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

A. 510(k) Number:
k032314

B. Analyte:
Gatifloxacin at equivalency concentrations of 0.5-4 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®2 Gram Positive 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):
   The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp*., *Enterococcus spp*., *Streptococcus agalactiae,* and *S. pneumoniae*.
2. Indication(s) for use:
   VITEK® 2 Gram Positive Gatifloxacin is designed for antimicrobial susceptibility testing of *Staphylococcus aureus* (methicillin susceptible strains only*)* and *Staphylococcus saprophyticus.* It is intended for use with the VITEK® 2 System as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents.
3. Special condition for use statement(s):
   Results on *Staphylococcus spp*. only will be reported
4. Special instrument Requirements:
   Not applicable

H. Device Description:
Each VITEK® 2 test card contains 64 microwells. A control well, that contains only microbiological culture medium is resident on all cards, with the remaining wells containing pre-measured 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 0.5 standard using the DensiChek. The desired card (s) is placed in the cassette along with an empty tube for the susceptibility card. The cassette is placed into the VITEK® 2 instrument where a susceptibility test will be automatically diluted from the ID suspension by the VITEK® 2. The cards are then automatically vacuum filled; the tubes are cut and the cards sealed prior to proceeding to the Incubator Loading Station. Cards are then transferred from the cassette into the carousel for incubation (35.5^{o} C) and optical scanning during testing. Readings are performed every 15 minutes. There is also a manual method for preparing the inoculum that is also supported in the package insert directions.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   VITEK®2 Gram Positive Sparfloxacin
2. Predicate K number(s):
   N50510/S141
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	same	Same
Test organism	*Staphylococcus spp.*	*Staphylococcus spp.*
Test Card	VITEK® 2 card format with base broth	same
Instrument	VITEK® 2 System	VITEK® 2 System
Differences		
Item	**Device**	**Predicate**
Antibiotic	Gatifloxacin	sparfloxacin
Reading algorithm	Unique for gatifloxacin	Unique for sparfloxacin

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 4 and 16 hours for an early reading of results. The VITEK® 2 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® 2 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:

Twenty five on-scale gram positive organisms were tested one time at each of three sites for an overall reproducibility of >95%. Twenty five on-scale organisms were also tested at one site three times each to determine intra reproducibility of >95%. This testing was performed using both the manual dilution of the inoculum and also the automatic dilution method.

b. Linearity/assay reportable range:

Not applicable

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

ORGANISM	**Conc in ug/ml**	**Reference**	**Conc in ug/ml**	**Auto dilution VITEK® 2**	**Manual dilution VITEK® 2**
S. aureus ATCC 29213 Range 0.03-0.12 ug/ml	**<.06**	**66**			
	.12	**4**			
	.25		**< .5**	**70**	**65**
	.5				
Enterococcus faecalis ATCC 29212 Range 0.12-1 ug/ml	0.06				
	0.12	**2**			
	0.25	**64**			
	0.5	**2**	**< .5**	**70**	**65**
	1	**2**			

Inoculum density control- Internal verification of the DensiChek was performed using 2 ATCC organisms and five instruments with 50 results available for each organism. The clinical sites also performed weekly standardization of the DensiChek used at that site.

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:

A comparison of the clinical was performed to the agar dilution reference method described in the NCCLS M7. A total of 365 *Staphylococcus* isolates were tested at three sites that included both clinical and challenge isolates. The "no growth" rate was less than

1%. Testing was performed using the auto dilution feature. The overall performance is listed in the table below:

	total	EA	%EA	Total evaluable	EA of evaluable	%EA	CA	%CA	#R	min	maj	vmj
Clinical	306	304	99.3	62	62	100	235	76.8	66	70	1	0
Challenge	59	59	100	4	4	100	59	100	2	0	0	0
Combined	365	363	99.5	66	66	100	294	80.5	68	70	1	0

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

The low CA is due to minor errors where most are more resistant than the reference method result by only one well. This rather low CA can be acceptable with a high EA of which this antibiotic has with an EA of 99.5%. Although trending to be more resistant in the VITEK® 2 system these are still in EA with the reference method.

Manual Dilution: Additional testing was performed using a manual method of preparing the inoculum on the 59 challenge isolates with exactly the same results.

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:
   ≤ 2 (S), 4 (I), ≥ 8(R)
   The expected value range, interpretative criteria and QC are the same as recommended in NCCLS M7-(M100-S13) document. 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.