February 16, 2023

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

Re: K223478
Trade/Device Name: VITEK 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/mL); VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL); VITEK 2 AST-GN Plazomicin
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: November 17, 2022
Received: November 18, 2022

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief,
General Bacteriology and Antimicrobial
Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223478

Device Name

VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Negative Plazomicin 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 Plazomicin is a quantitative test. Plazomicin 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:
Escherichia coli
Klebsiella pneumoniae
Enterobacter cloacae

In vitro data are available, but their clinical significance is unknown:
Citrobacter freundii
Citrobacter koseri
Klebsiella (Enterobacter) aerogenes
Klebsiella oxytoca
Proteus vulgaris
Serratia marcescens

The VITEK® 2 Gram-Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli 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.

510(k) SUMMARY

VITEK® 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/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:	November 17, 2022

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/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-GN Plazomicin (≤0.5 - ≥16 µg/mL)

C. Predicate Device:

VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563)

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[(1)] and Gerlach[(2)]. The VITEK® 2 AST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique[(3)].

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:

VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL) is substantially equivalent to VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563). A summary of the similarities and differences of the VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL) and VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563) are provided in **Table 1** below:

Table 1: Substantial Equivalence

New Device and Predicate Device:	New Device: VITEK® 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/mL)	Predicate Device: VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563)
General Device Characteristic Similarities		
Intended Use	The VITEK® 2 Gram-Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	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.
Test Methodology	Automated quantitative antimicrobial susceptibility test for use with the VITEK® 2 and VITEK® 2 Compact Systems to determine the *in vitro* susceptibility of microorganisms	Same
Inoculum	Saline suspension of organism	Same
Test Card	Gram-Negative (AST-GN)	Same

New Device and Predicate Device:	New Device: VITEK® 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/mL)	Predicate Device: VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563)
	Susceptibility Card	
Analysis Algorithms	Growth Pattern Analysis (GPA)	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
General Device Characteristic Differences		
Indications for Use	VITEK® 2 AST-Gram Negative Plazomicin 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 Plazomicin is a quantitative test. Plazomicin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. <u>Active both *in vitro* and in clinical infections:</u> *Escherichia coli* *Klebsiella pneumoniae* *Enterobacter cloacae* <u>*In vitro* data are available, but their clinical significance is unknown:</u> *Citrobacter freundii* *Citrobacter koseri* *Klebsiella (Enterobacter) aerogenes* *Klebsiella oxytoca* *Proteus vulgaris* *Serratia marcescens* The VITEK® 2 Gram-Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial	VITEK® 2 Gram Negative Gentamicin 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 Gram Negative Gentamicin is a quantitative test. Gentamicin 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 *Citrobacter species* *Enterobacter species* *Escherichia coli* *Klebsiella species* *Proteus species* *Serratia species* *Pseudomonas aeruginosa* 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.

New Device and Predicate Device:	New Device: VITEK® 2 AST-Gram Negative Plazomicin (≤0.5 - ≥16 µg/mL)	Predicate Device: VITEK® 2 AST-GN Gentamicin (≤ 1 – ≥16 µg/mL) (K163563)
	agents when used as instructed.	
Antimicrobial Agent	Plazomicin	Gentamicin
Concentrations	2, 4, 8 µg/mL	4, 8, 32 µg/mL

F. Intended Use:

The VITEK® 2 Gram-Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

G. Performance Overview and Conclusion:

VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/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-GN Plazomicin (≤0.5 - ≥16 µg/mL). 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 AST-GN Plazomicin by comparing its performance with the CLSI broth microdilution reference method incubated at 16-24 hours. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

The VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL) demonstrated acceptable performance as presented in **Table 2** below:

Table 2: VITEK® 2 AST-GN Plazomicin Performance

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment	Essential Agreement Category				Category Agreement				% Reproducibility
					% Error				% Error				
					%EA	VME	ME	mE	%CA	VME	ME	mE	
Plazomicin	PLZ	(plz01n)	FDA (CLSI)	#, E *Enterobacteriaceae*	(847/858) 98.7	N/A	N/A	N/A	(853/858) 99.4	(0/57) 0.0	(1/797) 0.1	(4/858) 0.5	97.0
The VITEK® 2 AST-GN Plazomicin MIC values tended to be in exact agreement or at least one doubling dilution lower when testing *E. coli*, and *S. marcescens* compared to the CLSI reference broth microdilution. The VITEK® 2 AST-GN Plazomicin MIC values tended to be one doubling dilution higher when testing *K. pneumoniae* compared to the CLSI reference broth microdilution.													

1 Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME = Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).
Key:
# = US Food and Drug Administration 510(k) cleared
E = External performance data

H. Quality Control:

CLSI® Quality Control Organisms VITEK® 2 Results			
Antimicrobic	Code	*E. coli* ATCC® 25922™	*P. aeruginosa* *ATCC® 27853™*
Plazomicin	plz01n	≤0.5 – 2* ◊ (*FDA/CLSI broth dilution expected QC range = 0.25 – 2 µg/mL)	1 - 4

Numerical values are expressed in µg/mL.
◊ Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.

Results for the VITEK® 2 AST-GN Plazomicin (≤0.5 - ≥16 µg/mL) were within the expected QC results range >95% of the time for both dilution options of the VITEK® 2 and manual dilution on the VITEK® 2 Compact.

I. Limitations:

Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s):

- Plazomicin (plz01n): *Morganella morganii, Proteus mirabilis, Providencia stuartii*

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing:

- Plazomicin (plz01n): *Citrobacter freundii, Citrobacter koseri, Klebsiella (Enterobacter) aerogenes, Klebsiella oxytoca, Proteus vulgaris, and Serratia marcescens*

J. 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 Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA, 1976.