



April 15, 2026

bioMerieux, Inc.
Jennifer McMurtrie
Staff Regulatory Affairs Professional
595 Anglum Rd., Hazelwood, MO 62042 USA

Re: K260282

Trade/Device Name: VITEK 2 AST-*Streptococcus* Inducible Clindamycin Resistance
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: January 29, 2026
Received: January 30, 2026

Dear Jennifer McMurtrie:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,


Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch 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)
K260282

Device Name
VITEK 2 AST-Streptococcus Inducible Clindamycin Resistance

Indications for Use (Describe)

VITEK 2 AST Streptococcus Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of Streptococcus species 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 Streptococcus Inducible Clindamycin Resistance is a qualitative test. Testing is indicated for Streptococcus pneumoniae and Streptococcus spp. β -hemolytic group.

VITEK 2 AST Streptococcus Inducible Clindamycin Resistance has demonstrated acceptable performance with the following organisms:

Streptococcus pneumoniae

Streptococcus spp. β -hemolytic group (Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus canis,

Streptococcus dysgalactiae equisimilis, Streptococcus equi zooepidemicus)

The VITEK 2 Streptococcus Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of Streptococcus pneumoniae, beta-hemolytic Streptococcus, and Viridans Streptococcus 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-ST Inducible Clindamycin Resistance icr02n

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jennifer McMurtrie Regulatory Affairs Specialist
Phone Number:	618-946-7428
Fax Number:	314-731-8689
Date of Preparation:	January 28, 2026

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Streptococcus Inducible Clindamycin Resistance
Classification Name:	21 CFR 866.1645 Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System Product Code LON 21 CFR 866.1640 Antimicrobial Susceptibility Test Powder Product Code LTT LTW
Common Name:	VITEK® 2 AST-ST Inducible Clindamycin Resistance

C. Predicate Device: VITEK® 2 Streptococcus Inducible Clindamycin Resistance (K111909)

D. Device Description:

The principle of the VITEK® 2 AST-ST cards is based on the microdilution minimum inhibitory concentration (MIC) technique reported by MacLowry and Marsh⁽¹⁾ and Gerlach⁽²⁾. The VITEK® 2 AST-ST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique⁽³⁾.

Each VITEK® 2 AST-ST 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 or has a manual filling, sealing and loading operation (Compact instruments). 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.

The VITEK® 2 Streptococcus Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*, Beta Hemolytic Streptococcus, and Viridans *Streptococcus* to antimicrobial agents when used as instructed.

VITEK® 2 ST Inducible Clindamycin Resistance has the following concentrations in the card:
Clindamycin 0.5µg/mL Clindamycin/Erythromycin 0.25/0.5 µg/mL.

NOTE: VITEK 2 Systems is in reference to the VITEK® 2, VITEK® 2 Compact, and VITEK® Compact PRO.

E. Substantial Equivalence Information

The similarities and differences of the VITEK 2 ST Inducible Clindamycin Resistance when compared to the predicate device, VITEK® 2 Streptococcus Inducible Clindamycin Resistance (K111909) are described in the following table. The only difference between both devices are the Antimicrobial Agent Concentrations Only and the test card type. The below table provides the similarities and differences:

Item	Device: VITEK® 2 AST-ST Inducible Clindamycin Resistance	Predicate: VITEK® 2 Streptococcus Inducible Clindamycin Resistance (K111909)
Similarities		
Intended Use	<p>VITEK 2 AST Streptococcus Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of Streptococcus species and is intended for use with the VITEK 2 Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents.</p> <p>VITEK 2 AST Streptococcus Inducible Clindamycin Resistance is a qualitative test. Testing is indicated for <i>Streptococcus pneumoniae</i> and <i>Streptococcus</i> spp. β-hemolytic group.</p> <p>The VITEK 2 <i>Streptococcus</i> 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 <i>Streptococcus pneumoniae</i>, <i>beta-hemolytic Streptococcus</i>, and <i>Viridans Streptococcus</i> to antimicrobial agents when used as instructed.</p>	<p>VITEK® 2 AST-ST Inducible Clindamycin Resistance is designed for antimicrobial susceptibility testing of Streptococcus agalactiae and Staphylococcus pyogenes. VITEK® 2 AST-ST Inducible Clindamycin Resistance is a qualitative test. It 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.</p> <p>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 yeast.</p>
Test Methodology	Automated qualitative antimicrobial susceptibility test for use with the VITEK 2 Systems to determine the <i>in vitro</i> susceptibility of Streptococcus species.	Same
Inoculum	Saline suspension of organism	Same
Test Card	VITEK 2 Streptococcus Susceptibility Card	Same
Analysis Algorith	Discriminant Analysis	Same

