



August 21, 2025

bioMerieux, Inc.  
Jared Bronson  
Regulatory Specialist  
595 Anglum Rd.  
Hazelwood, Missouri 63042

Re: K251579

Trade/Device Name: VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1 - \geq 32$   $\mu\text{g/mL}$ )

Regulation Number: 21 CFR 866.1645

Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System

Regulatory Class: Class II

Product Code: LON

Dated: May 22, 2025

Received: May 23, 2025

Dear Jared Bronson:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these

requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto: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  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K251579

Device Name  
VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1$ - $\geq 32$   $\mu\text{g/mL}$ )

### Indications for Use (Describe)

VITEK 2 AST-Gram Negative Cefazolin is designed for antimicrobial susceptibility testing of Gram-negative bacilli and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.

VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1$ - $\geq 32$   $\mu\text{g/mL}$ ) is a quantitative test. Testing is indicated for Enterobacteriales (from infections other than uncomplicated UTI) as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1$ - $\geq 32$   $\mu\text{g/mL}$ ) has demonstrated acceptable performance with the following organisms:

Enterobacteriales (Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Klebsiella oxytoca, Citrobacter koseri)

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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 Cefazolin

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

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jared Bronson Regulatory Affairs Specialist
Phone Number:	314 -731-8500
Fax Number:	314-731-8689
Date of Preparation:	August 21, 2025

#### B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Gram Negative Cefazolin ( $\leq 1 - \geq 32$ $\mu\text{g/mL}$ )
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON
Common Name:	VITEK® 2 AST-GN Cefazolin

**C. Predicate Device:** VITEK® 2 AST-Gram Negative Cefazolin (K222073)

#### 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<sup>(1)</sup> and Gerlach<sup>(2)</sup>. The VITEK® 2 AST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique<sup>(3)</sup>.

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 Cefazolin has the following concentrations in the card: 1, 2, and 8 (equivalent standard method concentration by efficacy in µg/mL).

**E. Substantial Equivalence Information**

The similarities and differences of the VITEK® 2 AST-GN Cefazolin when compared to the predicate device, VITEK® 2 AST-GN Cefazolin (K222073), are described in the following table. The only difference between both devices are the Indications for Use. The below table provides the similarities and differences:

<b>Item</b>	<b>Device: VITEK® 2 AST-GN Cefazolin</b>	<b>Predicate: VITEK® 2 AST-GN Cefazolin (K222073)</b>
<b>Similarities</b>		
<b>Intended Use</b>	<p>VITEK 2 AST-Gram Negative Cefazolin is designed for antimicrobial susceptibility testing of Gram-negative bacilli and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of <i>in vitro</i> susceptibility to antimicrobial agents.</p> <p>VITEK 2 AST-Gram Negative Cefazolin (≤1-≥32 µg/mL) is a quantitative test. Testing is indicated for Enterobacterales (from infections other than uncomplicated UTI) as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).</p> <p>The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an <i>in vitro</i> test to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents when used as instructed.</p>	<p>VITEK® 2 AST-Gram Negative Cefazolin 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 <i>in vitro</i> susceptibility to antimicrobial agents.</p> <p>The VITEK® 2 Gram Negative Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an <i>in vitro</i> test to determine the susceptibility of clinically significant aerobic gram-negative bacilli to antimicrobial agents when used as instructed.</p>

<b>Test Methodology</b>	Automated antimicrobial susceptibility test for use with the VITEK <sup>®</sup> 2 and VITEK <sup>®</sup> 2 Compact Systems to determine the <i>in vitro</i> susceptibility of microorganisms	Same
<b>Inoculum</b>	Saline suspension of organism	Same
<b>Test Card</b>	Gram Negative (AST-GN) Susceptibility Test Card	Same
<b>Analysis Algorithms</b>	Growth Pattern Analysis	Same
<b>Antimicrobial Agent</b>	Cefazolin	Same
<b>Antimicrobial Concentrations</b>	1, 2, 8	Same
<b>Breakpoints for <i>Enterobacterales</i></b>	<i>Enterobacterales</i> : ≤2 (S), 4 (I), ≥8 (R)	Same
<b>Differences</b>		
<b>Indications for Use</b>	VITEK 2 AST-Gram Negative Cefazolin (≤1-≥32 µg/mL) has demonstrated acceptable performance with the following organisms: <i>Enterobacterales (Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae, Klebsiella oxytoca, Citrobacter koseri)</i>	Cefazolin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial  <u>Active <i>in vitro</i> and in clinical infections:</u> <i>Escherichia coli</i> <i>Proteus mirabilis</i>
<b>Instruments*</b>	VITEK <sup>®</sup> 2, VITEK <sup>®</sup> 2 Compact, and VITEK <sup>®</sup> 2 Compact Pro Systems	VITEK <sup>®</sup> 2 and VITEK <sup>®</sup> 2 Compact Systems

