K083262

FEB 18 2009

# 510(k) Summary

**510(k) Submission Information:**

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|---|---|
| Device Manufacturer: | Siemens Healthcare Diagnostics |
| Contact name: | Libby Warriner, Regulatory Affairs Senior Compliance Specialist |
| Fax: | 916-374-3144 |
| Date prepared: | November 3, 2008 |
| Product Name: | Microdilution Minimum Inhibitory Concentration (MIC) Panels |
| Trade Name: | MicroScan Dried Gram-Negative MIC/Combo Panels |
| Intended Use: | To determine antimicrobial agent susceptibility |
| 510(k) Notification: | New antimicrobial - Tigecycline |
| Predicate device: | MicroScan Dried Gram-Negative MIC/Combo Panels |

**510(k) Summary:**

MicroScan Dried Gram-Negative 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-negative bacilli.

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-Negative MIC/Combo 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. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Negative MIC/Combo Panel with Tigecycline.

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 Dried Gram-Negative Panel by comparing its performance with an CLSI frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The Dried Gram-Negative Panel demonstrated acceptable performance with an overall Essential Agreement of 99.0% for Tigecycline when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Tigecycline, 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 Tigecycline.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2009

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

Re: k083262
Trade/Device Name: MicroScan® Dried Gram – Negative MIC/Combo Panels with Tigecycline (0.15 - 32mcg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: LTT, LRG,JWY,LTW
Dated: November 3, 2008
Received: November 5, 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): K083262

Device Name: MicroScan® Dried Gram-Negative MIC/Combo Panels with Tigecycline (0.015 – 32 mcg/ml)

Indications For Use:

The MicroScan® Dried Gram-Negative 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-negative bacilli. After inoculation, panels are incubated for 16 – 20 hours at 35°C +/- 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Tigecycline at concentrations of 0.015 to 32 mcg/ml to the test panel.

The gram-negative organisms which may be used for Tigecycline susceptibility testing in this panel are:

*Citrobacter freundii*
*Enterobacter cloacae*
*Escherichia coli*
*Klebsiella oxytoca*
*Klebsiella pneumoniae*

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