Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
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510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY

I Background Information:

A 510(k) Number

K192110

B Applicant

bioMerieux, Inc

C Proprietary and Established Names

Vitek Densichek

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

To add an accessory instrument for use with the VITEK 2 and VITEK 2 Compact Systems

B Type of Test:

Growth based

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for 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.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

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, named 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 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.

B Instrument Description Information:

Modes of Operation	Yes	No
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☒	☐
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☒	☐
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☒	☐

1. Instrument Name:

   VITEK DENSICHEK

2. Specimen Identification:

   N/A

3. Specimen Sampling and Handling:

   N/A

4. Calibration:

   Instrument verification is performed using one or more of the McFarland standards (0.5, 2.0, or 3.0) after zeroing the instrument with the 0.0 McFarland Standard blank. These standards are packaged for use with the VITEK DENSICHEK instrument.

5. Quality Control:

   Routine reference checks prior to use, on a monthly basis, and after cleaning

V Substantial Equivalence Information:

A Predicate Device Name(s):

DensiCHEK Plus

B Predicate 510(k) Number(s):

K083536

C Comparison with Predicate(s):

Device & Predicate Device(s):	Device: K192110	Predicate: K083536
Device Trade Name	**VITEK DENSICHEK**	**DENSICHEK PLUS**
General Device Characteristic Similarities		

Intended Use/Indications For Use	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.	Same
Sample Type	Microorganism suspension in saline	Same
Type of Test	Growth based	Same
Modes of Operation	Manual, only one test tube can be read with VITEK DENSICHEK at a time.	Same
Method of Testing	Designed to measure the optical density of microorganism suspended in a liquid medium and convert that optical density into a McFarland value	Same
Reading Range	0.00 to 4.00 McFarland	Same
Light Source	Light Emitting Diode	Same
Calibration Verification	Instrument verification is performed using one or more of the McFarland standards (0.5, 2.0, or 3.0) after zeroing the instrument with the 0.00 McFarland Standard blank	Same
General Device Characteristic Differences		
Instrument Components	VITEK DENSICHEK Pod VITEK DENSICHEK Display Base	DENSICHEK Plus DENSICHEK Plus Standards Kit

	VITEK DENSICHEK Connectivity Base VITEK DENSICHEK McFarland Reference Kit	
Test Tubes	Polystyrene test tubes only	Glass or polystyrene test tubes
Calibration verification	Do not have to change tube mode, RFID technology	Manual change of tube mode
Interface with PC	Communication with any configured PC running bioMerieux supplied interface software	Not Applicable
Power Source	Capable of running on A/C power source; rechargeable lithium ion polymer battery	4 AAA batteries, either alkaline or nickel-metal hydride (NIMH)
Light Source	LED is 635 nm	LED is 580 nm
Radio Communication	Bluetooth Low Energy and Radiofrequency identification	Not Applicable

VI Standards/Guidance Documents Referenced:

- Guidance for Industry and FDA - Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems – August 28, 2009.

- CLSI. Performance Standards for Antimicrobial Susceptibility Testing. 28th ed. CLSI supplement M100. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

- CLSI M7-A10: Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard – Tenth Edition

- IEC 61010-1: 2010 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements

- IEC 62471: 2006 Photobiological safety of lamps and lamp systems

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Three reproducibility studies were conducted to demonstrate the performance of the VITEK DENSICHEK. The first study (Study 1) evaluated the original design which is referred to as Product Build 1 (PB1). Study 1 was conducted in which both the predicate, DensiCHEK Plus, and PB1 were evaluated. A panel of 10 Gram-negative isolates, 10 Gram-positive isolates, and 10 yeast isolates were used to prepare the suspension, which was used to inoculate each antimicrobial within each test card (i.e., AST-GN69, AST-GP72, AST-ST02, AST-YS05). Both dilution options (automatic and manual dilutions) were used to inoculate AST cards noted below. Testing was conducted at three sites across three days for a total of 540 results per antimicrobial (3 x 2 x 3 x 3 x 10 = 540) using the following test cards with respective antimicrobials:

AST-GN69 (Gram-negative)
Ampicillin
Amoxicillin/Clavulanic Acid
Ceftazidime
Gentamicin
Imipenem
Levofloxacin
Trimethoprim/Sulfamethoxazole

AST-GP72 (Gram-positive)
Ampicillin
Chloramphenicol
Ciprofloxacin
Daptomycin

Nitrofurantoin
Minocycline

AST-ST02 (Gram-positive)
Benzylpenicillin
Erythromycin
Tetracycline

AST-YS05 (Yeast)
Caspofungin
Fluconazole

Reproducibility data was analyzed taking into consideration best case and worst-case analysis as described in the AST Special Controls Guidance Document. As shown in Tables 2 and 3, the best-case reproducibility for all drugs for both automatic and manual dilution methods was >95%. The drugs that demonstrated <95% reproducibility for worst case included isolates that were off-scale when compared to the mode of each isolate (e.g., result ≤2, mode =4), however, given that the majority of the worst-case results were >95% for all drugs and >95% for all best-case results, they were deemed acceptable.

Table 2: Reproducibility Results Using Automatic Dilution using the VITEK 2 for Product Build 1

Card	Antimicrobial	Best Case (%)	Worst Case (%)
AST-GN69	Ampicillin	100	99.26
	Amoxicillin/Clavulanic Acid	100	92.96*
	Ceftazidime	100	100
	Gentamicin	100	100
	Imipenem	100	100
	Levofloxacin	100	100
	Trimethoprim/Sulfamethoxazole	98.89	90.37*
AST-GP72	Ampicillin	99.63	97.78
	Chloramphenicol	100	99.63
	Ciprofloxacin	100	98.15
	Daptomycin	98.52	98.52
	Nitrofurantoin	100	100

	Minocycline	100	88.52*
	Vancomycin	100	100
AST-ST02	Benzylpenicillin	99.63	99.63
	Erythromycin	100	50*
	Tetracycline	100	47.41*
AST-YS05	Caspofungin	100	78.15*
	Fluconazole	95.93	88.89*

Table 3: Reproducibility Results Using Manual Dilution using the VITEK 2 Compact for Product Build 1

Card	Antimicrobial	Best Case	Worst Case
AST-GN69	Ampicillin	99.63	98.89
	Amoxicillin/Clavulanic Acid	99.63	93.70*
	Ceftazidime	100	99.63
	Gentamicin	100	100
	Imipenem	97.78	97.78
	Levofloxacin	100	100
	Trimethoprim/Sulfamethoxazole	98.89	91.11*
AST-GP72	Ampicillin	99.26	96.67
	Chloramphenicol	100	98.89
	Ciprofloxacin	100	96.30
	Daptomycin	99.63	99.63
	Nitrofurantoin	100	100
	Minocycline	99.26	89.26*
	Vancomycin	99.63	99.63
AST-ST02	Benzylpenicillin	99.26	99.26
	Erythromycin	98.15	48.15*
	Tetracycline	100	46.67*
AST-YS05	Caspofungin	100	78.52*
	Fluconazole	98.89	85.56*

*Included results that were off-scale.

After Study 1 was completed, a minor design change involving the spring torsion allowing tube rotation was made to PB1 to improve repeatability. The modified, final device was referred to as Product Build 2 (PB2). Two additional studies (see below) were conducted to evaluate reproducibility of PB2.

Study 2 was conducted at an internal site to demonstrate equivalency between the PB1 and PB2 to assess the impact of this design change. The same isolates and antimicrobials were tested for both automatic and manual dilution methods for PB2 and the results were compared to both PB1 and DensiCHEK Plus. Overall, the mode MIC values obtained using inocula prepared with VITEK DENSICHEK PB1 and VITEK DENSICHEK PB2 and Densicheck Plus (predicate) were compared. Modal MIC results were an exact match 89.5% of the time and were within +/- one dilution of each other 99.5% of the time between PB1 and PB2 (Table 4). Also, the mode MIC values were an exact match 85.5% of the time and were within +/- one dilution of each other 98.9% of the time between PB2 and DensiCHEK Plus (Table 5). Results for both analyses indicated that each device tested were comparable.

