K 111205

JUL 20 2011

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Siemens Healthcare Diagnostics
Contact name:	Shannon Popson, Regulatory Technical Specialist
Fax:	916-374-3330
Date prepared:	April 20, 2011
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan® MICroSTREP *plus*® Panels
Intended Use:	To determine antimicrobial agent susceptibility
510(k) Notification:	New antimicrobial - Moxifloxacin
Predicate device:	MicroScan MICroSTREP plus Panels – Levofloxacin (K020556)

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 aerobic streptococci, including *Streptococcus pneumoniae*.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in water 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 115 µl Mueller-Hinton broth supplemented with 2-5% lysed horse blood (LHB), after inoculation of the broth with a standardized suspension of the organism. 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. Alternatively, the panel can be incubated in and read by the MicroScan® WalkAway System.

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 August 28, 2009. The Premarket Notification (510[k]) presents data in support of the MicroScan MICroSTREP plus Panel with Moxifloxacin.

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 MICroSTREP plus Panel by comparing its performance with a CLSI frozen Reference panel. Challenge strains were compared to Expected Results determined prior to the evaluation. The MICroSTREP plus Panel demonstrated acceptable performance with an overall Essential Agreement of 97.3% for Moxifloxacin when compared with the frozen Reference panel.

Reproducibility testing demonstrated acceptable reproducibility and precision with Moxifloxacin, regardless of which read method (manual and WalkAway® instrument) was used with the turbidity inoculation method.

Quality Control testing demonstrated acceptable results for Moxifloxacin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Siemens Healthcare Diagnostics, Inc.
c/o Shannon Popson
Regulatory Technical Specialist
1584 Enterprise Blvd.
West Sacramento, CA 95691

JUL 20 2011

Re: k111205

Trade/Device Name:	MicroScan®MICroSTREP plus Panels
Regulation Number:	21CFR §866.1640
Regulation Name:	Antimicrobial Susceptibility Test Powder
Regulatory Class:	Class II
Product Code:	LRG, JWY, LTW
Dated:	July 14, 2011
Received:	July 15, 2011

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. 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 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, 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):

Device Name: MicroScan® MICroSTREP *plus*® with Moxifloxacin (0.03 – 8 µg/ml)

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. Alternatively, the panels can be incubated in and read by the MicroScan® WalkAway System, according to the Package Insert.

This particular submission is for the addition of the antimicrobial Moxifloxacin at concentrations of 0.03 to 8 µg/ml to the test panel.

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

Streptococcus pneumoniae (including penicillin resistant strains)
Streptococcus pyogenes
Streptococcus agalactiae
Streptococcus constellatus
Streptococcus anginosus
Viridans group streptococci

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

510(k) K111205