March 13, 2020

BioMerieux, Inc.
Jolyn Tenllado
Regulatory Affairs Expert
595 Anglum Road
Hazelwood, Missouri 63042

Re: K193572
Trade/Device Name: VITEK 2 AST-Gram Negative Imipenem/Relebactam (≤0.25/4 - ≥16/4 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, LTW, LTT
Dated: December 20, 2019
Received: December 23, 2019

Dear Jolyn Tenllado:

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

510(k) SUMMARY

VITEK® 2 AST-GN Imipenem/Relebactam

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado Regulatory Affairs Expert
Phone Number:	314 -731-8386
Fax Number:	314-731-8689
Date of Preparation:	December 20, 2019

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST- Gram Negative Imipenem/Relebactam (≤ 0.25/4 – ≥ 16/4 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-GN Imipenem/Relebactam

C. Predicate Device: VITEK® 2 AST-GN Imipenem (K183415)

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-GN Imipenem/Relebactam has the following concentrations in the card: 0.25/4, 1/4, 4/4 and 16/4 µg/mL (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information

The similarities and differences of the VITEK 2 AST-GN Imipenem/Relebactam when compared to the predicate device, VITEK 2 AST-GN Imipenem (K183415), are described in the following table.

Item	Device: VITEK® 2 AST-GN Imipenem/Relebactam	Predicate: VITEK® 2 AST-GN Imipenem (K183415)
	Similarities	
Intended Use	VITEK® 2 AST-Gram Negative Imipenem/Relebactam is designed for antimicrobial susceptibility testing of Gram negative 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 Negative Imipenem/Relebactam is a quantitative test. Imipenem/Relebactam has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. <u>Active *in vitro* and in clinical infections:</u> *Klebsiella (Enterobacter) aerogenes* *Enterobacter cloacae* *Escherichia coli* *Klebsiella pneumoniae* *Pseudomonas aeruginosa* *Citrobacter freundii* *Klebsiella oxytoca* <u>In vitro data are available, but clinical significance is unknown</u> *Citrobacter koseri* *Enterobacter asburiae*	VITEK® 2 AST-Gram Negative Imipenem is designed for antimicrobial susceptibility testing of Gram negative 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 Negative Imipenem is a quantitative test. Imipenem has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial. <u>Active *in vitro* and in clinical infections:</u> *Acinetobacter spp.* *Citrobacter spp.* *Enterobacter spp. (excluding E. aerogenes)* *Escherichia coli* *Klebsiella spp.* *Pseudomonas aeruginosa* The VITEK® 2 Gram-Negative 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-negative bacilli to antimicrobial agents when used as instructed.

Item	Device: VITEK® 2 AST-GN Imipenem/Relebactam	Predicate: VITEK® 2 AST-GN Imipenem (K183415)
Similarities		
Intended Use (Cont.)	The VITEK® 2 Gram-Negative 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-negative bacilli 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 Gram negative bacilli	Same
Inoculum	Saline suspension of organism	Same
Test Card	VITEK® 2 Gram Negative Susceptibility Test Card	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Analysis Algorithms	Growth Pattern Analysis	Same
Differences		
Antimicrobial Agent	Imipenem/Relebactam	Imipenem
Antimicrobial Concentrations	0.25/4, 1/4, 4/4, 16/4	0.5, 2, 8, 16

F. Intended Use:

VITEK® 2 AST-Gram Negative Imipenem/Relebactam is designed for antimicrobial susceptibility testing of Gram Negative 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 Negative Imipenem/Relebactam is a quantitative test. Imipenem/Relebactam 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:
Klebsiella (Enterobacter) aerogenes
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Pseudomonas aeruginosa
Citrobacter freundii
Klebsiella oxytoca

In vitro data are available, but clinical significance is unknown
Citrobacter koseri
Enterobacter asburiae

The VITEK® 2 Gram-Negative 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-negative bacilli to antimicrobial agents when used as instructed.

F. Performance Overview and Conclusion:

VITEK® 2 AST-GN Imipenem/Relebactam 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 August 28, 2009).

The Premarket Notification (510[k]) presents data in support of VITEK® 2 AST- GN Imipenem/Relebactam. 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-GN Imipenem/Relebactam by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20

hours. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

VITEK® 2 AST-GN Imipenem/Relebactam demonstrated acceptable performance of 95.3% Essential Agreement and 98.9% Category Agreement for *Enterobacteriaceae* and 96.2% Essential Agreement and 95.5% Category Agreement for *P. aeruginosa* with the reference method. Overall performance for *Enterobacteriaceae* and *P. aeruginosa* combined was 95.6% Essential Agreement and 98.0% Category Agreement. Reproducibility and Quality Control demonstrated acceptable results.

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.