December 15, 2020

BioMerieux, Inc.
Cherece Jones
Staff Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K193299
Trade/Device Name: VITEK 2 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 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, LTT, LTW

Dear Cherece Jones:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated September 28, 2020. Specifically, FDA is updating this SE Letter (i.e., correct inaccuracies in the Indications for Use form, 510(k) Summary, and device labeling) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ribhi Shawar, Ph.D., OHT7: Office of In Vitro Diagnostics and Radiological Health, 301-796-6698, Ribhi.Shawar@fda.hhs.gov.

Sincerely,

Ribhi Shawar -S

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

September 28, 2020

bioMérieux, Inc.
Cherece Jones
Staff Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K193299
Trade/Device Name: VITEK 2 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 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, LTT, LTW
Dated: November 26, 2019
Received: November 27, 2019

Dear Cherece Jones:

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 -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193299

Device Name

VITEK® 2 AST-Gram Negative Ceftazidime (≤ 0.5 - ≥ 32 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Negative Ceftazidime 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 Ceftazidime is a quantitative test. Ceftazidime 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:
Citrobacter species
Enterobacter species
Escherichia coli
Klebsiella species
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia species

In vitro data are available, but clinical significance is unknown:
Acinetobacter species
*Citrobacter koseri (*formerly *Citrobacter diversus)*
Citrobacter freundii
Providencia species *(*including *Providencia rettgeri)*
Salmonella species
Shigella species
Yersinia enterocolitica

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 µg/mL)

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Cherece L. Jones Staff Regulatory Affairs Specialist
Phone Number:	314 -731-8684
Fax Number:	314-731-8689
Date of Preparation:	November 26, 2019

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 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 Ceftazidime (≤0.5 - ≥32 µg/mL)

C. Predicate Device:

VITEK® 2 AST-GN Eravacycline (≤ 0.12 – ≥ 4 µg/mL) (K191766)

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 Ceftazidime (≤0.5 - ≥32 µg/mL) has the following concentrations in the card: 1, 2, 4, 8, and 32µg/mL (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information:

The similarities and differences of the VITEK® 2 AST-GN Ceftazidime (≤0.5 - ≥32 µg/mL) when compared to the predicate device, VITEK® 2 AST-GN Eravacycline (≤ 0.12 – ≥ 4 µg/mL), are described in the **Table 1** below.

Table 1: Substantial Equivalence

Item	Device: VITEK® 2 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 µg/mL)	Predicate: VITEK® 2 AST-GN Eravacycline (≤ 0.12 – ≥ 4 µg/mL) (K191766)
Similarities		
Intended Use	VITEK® 2 AST-Gram Negative Ceftazidime 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 Ceftazidime is a quantitative test. Ceftazidime 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:** *Citrobacter* species *Enterobacter* species *Escherichia coli*	VITEK® 2 AST-Gram Negative Eravacycline 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 Eravacycline is a quantitative test. Eravacycline 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:** *Citrobacter freundii* *Enterobacter cloacae* *Escherichia coli*

Item	Device: VITEK® 2 AST-Gram Negative Ceftazidime (≤0.5 - ≥32 µg/mL)	Predicate: VITEK® 2 AST-GN Eravacycline (≤ 0.12 – ≥ 4 µg/mL) (K191766)
Similarities		
	Klebsiella species *Proteus mirabilis* *Proteus vulgaris* *Pseudomonas aeruginosa* *Serratia* species ***In vitro* data are available, but clinical significance is unknown:** *Acinetobacter* species *Citrobacter koseri (*formerly *Citrobacter diversus)* *Citrobacter freundii* *Providencia* species *(*including *Providencia rettgeri)* *Salmonella* species *Shigella* species *Yersinia enterocolitica* 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.	*Klebsiella oxytoca* *Klebsiella pneumoniae* ***In vitro* data are available, but clinical significance is unknown:** *Citrobacter koseri* *Klebsiella (Enterobacter) aerogenes* 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 microorganisms	Same
Inoculum	Saline suspension of organism	Same
Test Card	Gram Negative (AST-GN) Susceptibility Card	Same
Analysis Algorithms	Growth Pattern Analysis	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Differences		
Antimicrobial Agent	Ceftazidime	Eravacycline
Concentrations	1, 2, 4, 8, 32	0.25, 1, 2, 4

F. Intended Use:

VITEK® 2 AST-Gram Negative Ceftazidime 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 Ceftazidime is a quantitative test. Ceftazidime 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:
Citrobacter species
Enterobacter species
Escherichia coli
Klebsiella species
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Serratia species

***In vitro* data are available, but clinical significance is unknown:**
Acinetobacter species
*Citrobacter koseri (*formerly *Citrobacter diversus)*
Citrobacter freundii
Providencia species *(*including *Providencia rettgeri)*
Salmonella species
Shigella species
Yersinia enterocolitica

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.

G. Performance Overview and Conclusion:

VITEK® 2 AST-GN Ceftazidime 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 Ceftazidime. 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 Ceftazidime 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.

The VITEK® 2 AST-GN Ceftazidime demonstrated acceptable performance as presented in **Table 2** below:

Table 2: VITEK® 2 AST-GN Ceftazidime Performance

Antimicrobial	Comment	Essential Agreement Category				Category Agreement				% Reproducibility
		% Error				% Error				
		%EA	VME	ME	mE	%CA	VME	ME	mE	
Ceftazidime	#, E (Overall)	(1054/1095) 96.3	N/A	N/A	N/A	(1062/1095) 97.0	(9/228) 3.9	(6/863) 0.7	(18/1095) 1.6	97.04
	#, E *Enterobacteriaceae*	(592/605) 97.9	N/A	N/A	N/A	(591/605) 97.7	(0/46) 0.0	(3/557) 0.5	(11/605) 1.8	
	#, E *Pseudomonas aeruginosa*	(400/423) 94.6	N/A	N/A	N/A	(411/423) 97.2	(9/155) 5.8*	(3/268) 1.1	N/A	
	#, E *Acinetobacter* spp.	(54/58) 93.1	N/A	N/A	N/A	(52/58) 89.7	(0/25) 0.0	(0/33) 0.0	(6/58) 10.3	
	* The overall categorical very major error rate for Ceftazidime when testing *Pseudomonas aeruginosa* with the VITEK ®2 system was 5.8% (9/155). The MIC values of five of the nine very major errors were one doubling dilution from the MIC value obtained from the reference method. Based on the essential agreement and lack of an intermediate breakpoint for ceftazidime with *P. aeruginosa*, the adjusted very major error rate for *P. aeruginosa* is 2.6% (4/155). Seven of the nine very major errors had MIC values of 8 µg/mL; therefore, alternative testing is required prior to reporting results *for P. aeruginosa* when the VITEK® 2 MIC value is 8 µg/mL. NOTES: VITEK® 2 AST-Gram Negative Ceftazidime values tended to be in exact agreement or at least one doubling dilution lower when testing *Yersinia enterocolitica* compared to the CLSI reference broth microdilution. A limited number of *Acinetobacter* isolates were available for testing with the manual dilution. Of the 18 isolates tested, 8 had MIC values that were not evaluable for essential agreement. Of the 10 evaluable MIC values, there were 2 minor categorical errors that were not in essential agreement.									

Key:

# = US Food and Drug Administration 510(k) cleared
E = External performance data

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.