October 31, 2019

bioMerieux, Inc.
Nathan Hardesty
Sr. Manager, Regulatory Affairs
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K192110
Trade/Device Name: VITEK DENSICHEK
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: August 2, 2019
Received: August 5, 2019

Dear Nathan Hardesty:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192110

Device Name
VITEK DENSICHEK

Indications for Use *(Describe)*
The VITEK DENSICHEK instrument is an accessory intended for use with the VITEK 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to the microorganism concentrations. VITEK DENSICHEK is intended for use with polystyrene tubes, and the reading range is 0.00 to 4.00 McFarland. The VITEK DENSICHEK has applications as an in vitro diagnostic medical device, or in an industry setting.

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® DENSICHEK®

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jennifer Jines
Phone Number:	314 -731-8352
Fax Number:	314-731-8689
Date of Preparation:	August 2, 2019

B. Device Name:

Formal/Trade Name:	VITEK® DENSICHEK®
Regulation Section:	21 CFR 866.1645
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Product Code:	LON
Panel:	Microbiology
Common Name:	VITEK® DENSICHEK®

C. Predicate Device:

Predicate Device Name:	DensiCHEK ® Plus
Predicate Device Number:	K083536

D. 510(k) Summary:

E. Intended Use:

The VITEK® DENSICHEK® instrument is an accessory intended for use with the VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units, proportional to the microorganism concentration. VITEK® DENSICHEK® is intended for use with polystyrene tubes, and the reading range is 0.00 to 4.00 McFarland. The VITEK® DENSICHEK® has applications as an *in vitro* diagnostic medical device, or in an industry setting.

F. Test Principle:

The VITEK® DENSICHEK® instrument is designed for use with the VITEK® 2 Systems to measure the optical density of a microorganism suspension. The instrument provides values in McFarland units,

proportional to the microorganism concentrations. It is intended for use with the VITEK® 2 Systems during the inoculum preparation phase of the Identification (ID) and Antimicrobial Susceptibility Test (AST) card testing process.

The VITEK® DENSICHEK® generates a McFarland value using basic colorimetry, which is a method of measurement that relates the amount of color in a transparent medium (liquid) to the amount of a particular substance in the liquid. In general the concentration of the substance being measured is proportional to the intensity of the color of the solution. The darker the color becomes, the higher the concentration.

The VITEK® DENSICHEK® measures the turbidity of the saline and microorganism suspension using a single wavelength, 635nm, light emitting diode (LED). The absorption of light determines the McFarland value measured by the instrument. The more turbid the suspension, the higher the McFarland measurement reported by the device. The light source in the VITEK® DENSICHEK® emits a narrow range of wavelengths, which pass through the test tube containing the measured suspension and into a photodiode detector. The instrument is first zeroed using a test tube filled with saline (blank). The technician then places the well-mixed organism suspension into the instrument and slowly rotates the test tube. The instrument will display a series of dashes followed by a McFarland reading, based on the amount of energy that was detected at the photodiode.

G. Device Description:

The VITEK® DENSICHEK® consists of the following accessories and components**:**

- VITEK® DENSICHEK® Pod
- VITEK® DENSICHEK® Display Base
- VITEK® DENSICHEK® Connectivity Base
- VITEK® DENSICHEK® McFarland Reference Kit
- USB Power Adaptor

The VITEK® DENSICHEK® is an optical reading device intended for professional use by laboratory health professionals in clinical or industry laboratory settings. The device determines the McFarland value by evaluating the absorption of light in the test tube containing the suspension. The more turbid the organism suspension is, the higher the McFarland value displayed by the device. An algorithm assesses results obtained from the turbidimetric reading and translates them into a McFarland value.

The VITEK® DENSICHEK® instrument contains a Base unit with a detachable optical interface, the Pod. The Pod calculates and automatically transmits the optical McFarland reading to the Base unit for display. The user can confirm the McFarland value by pressing a button on the Pod, optionally saving the value to the VITEK® FLEXPREP™ Software on a laboratory PC, where it is recorded with specimen setup information for traceability.

The Pod McFarland readings are communicated to the Base through a Bluetooth Low Energy (BTLE) wireless interface. When docked on a Base, the Pod is automatically paired and recharged through a wireless contact connection. The Display Base displays McFarland readings from the Pod on an LCD resistive touch screen, and can be integrated with VITEK® 2 software to record readings for traceability. The Connectivity Base is available for customers who only want to use the VITEK® DENSICHEK® with the VITEK® 2 software to display and record McFarland readings. McFarland Reference Standards featuring radio-frequency identification (RFID) tags are used to verify the measurement accuracy performance of the VITEK® DENSICHEK®.

H. FDA Recognized Consensus Standards Referenced:

- M100S, "Performance Standards for Antimicrobial Susceptibility Testing, 28th Edition", 28th Edition (January 2018)
- M07-A10, " Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard - Tenth Edition," Vol. 35 No.2 (January 2015)
- UL 61010-1: 2012 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- EN 62471: 2008 Photobiological safety of lamps and lamp systems

I. Performance Characteristics:

Clinical Studies

The Premarket Notification (510[k]) presents data in support of VITEK® DENSICHEK®. The purpose of this study/trial is to evaluate the reproducibility performance of the VITEK® DENSICHEK® device as used with the VITEK® 2 and VITEK® 2 Compact Systems in a clinical setting.

