



bioMérieux, Inc  
Cherece Jones  
Staff Regulatory Affairs Specialist  
595 Anglum Rd.  
Hazelwood, Missouri 63042

August 8, 2022

Re: K212243

Trade/Device Name: VITEK 2 AST- Gram Positive Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Regulation Number: 21 CFR 866.1645  
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System  
Regulatory Class: Class II  
Product Code: LON, LTT, LTW  
Dated: July 14, 2021  
Received: July 19, 2021

Dear Cherece Jones:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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,

Uwe Scherf, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
OHT7: Office of In Vitro Diagnostics  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K212243

Device Name

VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )

Indications for Use (Describe)

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

Active both in vitro and in clinical infections

*Staphylococcus aureus* (including methicillin-resistant isolates)

*Enterococcus faecalis* (vancomycin-susceptible isolates only)

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Traditional 510(k) Submission**

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**510(k) SUMMARY**

**VITEK® 2 AST Gram-Positive Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )**

**A. 510(k) Submission Information:**

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Cherece L. Jones Staff Regulatory Affairs Specialist
Phone Number:	314 -731-8684
Fax Number:	314-731-8689
Date of Preparation:	July 14, 2021

**B. Device Name:**

Formal/Trade Name:	VITEK® 2 AST Gram-Positive Telavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ )
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Product Code(s):	LON, LTT, LTW
Common Name:	VITEK® 2 AST-GP Telavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ )

**C. Predicate Device:** VITEK® 2 AST- GP Dalbavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ ) (K190616)

**D. Device Description:**

The principle of the VITEK® 2 AST cards is based on the microdilution minimum inhibitory concentration (MIC) technique reported by MacLowry and Marsh<sup>(1)</sup> and Gerlach<sup>(2)</sup>. The VITEK® 2 AST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique<sup>(3)</sup>.



**VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Traditional 510(k) Submission**

Each VITEK® 2 AST card contains 64 wells. A control well which only contains microbiological culture media is resident on all cards. The remaining wells contain premeasured portions of a specific antibiotic combined with culture media. The 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.

**E. Substantial Equivalence Information:**

The similarities and differences of the VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ ) when compared to the predicate device, VITEK® 2 AST-GP Dalbavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ ) (K190616), are described in the **Table 1** below.

**Table 1: Substantial Equivalence**

Item	Device: VITEK® 2 AST-GP Telavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ )	Predicate: VITEK® 2 AST-GP Dalbavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ ) (K190616)
<b>Similarities</b>		
<b>Intended Use</b>	<p>VITEK® 2 AST-Gram Positive Telavancin is designed for antimicrobial susceptibility testing of Gram positive microorganisms and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of <i>in vitro</i> susceptibility to antimicrobial agents. VITEK® 2 AST-Gram Positive Telavancin is a quantitative test. Telavancin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.</p> <p>Active both <i>in vitro</i> and in clinical infections</p> <p><i>Staphylococcus aureus</i> (including methicillin-resistant isolates)</p> <p><i>Enterococcus faecalis</i> (vancomycin-</p>	<p>VITEK® 2 AST-Gram Positive Dalbavancin is designed for antimicrobial susceptibility testing of Gram positive microorganisms and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of <i>in vitro</i> susceptibility to antimicrobial agents. VITEK® 2 AST-Gram Positive Dalbavancin is a quantitative test. Dalbavancin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.</p> <p>Active both <i>in vitro</i> and in clinical infections</p> <p><i>Staphylococcus aureus</i> (including methicillin-resistant isolates)</p> <p><i>Enterococcus faecalis</i> (vancomycin-</p>



**VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Traditional 510(k) Submission**

Item	Device: VITEK® 2 AST-GP Telavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ )	Predicate: VITEK® 2 AST-GP Dalbavancin ( $\leq 0.015$ - $\geq 1$ $\mu\text{g/mL}$ ) (K190616)
<b>Similarities</b>		
	susceptible isolates only)  The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an <i>in vitro</i> test to determine the susceptibility of <i>Staphylococcus</i> spp., <i>Enterococcus</i> spp., and <i>S. agalactiae</i> to antimicrobial agents when used as instructed.	susceptible isolates only) <i>Streptococcus agalactiae</i>  The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an <i>in vitro</i> test to determine the susceptibility of <i>Staphylococcus</i> spp., <i>Enterococcus</i> spp., and <i>S. agalactiae</i> to antimicrobial agents when used as instructed.
<b>Test Methodology</b>	Automated quantitative antimicrobial susceptibility test for use with the VITEK® 2 and VITEK® 2 Compact Systems to determine the <i>in vitro</i> susceptibility of microorganisms	Same
<b>Inoculum</b>	Saline suspension of organism	Same
<b>Test Card</b>	Gram-Positive (AST-GP) Susceptibility Card	Same
<b>Analysis Algorithms</b>	Growth Pattern Analysis	Same
<b>Instrument</b>	VITEK® 2 and VITEK® 2 Compact Systems	Same
<b>Differences</b>		
<b>Antimicrobial Agent</b>	Telavancin	Dalbavancin
<b>Concentrations</b>	0.015, 0.125, 0.25, 0.5	0.0625, 0.125, 0.25, 0.5

**F. Indications for Use:**

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

Active both *in vitro* and in clinical infections  
*Staphylococcus aureus* (including methicillin-resistant isolates)  
*Enterococcus faecalis* (vancomycin-susceptible isolates only)



**VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Traditional 510(k) Submission**

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

**G. Performance Overview and Conclusion:**

VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ ) 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® 2 AST-GP Telavancin. An external evaluation was conducted with contemporary and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of AST-GP Telavancin by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hours for *Staphylococci* and *Enterococci*, 20-24 hours for *Streptococci*. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

The VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ ) demonstrated acceptable performance as presented in **Table 2** below:

**Table 2: VITEK® 2 AST-GP Telavancin Performance**

Antimicrobial	Comment	Essential Agreement Category				Category Agreement				% Reproducibility
		% Error				% Error				
		%EA	VME	ME	mE	%CA	VME	ME	mE	
Telavancin	#, E <i>Enterococcus faecalis</i>	89.9 (331/368)	N/A	N/A	N/A	92.9 (342/368)	0.0 (0/1)	7.1 (26/367)*	N/A	100.0
	#, E <i>Staphylococcus aureus</i>	94.2 (490/520)	N/A	N/A	N/A	98.8 (514/520)	0.0 (0/0)	1.2 (6/520)	N/A	
<p>* Five major errors for <i>Enterococcus faecalis</i> were within essential agreement with the reference method; due to the lack of an intermediate breakpoint these five major errors were considered acceptable and the major error rate is adjusted to 5.7% which will still require retesting of non-susceptible strains with an alternate method.</p> <p>VITEK 2 AST-Gram Positive Telavancin MIC values tended to be in exact agreement or at least one doubling dilution higher when testing <i>E. faecalis</i>, and <i>S. aureus</i> compared to the CLSI reference broth microdilution method.</p>										

Key:

# = US Food and Drug Administration 510(k) cleared



**VITEK® 2 AST-GP Telavancin ( $\leq 0.015$  -  $\geq 1$   $\mu\text{g/mL}$ )  
Traditional 510(k) Submission**

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E = External performance data

Quality Control demonstrated acceptable results.

**H. References:**

1. MacLowry, J.D. and Marsh, H.H., Semi-automatic Microtechnique for Serial Dilution Antibiotic Sensitivity Testing in the Clinical laboratory, *Journal of Laboratory Clinical Medicine*, 72:685-687, 1968.
2. Gerlach, E.H., Microdilution 1: A Comparative Study, p. 63-76. *Current Techniques for Antibiotic Susceptibility Testing*. A. Balows (ed.), Charles C. Thomas, Springfield, IL, 1974.
3. Barry, A.L., *The Antimicrobial Susceptibility Test, Principles and Practices*, Lea and Febiger, Philadelphia, PA, 1976.