December 19, 2017

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

Re: K172944
Trade/Device Name: VITEK 2 AST-GN Ceftazidime/Avibactam (≤0.12 – ≥16 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: September 25, 2017
Received: September 26, 2017

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 For

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172944

Device Name
VITEK® 2 AST-GN Ceftazidime/Avibactam (≤0.12 – ≥16 µg/mL)

Indications for Use *(Describe)*
VITEK® 2 Gram Negative Ceftazidime/Avibactam 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 Gram Negative Ceftazidime/Avibactam is a quantitative test. Ceftazidime/Avibactam 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:
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

The following *in vitro* data are available, but clinical significance is unknown:
Citrobacter koseri
Enterobacter aerogenes
Morganella morganii
Providencia stuartii
Serratia marcescens

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp. and clinically significant yeast.

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.

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510(k) SUMMARY

VITEK® 2 AST-GN Ceftazidime/Avibactam

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:	September 25, 2017

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-GN Ceftazidime/Avibactam (≤ 0.12 – ≥ 16 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/Avibactam
C. Predicate Device:	VITEK® 2 AST-GN Ceftolozane/Tazobactam (≤0.25 - ≥ 32 µg/ml) (K161510)

D. 510(k) Summary:

VITEK® 2 Gram Negative Ceftazidime/Avibactam 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 Gram Negative Ceftazidime/Avibactam is a quantitative test. Ceftazidime/Avibactam has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

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Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

The following *in vitro* data are available, but clinical significance is unknown:
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Serratia marcescens

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp. and clinically significant yeast.

The antimicrobial presented in VITEK® 2 AST-GN 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 isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK® 2 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 antimicrobial contained on the card.

VITEK® 2 AST-GN Ceftazidime/Avibactam 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/Avibactam. 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/Avibactam 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/Avibactam (≤ 0.12 – ≥ 16 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for VITEK® 2 AST-GN Ceftazidime/Avibactam (≤ 0.12 – ≥ 16 µg/mL)

	% Essential Agreement	**% Category Agreement***
	(EA)	(CA)
Overall Performance (with the reference method)	94.5	98.7

* The overall categorical major error rate for *Enterobacteriaceae* and *Pseudomonas aeruginosa* combined was 1.4% (14/998). Nine (9) major errors were one dilution apart from the reference method and as such fall within essential agreement. Based on the essential agreement, and the lack of an intermediate breakpoint for Ceftazidime/Avibactam, the adjusted categorical major error rate is 0.5% (5/998).

Reproducibility and Quality Control demonstrated acceptable results.