Study 1
The purpose of Study 1 was to evaluate the reproducibility and quality control performance of the VITEK® DENSICHEK® device as used with the VITEK® 2 and VITEK® 2 Compact Systems in a clinical setting. Data was collected using VITEK® DENSICHEK® and the DensiCHEK® Plus. The VITEK® DENSICHEK® demonstrated acceptable quality control performance of >95% and reproducibility for isolates tested with Gram-negative, Gram-positive, *Streptococcus*, and Yeast AST card types. There were no exceptions for this performance data. As such, the overall quality control and reproducibility performance of VITEK® DENSICHEK® was acceptable.

Study 2
The purpose of Study 2 was an Equivalency Study to validate the equivalence of VITEK® DENSICHEK® Product Build 1, and the VITEK® DENSICHEK® Product Build 2. Reproducibility data was collected using both product builds and the performance of the VITEK® DENSICHEK® Product Build 1 was compared to the performance of the VITEK® DENSICHEK® Product Build 2.

The table below shows the distribution of two-fold dilution differences between modes by dilution method and combined. For this overall comparison, any strain / antimicrobial combination having a mode that was off-scale was ignored. The rationale for this is that variation between modes can be measured more accurately using only on-scale organisms.

Distribution of Dilution Differences Between Product Build Modes (PB2 – PB1)

Dilution Method	Dilution Difference					Essential Agreement
	≤ -2	-1	0	+1	≥ +2	
Auto	0 0.0%	12 6.3%	172 90.5%	6 3.2%	0 0.0%	190 / 190 100.0%
Manual	0 0.0%	11 5.8%	168 88.4%	9 4.7%	2 1.1%	188 / 190 98.9%
Combined	0 0.0%	23 6.1%	340 89.5%	15 3.9%	2 0.5%	378 / 380 99.5%

The table below provides a summary of the overall reproducibility rates by dilution method and combined for each product build.

Overall Reproducibility Rate Comparison

Dilution Method	Best Case			Worst Case		
	Product Build 1	Product Build 2	Difference	Product Build 1	Product Build 2	Difference
Auto	99.8%	99.4%	0.4%	98.9%	98.6%	0.3%
Manual	99.0%	98.5%	0.5%	98.0%	97.6%	0.4%
Combined	99.4%	99.0%	0.4%	98.4%	98.0%	0.4%

The overall comparison of modes between the two product builds reveals that the exact agreement rate was nearly 90.0%, and the essential agreement rate was 99.5%. Furthermore, the combined reproducibility rates for both product builds differ by no more than 0.4%, overall, for both best and worst case. The observed level of agreement between modes indicates that both product builds are associated with results that occur at a similar location on the MIC scale. The small difference in reproducibility rates provides evidence that AST result variability is nearly identical for both PB1 and PB2.

The best-case reproducibility was acceptable for all drugs evaluated for a representative class of Gram-negative, Gram-positive, Streptococcus, and Yeast drugs.

Study 3

The purpose of Study 3 was an Abbreviated Reproducibility Study was to assess the performance of the VITEK® DENSICHEK® Product Build 2 when end-user variability was introduced. A subset of the reproducibility data collected internally using VITEK® DENSICHEK® Product Build 2 was combined with data collected at two external sites.

VITEK® DENSICHEK® Product Build 2 met the performance criteria of >95% across all sites reproducibility with no observed exceptions.

Data analysis was then completed to compare reproducibility directly between Product Build 2 (PB2) and DENSICHEK Plus (Plus). **Table 1** provides a summary of the dilution differences between modes from the two devices by auto dilution, manual dilution, and combined. **Table 2** shows a comparison of reproducibility rates from the two devices. As with the original analysis completed comparing Product Build 1 and Product Build 2, organism/antimicrobial combinations having a mode that was off-scale were removed from the analysis. Again, the rationale being reproducibility or variation between results can be measured more accurately using on-scale organisms.

Table 1: Distribution of Dilution Differences Between Modes from Reproducibility Testing (PB2 – Plus)

Dilution Method	Dilution Difference					Essential Agreement
	≤ -2	-1	0	+1	≥ +2	
Auto	2 1.1%	23 12.1%	160 84.2%	5 2.6%	0 0.0%	188/190 98.9%
Manual	2 1.1%	20 10.5%	165 86.8%	3 1.6%	0 0.0%	188/190 98.9%
Combined	4 1.1%	43 11.3%	325 85.5%	8 2.1%	0 0.0%	376/380 98.9%

Table 2: Overall Reproducibility Rate Comparison

Dilution Method	Best Case			Worst Case		
	Plus	PB2	Difference	Plus	PB2	Difference
Auto	99.4%	99.7%	-0.3%	98.6%	98.8%	-0.2%
Manual	99.2%	99.1%	0.1%	98.2%	98.2%	0.0%
Combined	99.3%	99.4%	-0.1%	98.4%	98.5%	-0.1%

From the comparison of modes, the agreement rate within ± 1 doubling dilution is nearly 99% indicating a high level of correlation between results from the two devices. For the comparison of reproducibility rates, the differences are small for both dilution methods.