Table 4: Comparison of Modes Between PB1 and PB2

Dilution Method	Dilution Difference					Within +/- 1 Dilution
	≤ -2 (%)	-1 (%)	0 (%)	+1 (%)	≥ +2 (%)	
Automatic	0 (0)	12 (6.3)	172 (90.5)	6 (3.2)	0 (0)_	190/190 (100)
Manual	0 (0)	11 (5.8)	168 (88.4)	9 (4.7)	2 (1.1)	188/190 (98.9)
Combined	0 (0)	23 (6.1)	340 (89.5)	15 (3.9)	2 (0.5)	378/380 (99.5)

Table 5: Comparison of Modes Between PB2 and DensiCHEK Plus

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

Another reproducibility study (Study 3) was conducted with an additional 10-organism panel to assess reproducibility at three sites (two external clinical sites and one internal site). Reproducibility isolates were tested using the appropriate VITEK 2 AST card at each clinical trial site. The reproducibility sets were tested in triplicate on each of three days by VITEK 2 automatic dilution and VITEK 2 Compact manual dilution using 11 antimicrobials with McFarland suspensions prepared using the VITEK DENSICHEK PB 2 for a total of 108 results for each antimicrobial. Testing was performed using Greiner Bio-One polystyrene test tubes for VITEK 2. VITEK DENSICHEK PB 2 met the reproducibility performance criteria of >95% across all sites and therefore, acceptable.

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Accuracy (Instrument):

   See section B for supportive information.

5. Carry-Over:

   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Quality Control – VITEK 2 and VITEK 2 Compact Systems

Eight QC organisms were tested in Study 1 using Product Build 1 of the VITEK DENSICHEK and the VITEK 2 AST card at each clinical trial site. The organisms tested were:

E. coli	ATCC 25922
P. aeruginosa	ATCC 27853

E. coli	ATCC 35218
E. faecalis	ATCC 29212
S. aureus	ATCC 29213
S. pneumoniae	ATCC 49619
C. parapsilosis	ATCC 22019
C. krusei	ATCC 6528

A minimum of 20 replicates for each QC organism were collected without exceeding five replicates per day for each site (i.e., at least 60 results/drug), using a suspension prepared using the DENSICHEK Plus and a separate suspension prepared using the VITEK DENSICHEK PB1. Testing was performed using the VITEK 2 and VITEK 2 Compact Systems. The VITEK DENSICHEK PB1 demonstrated acceptable QC performance of >95% (Table 6) for isolates tested with Gram-negative, Gram-positive, Streptococcus, and Yeast AST cards and was therefore, deemed acceptable.

Table 6: Summary of QC Performance for Study 1 (PB1)

VITEK 2 AST-GN69	*E. coli* ATCC 25922	
	VITEK 2	VITEK 2 Compact
	% in Range	% in Range
Amoxicillin/Clavulanic Acid	100	100
Ampicillin	100	100
Ceftazidime	100	100
Gentamicin	100	100
Imipenem	100	100
Levofloxacin	100	100
Trimethoprim/sulfamethoxazole	100	100
VITEK 2 AST-GN69	*P. aeruginosa* ATCC 27853	
Ceftazidime	100	100
Gentamicin	100	100
Imipenem	100	100
Levofloxacin	100	100
Trimethoprim/sulfamethoxazole	100	100
VITEK 2 AST-GN69	*E. coli* 35218	
Amoxicillin/clavulanic Acid	100	100
VITEK 2 AST-GP72	*E. faecalis* ATCC 29212	

