February 14, 2020

BioMerieux, Inc.
Esther Hernandez
Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, Missouri 63042

Re: K193567
Trade/Device Name: VITEK 2 AST- Gram Negative Polymyxin B (<=0.25 - >=16 ug/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 Esther Hernandez:

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 Polymyxin B

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Esther Hernandez Regulatory Affairs Specialist
Phone Number:	314 -731-8841
Fax Number:	314-731-8689
Date of Preparation:	December 19, 2019

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST- Gram Negative Polymyxin B (≤ 0.25 – ≥ 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 Polymyxin B

C. Predicate Device: VITEK® 2 AST-GN Delafloxacin (K183524)

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 Polymyxin B has the following concentrations in the card: 0.125, 0.5, 2 and 8 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 Polymyxin B when compared to the predicate device, VITEK 2 AST-GN Delafloxacin (K183524), are described in the following table.

Item	Device: VITEK® 2 AST-GN Polymyxin B	Predicate: VITEK® 2 AST-G N Delafloxacin (K183524)
Similarities		
Intended Use	VITEK® 2 AST-Gram Negative Polymyxin B 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 Polymyxin B is a quantitative test. Polymyxin B 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> *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.	VITEK® 2 AST-Gram Negative Delafloxacin 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 laborato1y aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK® 2 AST-Gram Negative Delafloxacin is a quantitative test. Delafloxacin 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> *Escherichia coli* *Enterobacter cloacae* *Klebsiella pneumoniae* *Pseudomonas aeruginosa* The VITEK® 2 Gram-negative Susceptibility Card is intended to 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	Polymyxin B	Delafloxacin
Antimicrobial Concentrations	0.125, 0.5, 2, 8	0.06, 0.25, 0.5, 2

F. Intended Use:

VITEK® 2 AST-Gram Negative Polymyxin B 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 Polymyxin B is a quantitative test. Polymyxin B 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:
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.

F. Performance Overview and Conclusion:

VITEK® 2 AST-GN Polymyxin B 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 Polymyxin B. 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 Polymyxin B 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 Polymyxin B demonstrated acceptable performance of 93.9% overall Essential Agreement and 96.6% overall Category Agreement with the reference method. 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.