April 14, 2022

bioMerieux, Inc
Kyle Olney
Regulatory Affairs Specialist
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K214023
Trade/Device Name: VITEK 2 AST-Gram Negative Ciprofloxacin (≤0.06 - ≥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, LTT, LTW
Dated: December 21, 2021
Received: December 22, 2021

Dear Kyle Olney:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K214023

Device Name

VITEK 2 AST-GN Ciprofloxacin (≤ 0.06 – > 4 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Negative Ciprofloxacin (≤ 0.06 – > 4 µg/mL) 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 Ciprofloxacin is a quantitative test. Ciprofloxacin 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 Koseri
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa
Salmonella typhi
Serratia marcescens
Shigella sonnei

In vitro data available but clinical significance is unknown:
Enterobacter aerogenes
Klebsiella oxytoca
Salmonella enteritidis

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.

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510(k) SUMMARY

VITEK® 2 AST-GN Ciprofloxacin

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Kyle J. Olney Regulatory Affairs Specialist
Phone Number:	314 -731-8666
Fax Number:	314-731-8689
Date of Preparation:	December 21, 2021

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-GN Ciprofloxacin (≤ 0.06 – ≥ 4 µg/mL)
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Product Codes:	LON, LTT, and LTW
Common Name:	VITEK® 2 AST-GN Ciprofloxacin

C. Predicate Device: VITEK® 2 GN Eravacycline (K191766)

D. 510(k) Summary:

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).Ciprofloxacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

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 po1tions of a specific antibiotic combined with culture media. The 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 repo1t is generated that contains the MIC value along with the interpretive catego1y result for each antibiotic contained on the card.

E. Substantial Equivalence Information:

VITEK® 2 AST-GN Ciprofloxacin (≤ 0.06 – ≥ 4 µg/mL) is substantially equivalent to VITEK® 2 GN Eravacycline (K191766). A summary of the similarities VITEK® 2 AST-GN Ciprofloxacin (≤ 0.06 – ≥ 4 µg/mL) and VITEK® 2 GN Eravacycline (K191766). are provided in **Table 1** below:

Table 1: Substantial Equivalence

New Device and Predicate Device:	Device: VITEK® 2 AST-GN Ciprofloxacin (0.06 – ≥4 µg/mL)	Predicate: VITEK® 2 AST-GN Eravacycline (K191766)
General Device Characteristic Similarities		
Intended Use/Indications for Use	VITEK® 2 AST-Gram Negative Ciprofloxacin 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 Ciprofloxacin is a quantitative test. 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 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. 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.

New Device and Predicate Device:	Device: VITEK® 2 AST-GN Ciprofloxacin (0.06 – ≥4 µg/mL)	Predicate: VITEK® 2 AST-GN Eravacycline (K191766)
General Device Characteristic Similarities		
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	Ciprofloxacin	Eravacycline
Antimicrobial Concentrations	0.06, 0.12, 0.5, 1	0.25, 1, 2, 4
Indications for Use	Ciprofloxacin 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 koseri* *Citrobacter freundii* *Enterobacter cloacae* *Escherichia coli* *Klebsiella pneumoniae* *Morganella morganii* *Proteus mirabilis* *Proteus vulgaris* *Providencia rettgeri* *Providencia stuartii* *Pseudomonas aeruginosa* *Salmonella typhi* *Serratia marcescens* *Shigella sonnei* *In vitro* data available but clinical significance is unknown: *Klebsiella aerogenes*	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* *Klebsiella oxytoca* *Klebsiella pneumoniae* *In vitro* data are available, but clinical significance is unknown: *Citrobacter koseri* *Klebsiella (Enterobacter) aerogenes*

	Klebsiella oxytoca *Salmonella enteritidis*	

F. Intended Use:

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.

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.

Ciprofloxacin 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 koseri
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella pneumoniae
Morganella morganii
Proteus mirabilis
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Pseudomonas aeruginosa

Salmonella typhi
Serratia marcescens
Shigella sonnei

In vitro data available but clinical significance is unknown:
Klebsiella aerogenes
Klebsiella oxytoca
Salmonella enteritidis

G. Performance Overview and Conclusion:

To update the VITEK 2 Gram Negative Ciprofloxacin device labeling to include updated FDA-recognized breakpoints for *Enterobacterales (*excludes *Salmonella)* and *Pseudomonas aeruginosa* as published in the FDA STIC website. Breakpoints for *Salmonella*, as well as the FDA indications for use remain unchanged. Previously obtained QC and reproducibility data is applicable to this reevaluation.

VITEK® 2 AST-GN Ciprofloxacin (≤ 0.06 – ≥4 µg/mL) 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 Ciprofloxacin. 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 Ciprofloxacin 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. VITEK® 2 AST-GN Ciprofloxacin demonstrated acceptable performance of 97.2% overall Essential Agreement and 95.5% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.

The VITEK® 2 AST-GN Ciprofloxacin (≤ 0.06 – ≥4 µg/mL) demonstrated acceptable performance as presented in **Table 2** below:

Table 2: VITEK® 2 AST-GN Ciprofloxacin Performance

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp[1]	Comment[2]	Essential Agreement %				Category Agreement % Error				% Reproducibility
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Ciprofloxacin	CIP	cip02n	CLSI (FDA)*	#, E *Enterobacteriaceae* (excluding *Salmonella*)	97.9	N/A	N/A	N/A	95.2	0.4	0.1	4.6	100
				#, E *Pseudomonas aeruginosa*	93.6	N/A	N/A	N/A	96.6	0.0	0.0	3.4	
				#, E *Salmonella*	100.0	N/A	N/A	N/A	100.0	0.0	0.0	0.0	

*VITEK® 2 Systems Ciprofloxacin MIC values for *Enterobacter cloacae*, *Escherichia coli, Klebsiella pneumoniae*, *Proteus vulgaris*, *Providencia stuartii, Pseudomonas aeruginosa* and *Salmonella* species tended to be in exact agreement or at least one doubling dilution higher than the reference method.

*For specific information regarding susceptibility test interpretive criteria and associated test methods and quality controls standards recognized by FDA for this drug, please see: https://www.fda.gov/STIC.

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

Quality Control demonstrated acceptable results.

H. References

1. MacLow1y, J.D. and Marsh, H.H., Semi-automatic Microtechnique for Serial Dilution Antibiotic Sensitivity Testing in the Clinical laborato1y, Journal ofLaborato1y Clinical Medicine, 72:685-687, 1968.
2. Gerlach, E.H., Microdilution 1: A Comparative Study, p. 63-76. CU1Tent 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.