\* At the time of the original clearance (K222073), the VITEK 2 AST-GN Cefazolin card (cz05n) was not intended to be used on the VITEK2 COMPACT PRO Instrument because the instrument was not yet available. The current clearance (K251579) of the VITEK 2 AST-GN Cefazolin card (cz05n) allows testing with the VITEK2 COMPACT PRO Instrument which was cleared in K234012.

## F. Intended Use:

VITEK 2 AST-Gram Negative Cefazolin is designed for antimicrobial susceptibility testing of Gram-negative bacilli and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.

VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1$ - $\geq 32$   $\mu\text{g/mL}$ ) is a quantitative test. Testing is indicated for Enterobacterales (from infections other than uncomplicated UTI) as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

VITEK 2 AST-Gram Negative Cefazolin ( $\leq 1$ - $\geq 32$   $\mu\text{g/mL}$ ) has demonstrated acceptable performance with the following organisms:

Enterobacterales (*Escherichia coli*, *Proteus mirabilis*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, *Citrobacter koseri*)

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:

VITEK<sup>®</sup> 2 AST-GN Cefazolin 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 (Traditional 510[k]) presents data in support of VITEK<sup>®</sup> 2 AST-GN Cefazolin. 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<sup>®</sup> 2 AST-GN Cefazolin by comparing its performance with the CLSI broth microdilution reference method incubated for 16-20 hours. The data is representative of performance on both the VITEK<sup>®</sup> 2 and VITEK<sup>®</sup> 2 Compact instrument platforms.

VITEK<sup>®</sup> 2 AST-GN Cefazolin demonstrated acceptable performance of 97.6% overall Essential Agreement and 85.1% overall Category Agreement with the reference method.

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp1	Comment	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Cefazolin	CZ	cz05n	CLSI (FDA)	#, E Enterobacterales	(840/862) 97.5	N/A	N/A	N/A	(748/862) 86.8	(1/299) 0.3	(3/414) 0.7	(110/862) 12.8	100

					<p>The low Category Agreement as listed above is mainly the result of one doubling dilution minor errors with <i>E. coli</i> and <i>P. mirabilis</i>.</p> <p>VITEK 2 AST-Gram Negative Cefazolin MIC values tended to be in exact agreement or at least one doubling dilution higher when testing <i>Klebsiella oxytoca</i> by VITEK 2 auto-dilution method compared to the CLSI reference broth microdilution method.</p> <p>VITEK 2 AST-Gram Negative Cefazolin MIC values tended to be in exact agreement or at least one doubling dilution lower when testing <i>Klebsiella pneumoniae</i> by VITEK 2 manual-dilution method compared to the CLSI reference broth microdilution method.</p>
--	--	--	--	--	---

<sup>1</sup>Abbreviations — Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result).

# = US Food and Drug Administration 510(k) cleared

CLSI = Clinical and Laboratory Standards Institute

E = External performance data

N/A = Not applicable

Reproducibility and Quality Control demonstrated acceptable results.

#### H. Limitations:

A VITEK® 2 AST card cannot be used with a direct clinical specimen or sample or other sources containing mixed flora. Any change or modification in the procedure may affect the results.

A result for an antibiotic/organism combination, which may have a limitation, may be suppressed from reporting. This can be accomplished through the use of bioART rules in the VITEK® 2 Systems software. Refer to the software user manual for instructions.

Due to the occurrence of minor errors (resulting in a category agreement below 90% for the following species), perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination: Cefazolin (cz05n): *K. oxytoca* when the VITEK2 MIC is 8 µg/mL

The ability of the AST card to detect resistance with the following combination(s) is unknown because resistant strains were not available at the time of comparative testing: Cefazolin (cz05n): *Citrobacter koseri*

#### I. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. VITEK® 2 AST-GN Cefazolin (≤1–≥32 µg/mL) is substantially equivalent to VITEK® 2 AST-GN Cefazolin (K222073).

**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 Antimicrobial Susceptibility Test, Principles and Practices*, Lea and Febiger, Philadelphia, PA, 1976.