March 14, 2025

bioMerieux Inc.
Craig Buehler
Sr. Regulatory Affairs Specialist - Microbiology
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K234012
Trade/Device Name: Vitek Compact Pro
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: December 19, 2023
Received: December 19, 2023

Dear Craig Buehler:

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.

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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234012

Device Name
VITEK® COMPACT PRO

Indications for Use *(Describe)*

The VITEK® COMPACT PRO is intended for the automated quantitative and/or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp., and yeast.

The VITEK® COMPACT PRO is also intended for the automated identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and nonfermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.

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.

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510(k) SUMMARY

VITEK® COMPACT PRO

510(k) Submission Information:

Submitter's Name:	bioMerieux, Inc.
Manufacturer Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Craig Buehler Sr. Regulatory Affairs Specialist – Microbiology
Phone Number:	314 -731-8358
Fax Number:	314-731-8689
Date of Preparation:	March 5, 2025

B. Device Name:

Formal/Trade Name:	VITEK® COMPACT PRO
Regulation:	21 CFR 866.1645
Classification Name:	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
Common Name:	VITEK® COMPACT PRO

C. Predicate Device: VITEK® 2 SYSTEM (PMA Number N50510 Supplement Number S082)

D. 510(k) Summary:

The VITEK® COMPACT PRO is intended for laboratory use by professional users who are trained in microbiology and good laboratory practices.

This 510(k) submission introduces the VITEK® COMPACT PRO. The VITEK® COMPACT PRO instrument is an automated instrument designed for use in low-to medium-range applications in both Clinical and Industry laboratories. The instrument performs sample well filling, incubation, and optical readings. The VITEK® COMPACT PRO instrument is a two-step automated instrument for:

- Hydrating reagents with sample inoculum
- Pre-processing cards, incubating cards, and continuous reading for growth

The VITEK® 2 Systems Software receives the instrument optical readings and performs analysis. The instrument then ejects the completed reagent card into the waste area for disposal.

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The system includes a VITEK® COMPACT PRO instrument with an internal computer, monitor, keyboard, mouse, handheld barcode scanner, and USB hub. The software provided with the internal computer includes analysis and limited data management programs. A bidirectional computer interface (BCI) may transfer results automatically to the user's laboratory information system (LIS).

A Quality Control System is available to track the quality control results of the test cards. The Advanced Expert System™ (Clinical Use) is available to provide online, systematic validation of results and interpretation of resistant phenotypes found during susceptibility testing.

Intended Use:

The VITEK® COMPACT PRO is intended for the automated quantitative and/or qualitative antimicrobial susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp., and yeast.

The VITEK® COMPACT PRO is also intended for the automated identification of most clinically significant anaerobic organisms and Corynebacterium species, fermenting and nonfermenting Gram-negative bacilli, Gram-positive organisms, fastidious organisms, and yeasts and yeast-like organisms.

Comparison Table:

Function	**Device: VITEK® COMPACT PRO**	**Predicate: VITEK 2 SYSTEM (N50510 Supplement S082)**
Intended Use	See Above	Same
Reagents	VITEK® 2 AST 64-well cards and VITEK® 2 ID 64-well cards	Same
Type of Sample	Isolated colony from appropriate growth media	Same
Test set up	VITEK® FLEXPREP	Smart Carrier Station or VITEK FLEXPREP
Card capacity	15 cards with licenses to expand to 30 and 60 cards	60 for VITEK 2 and 120 for VITEK 2 XL
Cassette	10 cards/cassette	15 cards/cassette
Stages of Operation	Sample Preparation, Incubation and Optical Reading	Same
Reagent Processing		
Card Inoculum	Prepared with an approved VITEK® inoculation preparation device	Same
Filling Process	Vacuum Fill Process	Same
Sealer Process for test cards	Automated, heat seal	Same
AST dilution preparation	Manual	Manual and Auto
Incubation and Optical Reading		
Reader Optic for AST Cards	660 nm optics	Same
Reader Optic for ID Cards	(428/568/680) nm optics, depending on the card's well map	Same

Function	Device: VITEK® COMPACT PRO	Predicate: VITEK 2 SYSTEM (N50510 Supplement S082)
Control mechanism	Microprocessor-controlled electromechanical system	Same
Optical calibration	Self-calibrating	Same
Well Reading Frequency	Every 15 minutes	Same
Optical Measurement Algorithm	15 steps per well, taking three readings per step	Same
Incubation	Automated, 35.5^0C +/- 1^0C	Same
Card location during incubation	Carousel	Same
Waste	Automated removal of ejected test cards to waste container	Same
Analysis Interfaces		
Analysis/Algorithms	VITEK 2 System Software algorithms used for analysis	Same
AST Phenotypic Analysis	Advanced Expert System (AES)	Same
Average Time to Result	AST: 8-12 H depending on the bugs/drugs	Same
LIS communication	Bidirectional Computer Interface (BCI)	Same

Summary of System, Biological and Clinical Performance:

The verification and validation testing of the VITEK® COMPACT PRO included biological performance testing, as well as, instrument/software testing.

