510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k032711

B. Analyte:
Gatifloxacin at 1.5-10 ug/mL AST

C. Type of Test:
Quantitative growth based detection algorithm using optics light detection

D. Applicant:
bioMerieux, Inc.

E. Proprietary and Established Names:
VITEK® GNS Gatifloxacin

F. Regulatory Information:

1. Regulation section:
   866.1645 Short-Term Antimicrobial Susceptibility Test System
2. Classification:
   II
3. Product Code:
   LON System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
4. Panel:
   83 Microbiology

G. Intended Use:

1. Intended use(s):
   GRAM-NEGATIVE SUSCEPTIBILITY CARDS (GNS) are designed for antimicrobial susceptibility testing of rapidly-growing, aerobic and/or facultatively anaerobic gram-negative bacilli. They are intended for use with the VITEK® System as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. The antimicrobial panel presented in the CARD is in concentrations equivalent by efficacy to standard method concentrations in ug/mL.
2. Indication(s) for use:
   This will include the testing of gatifloxacin at concentrations of 1.5, 4 and 10 ug/mL for reporting of results between 0.5-8 ug/mL for the intended organisms using the VITEK® System.
3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   Not applicable

H. Device Description:
Each VITEK® test card contains thirty –forty-five microwells. A control well, that contains only microbiological culture medium is resident on all cards, with the remaining wells containing premeasured amounts of a specific antibiotic combined

with culture medium. A suspension of organism is made in 0.45-0.5% sterile saline from a pure culture and standardized to a McFarland 1 standard using the VITEK® Colorimeter. The CARD is inoculated by injecting the standardized dilution of organism to be tested into the CARD using a TRANSFER TUBE and FILLING MODE. This process rehydrates the antimicrobial medium. Cards are then incubated (35.5^{o} C). The computer determines when a well demonstrates growth (positive) based on attenuation of light measured by the optical scanner. Readings are completed throughout the 6-15 hour incubation cycle.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   VITEK® Gram Negative Susceptibility Test for Cefpodoxime
2. Predicate K number(s):
   N50510/S73
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Same	Same
Test organism	Colonies of intended gram negative organisms using direct colony suspension	Colonies of intended gram negative organisms using direct colony suspension
Test Card	VITEK® card format with base broth	same
Instrument	VITEK® System	VITEK® System
Differences		
Item	**Device**	**Predicate**
Antibiotic	Specific concentrations of gatifloxacin	Specific concentrations of cefpodoxime
Reading algorithm	Unique for gatifloxacin	Unique for cefpodoxime

J. Standard/Guidance Document Referenced (if applicable):

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA"; NCCLS M7 (M100-S13) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard"

K. Test Principle:

Optics systems use visible light to directly measure organism growth. These transmittance optics are based on an initial light reading of a well before significant growth has begun. Periodic light transmittance samplings of the same well measure organism growth by how much light is prevented from going through the well. An interpretive call is made between 6 and 15 hours. The VITEK® Susceptibility Card test is based on the microdilution minimum inhibitory concentration technique with concentrations equivalent to standard method concentrations. Several parameters based on the growth characteristics observed are used to provide appropriate input for the MIC

calculations. Discriminate analysis is used to develop the algorithm that determines the susceptibility result for all antimicrobials on the VITEK® system. The MIC result must be linked to organism identification in order to determine a category interpretation. A category interpretation will be reported along with a MIC.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility testing was performed on 25 on-scale isolates at each site to demonstrate >95% reproducibility. Within site reproducibility was also demonstrated to be >95% by testing 25 isolates 3 times at one site.

b. Linearity/assay reportable range:

Not applicable

c. Traceability (controls, calibrators, or method):

NCCLS recommended Quality Control strains were tested (see table below). The VITEK® results demonstrate that the system can produce QC results in the recommended range.

ORGANISM	**Reference conc.**	**Reference**	**VITEK® Conc.**	**VITEK®**
E. coli ATCC 25922 Range ≤ 0.25ug/mL				
	≤ 0.25	**71**	**≤ 0.5**	**70**
	0.5			1
	1			
P. aeruginosa ATCC 27853 Range 0.5-2 ug/mL				
	≤ .25			
	.5		**≤ 0.5**	**2**
	1	**17**	**1**	**72**
	2	**57**	**2**	
	4		4	
	8		8	

Quality Control performed during the studies demonstrated a trend of the Pseudomonas aeruginosa result to be slightly more susceptible for the VITEK®.

Inoculum density control: The VITEK® Colorimeter instrument was used for the preparation of the inoucla for the VITEK® and the agar dilution test. Standardization of the instrument was performed daily. Colony counts were also performed periodically at the test sites to demonstrate the appropriate inoculum was achieved.

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The NCCLS recommended agar dilution reference method was performed according to the NCCLS recommendation and was used to compare to the VITEK® results. Clinical testing was performed at three sites. The testing included both fresh clinical isolates and stock isolates of *Enterobacteriaceae* along with a challenge set with known results. All isolates grew in the test panels. A comparison was provided to the reference method with the following agreement.

	total	**EA**	**%EA**	**Total evaluable**	**EA of evaluable**	**%EA**	**CA**	**%CA**	**#R**	**min**	**maj**	**vmj**
Clinical	592	579	97.8	16	16	100	586	99	33	6	0	0
Challenge	85	84	98.8	21	21	100	78	91.8	14	7	0	0
Combined	677	663	97.9	37	37	100	664	98.1	47	13	0	0

EA-Essential Agreement
CA-Category Agreement
R-resistant isolates
maj-major discrepancies
vmj-very major discrepancies
min- minor discrepancies

Evaluable results are those that fall within the test range of the reference method and could also be on-scale with the new device if within the plus/minus one well variability. EA is when there is agreement between the reference method and the VITEK® within plus or minus one serial two-fold dilution of antibiotic. CA is when the interpretation of the reference method agrees exactly with the interpretation of the VITEK® result.

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
$\leq$ 2 (S), 4 (I), $\geq$ 8 (R)
The expected QC value ranges and interpretative criteria are the same as recommended in NCCLS. All values will be included in the package insert.

M. Conclusion:

The reproducibility, quality control results and overall performance is acceptable as described in the "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA" which was used in the design and evaluation of the study. The appropriate control organisms are included in the labeling and are the same as those recommended in the NCCLS M7-(M100-S13) document. This performance as compared to a standard method demonstrates substantial equivalency to the predicate.