



December 8, 2017

bioMérieux, Inc.  
Esther Hernandez  
Regulatory Affairs Specialist  
595 Anglum Road  
Hazelwood, Missouri 63042

Re: K172731

Trade/Device Name: VITEK 2 AST-GN Amikacin ( $\leq 1 - \geq 64$   $\mu\text{g/mL}$ )

Regulation Number: 21 CFR 866.1645

Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System

Regulatory Class: Class II

Product Code: LON, LTW, LTT

Dated: September 7, 2017

Received: September 11, 2017

Dear Esther Hernandez:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and Part 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

 Ribhi Shavar -S For

Uwe Scherf, 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)  
K172731

Device Name  
VITEK® 2 AST- GN Amikacin ( $\leq 1 - \geq 64 \mu\text{g/mL}$ )

### Indications for Use (Describe)

VITEK® 2 AST-Gram Negative Amikacin is designed for antimicrobial susceptibility testing of Gram Negative bacilli and 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. VITEK® 2 AST-Gram Negative Amikacin is a quantitative test. Amikacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

#### Active in vitro and in clinical infections:

Pseudomonas species  
Escherichia coli  
Proteus mirabilis  
Klebsiella species  
Enterobacter species  
Serratia species  
Acinetobacter species (excluding A. baumannii Complex)

In vitro data available but clinical significance unknown:  
Citrobacter freundii

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 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 spp. and clinically significant yeast.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) SUMMARY

### VITEK<sup>®</sup> 2 AST-GN Amikacin

#### 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Esther Hernandez Regulatory Affairs Specialist
Phone Number:	314-731-8841
Fax Number:	314-731-8689
Date of Preparation:	September 7, 2017

#### B. Device Name:

Formal/Trade Name:	VITEK <sup>®</sup> 2 AST- GN Amikacin ( $\leq 1 - \geq 64$ $\mu\text{g/mL}$ )
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON
Common Name:	VITEK <sup>®</sup> 2 AST-GN Amikacin

C. Predicate Device: VITEK<sup>®</sup> 2 AST-GN Cefepime (K161227)

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

VITEK<sup>®</sup> 2 AST-Gram Negative Amikacin is designed for antimicrobial susceptibility testing of Gram Negative bacilli and is intended for use with the VITEK<sup>®</sup> 2 and VITEK<sup>®</sup> 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK<sup>®</sup> 2 AST-Gram Negative Amikacin is a quantitative test. Amikacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

#### Active *in vitro* and in clinical infections:

*Pseudomonas* species

*Escherichia coli*

*Proteus mirabilis*

*Klebsiella* species  
*Enterobacter* species  
*Serratia* species  
*Acinetobacter* species (excluding *A. baumannii* Complex)

*In vitro* data available but clinical significance unknown:

*Citrobacter freundii*

The VITEK<sup>®</sup> 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK<sup>®</sup> 2 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* spp. and clinically significant yeast.

The antimicrobial presented in VITEK<sup>®</sup> 2 AST-GN Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK<sup>®</sup> 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK<sup>®</sup> 2 automatically fills, seals and places the card into the incubator/reader. The VITEK<sup>®</sup> 2 Compact has a manual filling and sealing operation. The VITEK<sup>®</sup> 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK<sup>®</sup> 2 AST-GN Amikacin demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA 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<sup>®</sup> 2 AST-GN Amikacin. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of VITEK<sup>®</sup> 2 AST-GN Amikacin by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hours (20-24 hours for *Acinetobacter* species). The data is representative of performance on both the VITEK<sup>®</sup> 2 and VITEK<sup>®</sup> 2 Compact instrument platforms. VITEK<sup>®</sup> 2 AST-GN Amikacin demonstrated acceptable performance of 94.9% overall Essential Agreement and 98.4% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.