[redacted]

K091264

JUL 22 2009

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:	April 21, 2009
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan Dried Gram-Positive MIC/Combo Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	Device Modification – Evaluation of reformulated Vancomycin (K051202) versus *S. aureus* interpretive criteria ($S \leq 2$, $I = 4$ -8, $R \geq 16$).
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 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 Premarket Notification [510(k)] presents support of a request for a device modification and the updating of the product labeling with *S. aureus* interpretive criteria of ($S \leq 2$, $I = 4$ -8, $R \geq 16$).

Data collected from the external validation of vancomycin (K051202) was processed using the modified *S. aureus* interpretive criteria ($S \leq 2$, $I = 4$ -8, $R \geq 16$). The Dried panel performance was compared with frozen Reference panels using stock and fresh isolates (Efficacy phase), and challenge strains (Challenge phase). Challenge strains were compared to Expected Results determined prior to the evaluation. The Dried Gram-Positive Panel demonstrated acceptable performance with an overall Essential Agreement of 99.3% for vancomycin when compared with the frozen Reference panel.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 22 2009

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

Re: k091264
Trade/Device Name: MicroScan® Dried Gram – Positive MIC/Combo Panels with Vancomycin (0.25 – 128 mcg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: LTT, LRG,JWY,LTW
Dated: July 14, 2009
Received: July 15, 2009

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 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 (301) 594-3084. 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,

Freddie Poole, MS
Acting for:
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

510(k) Number (if known):

Device Name: MicroScan® Dried Gram-Positive MIC/Combo Panels with Vancomycin (0.25 – 128 mcg/ml)

Indication 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.

This particular submission is for the evaluation of antimicrobial agent vancomycin on the MicroScan Dried Gram-Positive MIC/Combo Panels utilizing the updated *Staphylococcus aureus* interpretative criteria ($S \leq 2$, $I = 4$ -8, $R \geq 16$).

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

Enterococcus spp. (e.g., *Enterococcus faecalis*)
Staphylococcus spp. (including *Staphylococcus aureus*)
Staphylococcus epidermidis (including methicillin-resistant strains)
Streptococcus agalactiae
Streptococcus bovis

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) K091264