K113783

BIOMÉRIEUX

AUG 7 2012

510(k) SUMMARY

VITEK® 2 AST – Gram Positive Penicillin for *Streptococcus pneumoniae*

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	100 Rodolphe Street Durham, NC 27712
Contact Person:	Elizabeth (Betty) Landon Staff Regulatory Affairs Specialist
Phone Number:	919-620-2329
Fax Number:	919-620-2548
Date of Preparation:	December 20, 2011

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST - Gram Positive Penicillin for *Streptococcus pneumoniae*
Classification Name:	21 CFR 866.1645 Antimicrobial Susceptibility Test Product Code LON
Common Name:	VITEK® 2 AST-GP Penicillin for *Streptococcus pneumoniae*

C. Predicate Device: VITEK® 2 Gram Positive Amoxicillin for *Streptococcus pneumoniae* (K063597)

D. 510(k) Summary:

VITEK 2 Gram Positive Penicillin for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae*. It is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. The antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK 2 AST Cards are essentially miniaturized versons of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration with 0.45 – 0.5% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

VITEK 2 Gram Positive Penicillin for *Streptococcus pneumoniae* demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA, issued August 28, 2009.

The Premarket Notification (510(k)) presents data in support of VITEK 2 Gram Positive Penicillin for *Streptococcus pneumoniae.* An external evaluation was conducted with fresh and stock clinical isolat4es and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK 2 Gram Positive Penicillin for *Streptococcus pneumoniae* by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms, as evidenced in the AST equivalency study presented in the VITEK 2 Compact 510(k), K050002. VITEK 2 Gram Positive Penicillin for *Streptococcus pneumoniae* demonstrated acceptable performance of 92.3% and 96.9% Category Agreement based on the pneumonia and meningitis breakpoints, respectively. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

bioMerieux, Inc.
c/o Elizabeth Landon
100 Rodolphe Street
Durham, NC 27712

AUG 7 2012

Re: k113783
Trade Name: VITEK® 2 AST – Gram Positive Penicillin for Streptococcus pneumoniae
Regulation Number: 21 CFR §866.1645
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Codes: LON
Dated: July 24, 2012
Received: July 26, 2012

Dear Ms. Landon:

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.

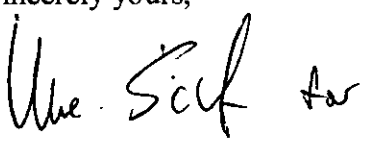
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); 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).

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 (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Indications for Use

510(k) Number (if known): K113783

Device Name: VITEK® 2 AST – Gram Positive Penicillin for *Streptococcus pneumoniae* (≤ 0.06 – ≥ 8 µg/mL)

Indications For Use:

VITEK® 2 AST – Gram Positive Penicillin for *Streptococcus pneumoniae* is designed for antimicrobial susceptibility testing of *Streptococcus pneumoniae*. VITEK 2 AST – Gram Positive Penicillin for *Streptococcus pneumoniae* is a quantitative test intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. Penicillin has been shown to be active against most strains of the microorganism listed below, according to the FDA label for this antimicrobial.

Streptococcus pneumoniae (pneumonia and meningitis)

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 and VITEK 2 Compact Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus agalactiae*, and *S. pneumoniae*.

Prescription Use ___X___ (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

510(k) K113783