *mec*A PCR results.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with the Cefoxitin Screen, regardless of which inoculum method (i.e., Turbidity and Prompt™), or instrument (autoSCAN-4® and WalkAway®) was used.

Quality Control testing demonstrated acceptable results for the Cefoxitin Screen Well (CfxS), cefoxitin at a concentration of 4 mcg/ml.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2008

Ms. Libby Warriner
Regulatory Affairs Compliance Specialist
Siemens Healthcare Diagnostics
2040 Enterprise Blvd
West Sacramento, CA 95691

Re: k081013
Trade/Device Name: MicroScan® Dried Gram – Positive MIC/Combo Panels with Cefoxitin Screen (4 mcg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: LRG
Dated: August 25, 2008
Received: August 28, 2008

Dear Ms Warriner:

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 advice for your device on our labeling regulation (21 CFR Part 801), 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K081013

Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with the Cefoxitin Screen (4 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Positive MIC/Combo Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive cocci. After inoculation, panels are incubated for 16 – 24 hours at 35°C +/- 1°C in a non-CO_2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

The MicroScan Cefoxitin Screen is intended to determine the susceptibility of staphylococci to the penicillinase-stable beta-lactams.

This particular submission is for the addition of the antimicrobial test the **Cefoxitin Screen**, at a concentration of 4 mcg/ml, to the test panel.

The gram-positive organisms which may be used for Cefoxitin Screen susceptibility testing in this panel are:

Staphylococcus aureus
Staphylococcus lugdunensis

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(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

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