ms		
Antimicrobial Agent Concentrations	Clindamycin 0.5µg/mL Clindamycin/Erythromycin 0.25/0.5 µg/mL	Clindamycin 0.5µg/mL Clindamycin/Erythromycin 0.25/0.5µg/mL
Breakpoints	POS/NEG	POS/NEG
Differences		
Indications for Use	Testing is indicated for <i>Streptococcus pneumoniae</i> and <i>Streptococcus</i> spp. β-hemolytic group. VITEK 2 AST Streptococcus Inducible Clindamycin Resistance has demonstrated acceptable performance with the following organisms: <i>Streptococcus pneumoniae</i> <i>Streptococcus</i> spp. β-hemolytic group (<i>Streptococcus pyogenes</i> , <i>Streptococcus agalactiae</i> , <i>Streptococcus canis</i> , <i>Streptococcus dysgalactiae equisimilis</i> , <i>Streptococcus equi zooepidemicus</i>)	Active in vitro and in clinical infections: <i>Streptococcus agalactiae</i> <i>Streptococcus pyogenes</i>
Instrument	VITEK® 2, VITEK® 2 Compact, and VITEK® COMPACT PRO	VITEK® 2 and VITEK® 2 Compact

F. Intended Use:

VITEK 2 AST Streptococcus Inducible Clindamycin Resistance (pos/neg) is designed for antimicrobial susceptibility testing of *Streptococcus* species and is intended for use with the VITEK(R) 2 Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 AST Streptococcus Inducible Clindamycin Resistance (pos/neg) is a qualitative test

The VITEK 2 Streptococcus Susceptibility Card is intended for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of *Streptococcus pneumoniae*,

beta-hemolytic *Streptococcus*, and Viridans *Streptococcus* to antimicrobial agents when used as instructed.

G. Performance Overview:

The VITEK® 2 AST-Streptococcus card is used in laboratories to determine the test results (positive or negative) for the following: inducible clindamycin resistance test (icr02n).

Inducible Clindamycin Resistance (icr02n): Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic. ICR is a disk diffusion screen test (D test) used in clinical laboratories to determine macrolide-mediated inducible clindamycin resistance.

Clinical and challenge isolates were tested with VITEK® 2 icr02n and were compared to the reference values of the D-test method containing clindamycin and erythromycin disks.

Performance Characteristics Antimicrobial Susceptibility Testing

Antimicrobial	Antimicrobial Code	Antibiotic Version	Bp ²	Comment	Essential Agreement				Category Agreement				% Reproducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Inducible Clindamycin Resistance	ICR	icr02n	CLSI (FDA)	#, E <i>Streptococcus pneumoniae</i>	N/A	N/A	N/A	N/A	(306/310) 98.7	(0/0) 0.0	(4/310) 1.3	N/A	100
				#, E <i>Streptococcus spp. β-hemolytic group</i>	N/A	N/A	N/A	N/A	(280/283) 98.9	(0/42) 0.0	(3/241) 1.2	N/A	

1 The VITEK® 2 AST antimicrobial code may not match the BCI host code. Please contact your local bioMérieux representative for correct BCI code.

2 Abbreviations — Bp = breakpoint committee; EA = essential 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).

Key:
 # = US Food and Drug Administration 510(k) cleared
 CLSI® = Clinical and Laboratory Standards Institute
 E = External performance data

Based upon combined clinical and automatic challenge results for VITEK® 2 AST-ST icr02n, the overall performance met the expected FDA acceptance criteria for *Streptococcus pneumoniae* and Beta-hemolytic *Streptococcus*. Reproducibility and Quality Control demonstrated acceptable results.

H. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. VITEK® 2 AST-Streptococcus Inducible Clindamycin Resistance) is substantially equivalent to VITEK® 2 AST-ST Inducible Clindamycin Resistance (K111909).

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.