K122547

OCT 15 2012

# 510(k) SUMMARY

## VITEK® 2 AST- Gram Positive Clindamycin

**510(k) Submission Information:**

| | |
|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 100 Rodolphe Street<br>Durham, NC 27712 |
| Contact Person: | Elizabeth (Betty) Landon<br>Staff Regulatory Affairs Specialist |
| Phone Number: | 919-620-2329 |
| Fax Number: | 919-620-2548 |
| Date of Preparation: | August 20, 2012 |

**B. Device Name:**

| | |
|---|---|
| Formal/Trade Name: | VITEK® 2 AST - Gram Positive Clindamycin |
| Classification Name: | 21 CFR 866.1645<br>Antimicrobial Susceptibility Test<br>Product Code LON |
| Common Name: | VITEK® 2 AST - GP Clindamycin |

**C. Predicate Device:** VITEK® 2 Gram Positive Linezolid (k032766)

**D. 510(k) Summary:**

VITEK 2 AST - Gram Positive Clindamycin is designed for an antimicrobial susceptibility testing of *Staphylococcus aureus* and *Staphylococcus epidermidis*. 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 versions 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 AST - Gram Positive Clindamycin for *Staphylococcus aureus* and *Staphylococcus epidermidis* 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 AST - Gram Positive Clindamycin for *Staphylococcus aureus* and *Staphylococcus epidermidis*. An external evaluation was

conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK AST - Gram Positive Clindamycin for *Staphylococcus aureus* and *Staphylococcus epidermidis* 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 AST - Gram Positive Clindamycin for *Staphylococcus aureus* and *Staphylococcus epidermidis* demonstrated acceptable performance of 99.4% overall Category Agreement. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 15, 2012

OCT 15 2012

bioMérieux, Inc.
c/o Elizabeth Landon
Staff Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, MO 63042

Re: K122547
Trade/Device Name: VITEK®2 AST- Gram Positive Clindamycin (≤ 0.12- ≥4 µg/mL)
Regulation Number: 21 CFR 866.1645
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: LON
Dated: August 20, 2012
Received: August 21, 2012

Dear 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 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 Part 801); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122547

Device Name: VITEK® 2 AST - Gram Positive Clindamycin
( ≤ 0.12 – ≥ 4 µg/mL )

Indications For Use:

VITEK® 2 AST-GP Clindamycin is designed for antimicrobial susceptibility testing of *Staphylococcus aureus* and *Staphylococcus epidermidis*. VITEK 2 AST-GP Clindamycin 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. Clindamycin has been shown to be active against most strains of the microorganism listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections
*Staphylococcus aureus* (methicillin-susceptible strains) and *Staphylococcus epidermidis* (methicillin-susceptible strains)

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 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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