August 30, 2021

bioMérieux, Inc
Mary Beth Anheuser
Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042 USA

Re: K211630
Trade/Device Name: VITEK 2 AST-Gram Negative Piperacillin / Tazobactam (≤4 ≥128 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: May 25, 2021
Received: May 27, 2021

Dear Mary Beth Anheuser:

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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Special 510(k) SUMMARY

VITEK ®2 Gram Negative Piperacillin/Tazobactam
Special 510(k): Device Modification

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Mary Beth Anheuser Staff, Regulatory Affairs Specialist
Phone Number:	618-667-3179
Fax Number:	314-731-8689
Date of Preparation:	May 25, 2021

B. Device Name:

Formal/Trade Name:	VITEK® 2 Gram Negative Piperacillin/Tazobactam (≤4 - ≥128 µg/mL)
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK 2 AST-GN Piperacillin/Tazobactam

C. Predicate Device: VITEK 2 AST-GN Piperacillin/Tazobactam (K113200)

D. 510(k) Summary:

VITEK®2 Gram Negative Piperacillin/Tazobactam is designed for antimicrobial susceptibility testing of *Acinetobacter baumanii, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Citrobacter koseri, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia rettgeri, Providencia stuartii,* and *Salmonella enterica*. 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 antimicrobial presented in VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/mL. The VITEK 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The bacterial isolate to be tested is diluted to a standardized concentration in 0.45% 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 and sealing operation. The VITEK 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). 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 Gram Negative Piperacillin/Tazobactam 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 Feb. 5, 2003.

This submission is the result of a FDA 2019 breakpoint change, as published on the FDA STIC website, for *Pseudomonas aeruginosa* tested with Piperacillin/Tazobactam (≤16, 32-64, 128 ≥). The intended use of the VITEK 2 Gram Negative Piperacillin/Tazobactam, as described in the labeling (package insert), has not changed as a result of this modification to the breakpoints specific to *Pseudomonas aeruginosa.* The overall performance of the device has been updated to reflect the performance of *Pseudomonas aeruginosa* when the updated breakpoints are applied. This modification does not affect the fundamental scientific technology of this device.

This premarket Notification (510(k)) presents the data in support of the VITEK 2 Gram Negative Piperacillin/Tazobactam test when the updated breakpoints for *Pseudomonas aeruginosa* (≤16, 32-64, 128 ≥) are applied. The data are representative of performance on both the VITEK 2 and VITEK 2 COMPACT instrument platforms. VITEK 2 Gram Negative Piperacillin/Tazobactam demonstrated an overall acceptable performance of 92.3% Category Agreement. Quality control and reproducibility are acceptable and remain unchanged from the original clearance (K113200).

The VITEK 2 Gram Negative Piperacillin/Tazobactam test demonstrated acceptable performance during verification of the breakpoint change specific to *Pseudomonas aeruginosa*. No new risks were introduced through this modification and the performance equivalency has been established through verification testing. This allows for a substantial equivalence decision when compared to the current device cleared under K113200.