March 11, 2024

bioMerieux, Inc.
Anne Rasponi
Senior Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, Missouri 63042

Re: K234000
Trade/Device Name: VITEK 2 AST-Gram Positive Lefamulin (<=0.03 - >=4 µg/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: December 15, 2023
Received: December 18, 2023

Dear Anne Rasponi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Natasha Griffin -S

Natasha Griffin
O.B.O. 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)*

K234000

Device Name

VITEK 2 AST-Gram Positive Lefamulin (≤0.03 - ≥4 µg/ml)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Positive Lefamulin 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 Lefamulin is a quantitative test. Lefamulin 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 (methicillin-susceptible isolates)

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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510(k) SUMMARY

VITEK® 2 AST-GP Lefamulin (≤ 0.03 – ≥4 µg/mL)

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Anne Rasponi Regulatory Affairs Specialist
Phone Number:	314 -506-8223
Fax Number:	314-731-8689
Date of Preparation:	December 15, 2023

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram-Positive Lefamulin (≤ 0.03 – ≥4 µg/mL)
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON, LTT, LTW
Common Name:	VITEK® 2 AST-GP Lefamulin

C. Predicate Device:

VITEK® 2 AST-GP Daptomycin (≤0.12 - ≥8 µg/mL) (K230864)

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 bacterial or yeast 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-GP Lefamulin (≤ 0.03 – ≥4 µg/mL) has the following concentrations in the card: 0.125, 0.5, 1, and 2 (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information

The similarities and differences of the VITEK 2 AST-GP Lefamulin (≤ 0.03 – ≥4 µg/mL) when compared to the predicate device, VITEK 2 AST-GP Daptomycin (≤0.12 - ≥8 µg/mL) (K230864), are described in the following table.

Table 1: Substantial Equivalence

Item	Device: VITEK® 2 AST-GP Lefamulin	Predicate Device: VITEK® 2 AST-GP Daptomycin (K230864)
General Device Characteristic Similarities		
Intended Use	VITEK® 2 AST-GP Lefamulin (≤ 0.03 – ≥4 µg/mL) 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-GP Lefamulin is a quantitative test. Lefamulin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. 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 *Enterococcus* spp., *Staphylococcus* spp., and	VITEK® 2 AST-GP Daptomycin (≤0.12 - ≥8 µg/mL) 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-GP Daptomycin is a quantitative test. Daptomycin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. 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 *Enterococcus* spp., *Staphylococcus* spp., and *Streptococcus agalactiae* to

Item	Device: VITEK® 2 AST-GP Lefamulin	Predicate Device: VITEK® 2 AST-GP Daptomycin (K230864)
General Device Characteristic Similarities		
	Streptococcus agalactiae to antimicrobial agents when used as instructed.	antimicrobial agents when used as instructed.
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-positive (AST-GP) Susceptibility Card	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Type of test	Quantitative test	Same
Differences		
Antimicrobial Agent	Lefamulin	Daptomycin
Concentrations	0.125, 0.5, 1, 2	0.5, 1, 2, 4, 16
Breakpoints	*Staphylococcus aureus (MSSA)* (S/I/R) $\leq$ 0.25 / – / –	*Staphylococcus aureus* (S/I/R) $\leq$ 1 / – / – *Enterococcus faecalis* (S/I/R) $\leq$ 2 / 4 / $\geq$ 8
Indicated Organisms	Active *in vitro* and in clinical infections: *Staphylococcus aureus* (methicillin-susceptible isolates)	Active both *in vitro* and in clinical infections: *Enterococcus faecalis* (vancomycin- susceptible isolates only) *Staphylococcus aureus* (including methicillin-resistant isolates) *In vitro* data are available. but their clinical significance is unknown: *Enterococcus faecalis* (vancomycin- resistant isolates)

F. Intended Use:

VITEK® 2 AST-GP Lefamulin is designed for antimicrobial susceptibility testing of Gram-positive microorganisms and is intended for use with the VITEK® 2 and VITEK® 2 COMPACT Systems in clinical laboratories as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents when used as instructed. VITEK® 2 AST-GP Lefamulin is a quantitative test. Lefamulin has been shown to be active against the microorganisms listed below, according to the FDA label for this antimicrobial.

Active *in vitro* and in clinical infections:
Staphylococcus aureus (methicillin-susceptible isolates)

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

G. Performance Overview and Conclusion:

VITEK® 2 AST-GP Lefamulin demonstrated substantially equivalent performance when compared with the 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 (Traditional 510(k)) presents data in support of VITEK® 2 AST-GP Lefamulin. 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® 2 AST-GP Lefamulin by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hrs. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

The VITEK 2 AST-GP Lefamulin demonstrated acceptable performance as presented in Table 2 below:

Table 2: VITEK 2 AST-GP Lefamulin 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**	
Lefamulin	LMU	(lmu01n)	CLSI (FDA)	#, E *Staphylococcus aureus*	(367/404) 90.8	N/A	N/A	N/A	(403/404) 99.8	(0/3) 0.0	(1/401) 0.2	N/A	100.0
			• VITEK® 2 Lefamulin MIC values tended to be in exact agreement or at least one doubling dilution lower when testing methicillin-susceptible S. aureus compared to the CLSI reference method, broth microdilution. • The incubation time (Time of Call) for AST GP cards containing Lefamulin may exceed 16 hours. This extended incubation time is required to generate MIC values.								

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).

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Key:
= US Food and Drug Administration 510(k) cleared
CLSI® = Clinical and Laboratory Standards Institute
E = External performance data

Reproducibility and Quality Control demonstrated acceptable results.

The performance data presented in this submission support a substantial equivalence decision. VITEK® 2 AST-GP Lefamulin (≤ 0.03 – ≥4 µg/mL) is substantially equivalent to VITEK® 2 AST-GP Daptomycin (K230864).

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.