Verification testing was completed on Beta and Pilot units, which are representative & equivalent to the final instrument design & manufacturing specifications. Results of the VITEK®COMPACT PRO system verification tests (i.e. for instrument, and software/firmware interfaces) were successfully completed and results passed in comparison with the documented requirements. The VITEK®COMPACT PRO verification testing included the VITEK® COMPACT PRO Instrument, the VITEK® firmware, the VITEK® Systems 10.0 software, the VITEK® COMPACT PRO User Interface, and the VITEK Systems Communications protocols. However, knowledge task questions revealed the majority of participants had a good understanding of the VITEK® COMPACT PRO System and the potential risks. The outcome of the testing determined that VITEK® COMPACT PRO has been found to be safe and effective for the intended users, uses, and use environments.

Human Factor Usability was also included as part of the VITEK® COMPACT PRO testing. The overall, session results were favorable with respect to usability. Within the use scenarios, the most common cause of minor usability errors was in the change of workflow (as compared to the VITEK® 2 Systems), and risk of users ignoring warnings in the card processing steps. With appropriate mitigations, the VITEK® COMPACT PRO instrument was found to be safe and effective for the intended users, uses, and use environments.

Prior to the clinical performance evaluation, verification testing included a performance evaluation, which utilized all the VITEK® 2 Antimicrobial Susceptibility Testing – i.e. GN, GP, YS, and ST test card classes.

Quality Control (QC) Testing

The quality control testing evaluated the performance of the VITEK® COMPACT PRO instrument as compared to the established package insert quality control ranges for thirty-nine antimicrobial agents, covering all the VITEK® 2 Antimicrobial Susceptibility Testing card classes (i.e. GN, GP, YS, and ST test cards). Thirteen quality control organisms were tested. Each isolate was tested at least twenty times at least three of the clinical evaluation trial sites. Quality control isolates were tested with the VITEK® 2 60 using manual dilution mode and the VITEK® EVO Compact, using the same initial McFarland suspension. Testing demonstrated the VITEK® COMPACT PRO gave acceptable quality control results with QC passing >99% for each of the AST card classes tested.

Reproducibility

Reproducibility performance was evaluated by testing isolates in triplicate for three days at three trial sites. Reproducibility test sets were selected based on the following criteria:

- Separate test sets were selected for each antimicrobial.
- Each set included at least 10 strains.
- Each set included at least 2 strains with on-scale results for each antimicrobial.

The overall reproducibility rate was calculated as the percentage of the total number of results that were within one doubling dilution of the modal card result. If a mode could not be established, the median result was used. Results within ± one doubling dilution from the mode were used to calculate reproducibility performance. Analysis was performed for each drug/organism combination which revealed acceptable reproducibility. The VITEK® COMPACT PRO reproducibility testing demonstrated that all the VITEK® 2 AST test cards/antimicrobials showed a >97% reproducibility in the best case and a >95% reproducibility in the worst case.

Clinical Performance Evaluation

The accuracy of MICs obtained by the VITEK® COMPACT PRO was evaluated using representative, clinically relevant strains, tested on all the VITEK® 2 AST test class (i.e. AST GN, GP, ST, and YS). Each strain was grown on appropriate agar media for appropriate incubation times and the cultured isolates were tested one time with both the VITEK® 2 and the VITEK® COMPACT PRO, using the same initial McFarland suspension with each antibiotic panel.

The MICs obtained using the VITEK® COMPACT PRO were then compared to the MICs obtained using the VITEK® 2. MICs obtained using the VITEK® COMPACT PRO demonstrated very high agreement in essential agreement (EA) and categorical agreement (CA) with the MICs obtained using the VITEK® 2. Essential Agreement (EA) was defined as MIC results obtained from the VITEK COMPACT PRO that were within one doubling dilution of the MIC results obtained from the VITEK 2. Category Agreement (CA) was defined as MIC interpretations (S/SDD/I/R) that were the same between the VITEK COMPACT PRO and VITEK 2. Analysis was performed for each drug/organism combination which revealed acceptable EA and CA. The clinical performance evaluation demonstrated that in comparison with the accuracy for the VITEK® 2 AST GN cards was 98.8% EA and 97.3% CA, the VITEK® 2 AST GP cards was 99.5% EA and 97.4% CA, the VITEK® 2 AST ST cards was 98.5% EA and 98.7% CA, and the VITEK® 2 AST YS cards was 100% on both EA and CA.

Conclusion:

Based on the clinical performance data presented to support substantial equivalence decision, the VITEK® COMPACT PRO is substantially equivalent to the VITEK® 2 System (N50510, Supp 82). The VITEK® COMPACT PRO has the same intended use and the same technological characteristics as the VITEK® 2 System. The clinical performance evaluation demonstrated that the VITEK® COMPACT PRO is as safe and effective as the predicate VITEK® 2 System. No new questions of safety and effectiveness were raised during the verification, validation, and/or clinical performance evaluation.