	VITEK 2	VITEK 2 Compact
	% in Range	% in Range
Ampicillin	100	100
Chloramphenicol	100	100
Ciprofloxacin	100	100
Daptomycin	100	98.3
Nitrofurantoin	100	100
Minocycline	100	100
Vancomycin	100	100
VITEK 2 AST-GP72	*S. aureus* ATCC 29213	
Chloramphenicol	100	100
Ciprofloxacin	100	100
Daptomycin	100	100
Nitrofurantoin	100	100
Minocycline	100	100
Vancomycin	100	100
VITEK 2 AST-ST02	*S. pneumoniae* ATCC 49619	
	VITEK 2	VITEK 2 Compact
	% in Range	% in Range
Benzylpenicillin	100	100
Erythromycin	100	100
Tetracycline	100	100
VITEK 2 AST-YS05	*C. parapsilosis* ATCC 22019	
	VITEK 2	VITEK 2 Compact
	% in Range	% in Range
Caspofungin	100	100
Fluconazole	100	100
	C. krusei ATCC 6528	
Caspofungin	100	100
Fluconazole	100	100

QC testing was also conducted for VITEK DENSICHEK PB 2 for both the VITEK 2 and VITEK 2 Compact instruments for the same drugs and QC organisms at one site (i.e., 20 per drug/organism combination). Results were acceptable at >95%.

The sponsor also conducted the following microbiological verification studies:

Repeatability
Repeatibility testing on the subject device was based on multiple dilutions of one suspension of ATCC *E. coli* 25922 suspended in 0.45% saline. The dilutions were confirmed to be within the appropriate CFU ranges equivalent for each McFarland target using a calibrated spectrophotometer and colony count testing. A total of 270 results (10 devices x 9 tubes x 3 lots of Greiner 12x75 polystyrene tubes) for each the subject and predicate devices across six McFarland ranges (i.e., 0.2, 0.5, 1, 2, 3, and 3.69 McFarland = 3240 results) was evaluated for accuracy. All results fell within the appropriate McFarland ranges >95% of the time and were acceptable.

AST Verification and Supplemental QC Testing
The sponsor tested a variety of available isolates with internally validated QC ranges. Testing was done across three different subject devices and the one predicate device to ensure that the McFarland readings were producing accurate results according to their validated QC ranges. The following drugs were tested 59 times using the AST-GN69 card (Gram-negative isolates) with each of the devices (i.e., 177 results) with the exception of piperacillin/tazobactam which was tested 57 (i.e., 174 results) times with each: amoxicillin/clavulanic acid, ampicillin, ampicillin/sulbactam, cefazolin, cefepime, ceftazidime, ceftriaxone, ciprofloxacin, ESBL screen, ertapenem, gentamicin, imipenem, levofloxacin, nitrofurantoin, piperacillin/tazobactam, tobramycin, and trimethoprim/sulfamethoxazole. For these isolates tested, the overall QC results for the VITEK DensiCHEK indicated that the devices were performing acceptably at >95% within range. When evaluated separately, performance for nitrofurantoin was 89.3% (158/177), however, given the combined performance for all drugs was >95%, the overall performance was considered acceptable.

The following drugs were tested 64 times using the AST-GP67 card (Gram-positive isolates) with each of the three subject devices: ampicillin, benzypenicillin, cefoxitin, ciprofloxacin, clindamycin, erythromycin, gentamicin, gentamicin high-level synergy, inducible-clindamycin resistance, levofloxacin, linezolid, moxifloxacin, nitrofurantoin, oxacillin, quinupristin/dalfopristin, rifampicin, streptomycin high-level synergy, tetracycline, tigecycline, trimethoprim/sulfamethoxazole, and vancomycin. For these isolates tested, the overall QC results indicated that the devices were performing acceptably at >95% within range.

The following drugs were tested 53 times using the AST-ST02 card (*Streptococcus* spp. isolates) with each of the three subject devices: ampicillin, benzypenicillin, cefotaxime, ceftriaxone, clindamycin, erythromycin, inducible-clindamycin resistance,

levofloxacin, linezolid, moxifloxacin, tetracycline, tigecycline, trimethoprim/sulfamethoxazole, and vancomycin. For these isolates tested, the overall QC results indicated that the devices were performing acceptably at >95% within range.

The following drugs were tested 36 times using the AST-YS07 card (*Candida* spp. isolates) with each of the three subject devices: amphotericin B, caspofungin, fluconazole, flucytosine, micafungin, and voriconazole. For these isolates tested, the overall QC results indicated that the devices were performing acceptably at >95% within range.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.