October 13, 2022

bioMérieux, Inc
Nathan Hardesty
Associate Director, Regulatory Affairs Clinical Microbiology
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K220805
Trade/Device Name: VITEK 2 AST-Gram Positive Cefoxitin Screen
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: March 17, 2022
Received: March 18, 2022

Dear Nathan Hardesty:

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,

For: Uwe Scherf, 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

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 Cefoxitin Screen

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nathan Hardesty Associate Director Regulatory Affairs, Microbiology
Phone Number:	314 -731-8666
Fax Number:	314-731-8689
Date of Preparation:	January 31, 2022

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram Positive Cefoxitin Screen
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code: LON, LTW, LTT
Common Name:	VITEK® 2 AST-GP Cefoxitin Screen
C. Predicate Device:	VITEK® 2 Gram Positive Cefoxitin Screen (K053097)

D. Device Description:

VITEK® 2 AST-GP Cefoxitin Screen is designed to predict mecA-mediated oxacillin resistance in *Staphylococcus spp.* The cefoxitin screen and oxacillin work in combination to determine the final interpretation reported for oxacillin. The VITEK® 2 AST-GP Cefoxitin Screen is a qualitative test based on the CLSI, "Disk Diffusion Test for Prediction of mecA-mediated resistance in Staphylococci." The VITEK® 2 AST-GP Cefoxitin Screen test 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.

The VITEK® 2 card is inoculated with a standardized organism suspension, and growth inside the card is optically monitored throughout the incubation cycle. Results are automatically calculated once a predetermined growth threshold is reached and a report is generated that contains the MIC result and the interpretive category result.

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. For the VITEK 2 Cefoxitin Screen, the report will list either a positive or negative result. The VITEK 2 Cefoxitin Screen and oxacillin work in combination to determine the final oxacillin interpretation based on the CLSI recommendations.

> **NOTE:** Final determination of the oxacillin interpretation is based on forcing rules as managed by the VITEK 2 Systems software. Both the VITEK 2 AST-GP Cefoxitin Screen test and Oxacillin test must finalize before any forcing rules are applied.

VITEK® 2 AST-GP Cefoxitin Screen has the following concentrations in the card: 4 and 5 µg/mL (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information:

The similarities and differences of the VITEK® 2 AST-GP Cefoxitin Screen when compared to the predicate device, VITEK® 2 Cefoxitin Screen (K053097), are described in the **Table 1** below.

Table 1: Substantial Equivalence

Item	Device: VITEK® 2 AST-Gram Positive Cefoxitin Screen	Predicate: VITEK® 2 AST-Gram Positive Cefoxitin Screen (K053097)
Similarities		
Intended Use	VITEK® 2 AST-Gram Positive Cefoxitin Screen test is designed to predict mecA-mediated oxacillin resistance in Staphylococcus spp. It 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. The VITEK® 2 AST 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 *Streptococcus agalactiae* to antimicrobial agents when used as instructed.	VITEK® 2 Gram Positive Cefoxitin Screen test is designed to predict mecA-mediated resistance in *Staphylococci.* It 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. The VITEK® 2 AST 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 *Streptococcus agalactiae* to antimicrobial agents when used as instructed.
Test Methodology	Automated qualitative 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
Analysis Algorithm	Discriminant Analysis	Same
Antimicrobial Agent	Cefoxitin	Same
Differences		
Concentrations	4, 5	6

F. Intended Use:

VITEK® 2 AST-GP Cefoxitin Screen is designed to predict mecA-mediated oxacillin resistance in *Staphylococcus spp*. It 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.

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 *Streptococcus agalactiae* to antimicrobial agents when used as instructed.

G. Performance Overview and Conclusion:

VITEK® 2 AST-GP Cefoxitin Screen demonstrated substantially equivalent performance when compared with the CLSI disk diffusion method, as defined "Performance Standards for Antimicrobial Disk Susceptibility Tests", Approved Standard -13th Edition (January 2018).

The Premarket Notification (510[k]) presents data in support of VITEK® 2 AST-GP Cefoxitin Screen. 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 Cefoxitin Screen by comparing its performance with the CLSI test for detecting methicillin (oxacillin) resistance with cefoxitin disk diffusion incubated at 33-35°C for 16-18 hrs with *S. aureus* and *S. lugdunensis*, and 24 hours for other *Staphylococcus* (excluding *S. pseudintermedius* & *S. schleiferi*). The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

The VITEK® 2 AST-GP Cefoxitin Screen demonstrated acceptable performance as presented in **Table 2** below:

Table 2

Antimicrobial	Comment2	Essential Agreement				Category Agreement			
		% Error				% Error			
		% EA	VME	ME	mE	% CA	VME	ME	mE
Oxacillin + Cefoxitin Screen	*S. aureus* & *S. lugdunensis* #, E, Ref. = CLSI Disk Diffussion	-	-	-	-	98.7% (525 / 532)	0.6% (1 / 177)	1.7% (6 / 355)	N/A

	Other Staphylococcus species (not including *S. Pseudintermedius* or *S. Schleiferi*) #, E, Ref. = CLSI Disk Diffussion	-	-	-	-	97.8% (261 / 267)	0.0 % (0 / 125)	4.2% (6 / 142)	N/A

Reproducibility and Quality Control demonstrated acceptable results.

In conclusion the performance data presented in this submission supports a substantial equivalence decision. VITEK® 2 AST Gram Positive Cefoxitin Screen test in this 510(k) is substantially equivalent to the predicate VITEK® 2 AST Gram Positive Cefoxitin Screen Test (K053097).

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.
4. CLSI M02, "Performance Standards for Antimicrobial Disk Susceptibility Tests", Approved Standard -13th Edition (January 2018)
5. CLSI M100, "Performance Standards for Antimicrobial Susceptibility Testing; 31st Edition", (March 2021)