September 14, 2021

bioMérieux, Inc.
Debra Broyles
Sr. Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, Missouri 63042

Re: K202396
Trade/Device Name: VITEK 2 AST-Gram Positive Fosfomycin (≤8 - ≥256 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, LTW, LTT
Dated: August 20, 2020
Received: August 21, 2020

Dear Debra Broyles:

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, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
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)*

Device Name

Indications for Use *(Describe)*

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

VITEK® 2 AST-Gram Positive Fosfomycin (≤8 - ≥256 µg/mL)

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Debra Broyles Senior Regulatory Affairs Specialist
Phone Number:	314 -731-8805
Fax Number:	314-731-8689
Date of Preparation:	August 5, 2020

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram Positive Fosfomycin (≤8 - ≥256 µg/mL)
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code: LON
Common Name:	VITEK® 2 AST-GP Fosfomycin (≤8 - ≥256 µg/mL)

C. Predicate Device:

VITEK® 2 AST-GP Dalbavancin (≤0.015 – ≥1 µg/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[(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 Fosfomycin (≤8 - ≥256 µg/mL) has the following concentrations in the card: 8, 16, 32 and 128 µg/mL (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information:

The similarities and differences of the VITEK® 2 AST-Gram Positive Fosfomycin (≤8 - ≥256 µg/mL) when compared to the predicate device, VITEK® 2 AST-Gram Positive Dalbavancin (≤0.015 – ≥1 µg/mL), are described in the **Table 1** below.

Table 1: Substantial Equivalence

Item	Device: VITEK® 2 AST-GP Fosfomycin (≤8 - ≥256 µg/mL)	Predicate: VITEK® 2 AST-GP Dalbavancin (≤ 0.015 – ≥ 1 µg/mL) (K190616)
Similarities		
Intended Use	VITEK® 2 AST-Gram Positive Fosfomycin 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 Fosfomycin is a quantitative test. Fosfomycin	VITEK® 2 AST-Gram Positive Dalbavancin is designed for antimicrobial susceptibility testing of Gram positive 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 Positive Dalbavancin is a quantitative test. Dalbavancin

Item	Device: VITEK® 2 AST-GP Fosfomycin (≤8 - ≥256 µg/mL)	Predicate: VITEK® 2 AST-GP Dalbavancin (≤ 0.015 – ≥ 1 µg/mL) (K190616)
Similarities		
	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:** *Enterococcus faecalis* 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 clinically significant aerobic Gram positive microorganisms to antimicrobial agents when used as instructed.	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) *Streptococcus agalactiae* 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.
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

Item	Device: VITEK® 2 AST-GP Fosfomycin (≤8 - ≥256 µg/mL)	Predicate: VITEK® 2 AST-GP Dalbavancin (≤ 0.015 – ≥ 1 µg/mL) (K190616)
Similarities		
Inoculum	Saline suspension of organism	Same
Test Card	Gram Positive (AST-GP) Susceptibility Card	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Analysis Algorithm	Growth Pattern Analysis	Same
Differences		
Antimicrobial Agent	Fosfomycin	Dalbavancin
Concentrations	8, 16, 32, 128	0.0625, 0.125, 0.25, 0.5
Indicated organisms	*Enterococcus faecalis*	*Staphylococcus aureus* (including methicillin-resistant isolates) *Enterococcus faecalis* (vancomycin-susceptible isolates only) *Streptococcus agalactiae*

F. Intended Use:

VITEK® 2 AST-Gram Positive Fosfomycin 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 Fosfomycin is a quantitative test. Fosfomycin 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:
Enterococcus faecalis

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 clinically significant aerobic Gram-positive microorganisms to antimicrobial agents when used as instructed.

G. Performance Overview and Conclusion:

VITEK® 2 AST-GP Fosfomycin demonstrated substantially equivalent performance when compared with the CLSI agar dilution 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 Fosfomycin. 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 Fosfomycin by comparing its performance with the CLSI agar dilution 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 Fosfomycin demonstrated acceptable performance as presented in **Table 2** below:

Table 2: VITEK® 2 AST-GP Fosfomycin Performance

		%EA	VME	ME	mE	%CA	VME	ME	mE
Overall Performance (with the reference method)		(388/399) 97.2	N/A	N/A	N/A	(386/399) 96.7	(0/1) 0.0	(0/385) 0.0	(13/399) 3.3

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