October 23, 2023

bioMerieux, Inc
Jared Bronson
Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K232201
Trade/Device Name: VITEK 2 AST-Streptococcus Penicillin (<=0.06 - >=8 µg/mL), VITEK 2 Streptococcus Penicillin (<=0.06 - >=8 µg/mL), VITEK 2 Streptococcus Penicillin
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: July 20, 2023
Received: July 25, 2023

Dear Jared Bronson:
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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABBM)
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)*
K232201

Device Name

VITEK® 2 Streptococcus Penicillin (≤0.06 - ≥8 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 Streptococcus Penicillin is designed for antimicrobial susceptibility testing of *Streptococcus* species 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 Streptococcus Penicillin is a quantitative test. Penicillin 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:
Beta hemolytic *Streptococci* groups C and G
Streptococcus pyogenes
Streptococcus agalactiae
Streptococcus viridans group
Streptococcus pneumoniae

The VITEK® 2 *Streptococcus* Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* 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.

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

VITEK® 2 Streptococcus Penicillin (≤ 0.06 – ≥ 8 µg/mL)

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jared Bronson Regulatory Affairs Specialist
Phone Number:	314-201-8799
Fax Number:	314-731-8689
Date of Preparation:	June 12, 2023

B. Device Name:

Formal/Trade Name:	VITEK® 2 Streptococcus Penicillin (≤0.06 - ≥8 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 Streptococcus Penicillin

C. Predicate Device:

VITEK® 2 Streptococcus Penicillin (≤0.06 - ≥8 µg/mL) (K112000)

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 Streptococcus Penicillin has the following concentrations in the card: 0.06, 0.12, 0.5, and 2µg/mL (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information:

The similarities and differences of the VITEK® 2 Streptococcus Penicillin when compared to the predicate device, VITEK® 2 Streptococcus Penicillin (K112000), are described in the following table. There is no difference between the new device and the predicate device.

Table 1: Substantial Equivalence

Device and Predicate Device(s):	Device:	Predicate Device: K112000
Device Trade Name	VITEK® 2 Streptococcus Penicillin	VITEK® 2 Streptococcus Penicillin
General Device Characteristic Similarities		
Intended Use/Indications for Use	VITEK® 2 Streptococcus Penicillin 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 Streptococcus Penicillin is a quantitative test. The VITEK® 2 *Streptococcus* Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and	VITEK® 2 Streptococcus Penicillin 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 Gram Positive Penicillin is a quantitative test. The VITEK® 2 *Streptococcus* Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* to antimicrobial agents

	Viridans *Streptococcus* to antimicrobial agents when used as instructed. Penicillin 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: Beta hemolytic S*treptococci* groups C and G *Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus* viridans group *Streptococcus pneumoniae*	when used as instructed. Penicillin has an antimicrobial activity against the microorganisms listed below, according to the FDA label for this antimicrobial. Active in vitro and in clinical infections: Beta hemolytic *Streptococci* groups C and G *Streptococcus pyogenes* *Streptococcus agalactiae* *Streptococcus* viridans group *Streptococcus pneumoniae*
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
Antimicrobial Agent	Penicillin	Same
Inoculum	Saline suspension of organism	Same
Test Card	Streptococcus (AST-ST) Susceptibility Card	Same
Analysis Algorithms	Discriminant Analysis	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Concentrations	0.06, 0.12, 0.5, 2	Same
General Device Characteristic Differences		
Breakpoints	• *S. pneumoniae (non-meningitis) [≤2 / 4 / ≥8]* • *S. pneumoniae (meningitis) [≤0.06/ - / ≥0.12]* •*Viridans Streptococci [≤0.12/ 0.25-2 / ≥4]* • *Beta-hemolytic Streptococcus [≤0.12/ - / -]* • *S. pneumoniae (oral/non-meningitis) [≤0.06/ 0.12-1/ ≥2]*	• *S. pneumoniae (non-meningitis) [≤2 / 4 / ≥8]* • *S. pneumoniae (meningitis) [≤0.06/ - / ≥0.12]* • *Viridans Streptococci [≤0.12/ 0.25-2 / ≥4]* • *Beta-hemolytic Streptococcus [≤0.12/ - / -]* • *S. pneumoniae (oral) [none]*

F. Intended Use:

VITEK® 2 Streptococcus Penicillin 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 Streptococcus Penicillin is a quantitative test. Penicillin has been shown to be active against the microorganisms listed below, according to the FDA label for this antimicrobial.

Active both *in vitro* and in clinical infections:
Beta hemolytic Streptococci groups C and G
Streptococcus pyogenes
Streptococcus agalactiae
Streptococcus viridans group
Streptococcus pneumoniae

The VITEK® 2 Streptococcus Penicillin Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of *Streptococcus pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus* to antimicrobial agents when used as instructed.

G. Performance Overview and Conclusion:

VITEK® 2 Streptococcus Penicillin 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 (PMA) presents data in support of VITEK® 2 Streptococcus Penicillin. 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 Streptococcus Penicillin 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.

VITEK® 2 Streptococcus Penicillin (≤0.06 - ≥8 µg/mL) demonstrated acceptable performance as presented in Table 2 below:

Table 2: VITEK® 2 Streptococcus Penicillin Performance

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp1	Comment	Essential Agreement Category				Category Agreement			
					% Error				% Error			
					%EA	**VME**	**ME**	**mE**	**%CA**	**VME**	**ME**	**mE**
Penicillin	P	(p01n)	CLSI (FDA)	#, *E Streptococcus pneumoniae* (*non-meningitis*).	(342/350 97.7	N/A	N/A	N/A	(323/350) 92.3	(0/0) 0.0	(0/304) 0.0	(27/350) 7.7
				#, *E Streptococcus pneumoniae* (oral).	(342/350) 97.7%	N/A	N/A	N/A	(314/350) 89.7%	(0/94) 0.0%	(0/189) 0.0%	(36/350) 10.3%
				#, *E Streptococcus pneumoniae* (meningitis).	(342/350) 97.7%	N/A	N/A	N/A	(342/350) 97.7%	(2/161) 1.2%	(6/189) 3.2%	N/A
				#, *E Streptococcus* Viridans group (except *Streptococcus pneumoniae*).	(385/391) 98.5%	N/A	N/A	N/A	(368/391) 94.1%	(0/15) 0.0%	(0/268) 0.0%	(23/391) 5.9%
				#, *E* Beta-hemoly-tic *Streptococcus*	(833/833) 100%	N/A	N/A	N/A	(833/833) 100%	(0/0) 0.0%	(0/833) 0.0%	N/A

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.