January 27, 2023

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

Re: K220803
Trade/Device Name: VITEK 2 AST-Gram Positive Moxifloxacin (≤ 0.25 - ≥ 8 µg/ml), VITEK 2 AST-GP Moxifloxacin (≤ 0.25 - ≥ 8 µg/mL), VITEK 2 AST-GP Moxifloxacin
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: March 17, 2022
Received: March 18, 2022

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K220803

Device Name

VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL)

Indications for Use *(Describe)*

VITEK® 2 AST-Gram Positive Moxifloxacin is designed for antimicrobial susceptibility testing of Gram positive microorganisms 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 Positive Moxifloxacin is a quantitative test. Moxifloxacin 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:
*Enterococcus faecalis*
*Staphylococcus aureus*

*In vitro* data are available, but their clinical significance is unknown:
*Staphylococcus epidermidis*

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* 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.***

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## 510(k) SUMMARY

## VITEK® 2 AST Gram-Positive Moxifloxacin (≤0.25 - ≥8 µg/mL)

### A. 510(k) Submission Information:

| | |
|---|---|
| Submitter's Name: | bioMérieux, Inc. |
| Address: | 595 Anglum Road<br>Hazelwood, MO 63042 |
| Contact Person: | Cherece L. Jones<br>Staff Regulatory Affairs Specialist |
| Phone Number: | 314 -731-8684 |
| Fax Number: | 314-731-8689 |
| Date of Preparation: | March 16, 2022 |

### B. Device Name:

| | |
|---|---|
| Formal/Trade Name: | VITEK® 2 AST Gram-Positive Moxifloxacin (≤0.25 - ≥8 µg/mL) |
| Classification Name: | 21 CFR 866.1645<br>Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System |
| Product Code(s): | LON, LTT, LTW |
| Common Name: | VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) |

### C. Predicate Device:

VITEK® 2 AST- GP Moxifloxacin (≤0.25 - ≥8 µg/mL) (K032399)

### 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 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.

## E. Substantial Equivalence Information:

VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) is substantially equivalent to VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) (K032399). A summary of the similarities and differences of the VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) and VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) (K032399) are provided in **Table 1** below:

**Table 1: Substantial Equivalence**

| New Device and Predicate Device: | New Device: VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) | Predicate Device: VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) (K032399) |
|---|---|---|
| **General Device Characteristic Similarities** | | |
| **Intended Use/Indications for Use** | VITEK® 2 AST-Gram Positive Moxifloxacin is designed for antimicrobial susceptibility testing of Gram positive microorganisms 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 Positive Moxifloxacin is a quantitative test. Moxifloxacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.<br><br><u>Active both *in vitro* and in clinical infections:</u><br>*Enterococcus faecalis* | VITEK 2® Gram Positive Moxifloxacin is designed for antimicrobial susceptibility testing of *Staphylococcus aureus* (methicillin-susceptible strains only). It is intended for use with the VITEK 2® System as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.<br><br>The VITEK® 2 Gram Positive Susceptibility Card is intended for use with the VITEK® 2 System in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus spp.*, *Enterococcus spp.*, and *S. agalactiae* to antimicrobial agents when used as instructed in the Online Product |

| New Device and Predicate Device: | New Device: VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) | Predicate Device: VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) (K032399) |
|---|---|---|
| **General Device Characteristic Similarities** | | |
| | *Staphylococcus aureus*<br><br>*In vitro* data are available, but their clinical significance is unknown:<br>*Staphylococcus epidermidis*<br><br>The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed. | Information. |
| **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 |
| **Antimicrobial Agent** | Moxifloxacin | Same |
| **Concentrations** | 0.25, 2, and 8 | Same |
| **Inoculum** | Saline suspension of organism | Same |
| **Test Card** | Gram-Positive (AST-GP) Susceptibility Card | Same |
| **Analysis Algorithms** | Discriminant Analysis | Same |
| **Instrument** | VITEK® 2 and VITEK® 2 Compact Systems | Same |
| **General Device Characteristic Differences** | | |
| **Breakpoints** | *Enterococcus faecalis*<br>S ≤ 1, I 2, ≥ 4R<br>*Staphylococcus spp.*<br>S ≤ 0.5, I 1, ≥ 2R | *Staphylococcus spp.*<br>S ≤ 2, I 4, ≥ 8R |

## F. Intended Use:

VITEK® 2 AST-Gram Positive Moxifloxacin is designed for antimicrobial susceptibility testing of Gram positive microorganisms 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 Positive Moxifloxacin is a quantitative test.

Moxifloxacin 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:
*Enterococcus faecalis*
*Staphylococcus aureus*

*In vitro* data are available, but their clinical significance is unknown:
*Staphylococcus epidermidis*

The VITEK® 2 Gram-positive Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Staphylococcus* spp., *Enterococcus* spp., and *S. agalactiae* to antimicrobial agents when used as instructed.

**G. Performance Overview and Conclusion:**

VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) demonstrated substantially equivalent performance when compared with the CLSI agar dilution 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-GP Moxifloxacin. 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 AST-GP Moxifloxacin by comparing its performance with the CLSI agar dilution reference method incubated at 16-20 hours. The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

The VITEK® 2 AST-GP Moxifloxacin (≤0.25 - ≥8 µg/mL) demonstrated acceptable performance as presented in **Table 2** below:

## Table 2: VITEK® 2 AST-GP Moxifloxacin Performance

| Antimicrobial | Antimicrobial Code | Antibiotic Version | Bp[1] | Comment[2] | Essential Agreement Category | | | | Category Agreement | | | | % Reproducibility |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | % Error | | | | % Error | | | | |
| | | | | | %EA | VME | ME | mE | %CA | VME | ME | mE | |
| Moxifloxacin | MXF | (mxf02n) | FDA (CLSI) | #, E *Enterococcus faecalis* | (152/154) 98.7 | N/A | N/A | N/A | (153/154) 99.4 | (0/43) 0.0 | (0/110) 0.0 | (1/154) 0.6 | 100.0 |
| | | | | #, E *Staphylococcus spp.* | (329/331) 99.4 | N/A | N/A | N/A | (314/331) 94.9 | (1/152) 0.7 | (0/163) 0.0 | (16/331) 4.8 | |
| The VITEK 2 AST-GP Moxifloxacin MIC values tended to be in exact agreement or at least one doubling dilution higher when testing *Enterococcus faecalis and Staphylococcus aureus* compared to the CLSI reference agar dilution method. | | | | | | | | | | | | | |

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

- Quality Control demonstrated acceptable results.

**Table 3: CLSI® Quality Control Organisms VITEK® 2 Results**

| Antimicrobic | Code | *E. faecalis* ATCC® 29212™ | *S. aureus* ATCC® 29213™ |
|---|---|---|---|
| Moxifloxacin | mxf02n | ≤ 0.25 - 0.5◊ (FDA/CLSI QC range is 0.06 – 0.5) | ≤ 0.25◊ (FDA/CLSI QC range is 0.03-0.12 ug/mL) |

Numerical values are expressed in µg/mL.
◊ Does not include the full CLSI/FDA-recommended dilution range for QC testing with this organism.

## 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.