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

A. 510(k) Number:

K183524

B. Purpose for Submission:

To obtain a substantial equivalence determination for Delafloxacin for testing of Gram-negative bacilli on the VITEK 2 and VITEK 2 Compact Antimicrobial Susceptibility Test (AST) Systems

C. Measurand:

Delafloxacin ≤0.06 – ≥4 µg/mL for *Enterobacteriaceae* and ≤ 0.125 – ≥4 µg/mL for *Pseudomonas aeruginosa*.

D. Type of Test:

Automated quantitative or qualitative antimicrobial susceptibility test for Delafloxacin

E. Applicant:

bioMérieux, Inc.

F. Proprietary and Established Names:

VITEK 2 AST-Gram Negative Delafloxacin (≤ 0.06 – ≥4 µg/mL)

G. Regulatory Information:

1. Regulation section:

   21 CFR 866.1645: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System

2. Classification:

   Class II

3. Product code(s):

   LON – Fully automated short-term incubation cycle antimicrobial susceptibility system
   LTW – Susceptibility Test Cards, Antimicrobial
   LTT – Panels, Test, Susceptibility, Antimicrobial

4. Panel:

   Microbiology, 83

H. Intended Use/Indications for Use:

1. Intended Use (s):

   The VITEK 2 Gram-negative Susceptibility Card is intended to for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

2. Indications for Use:

   VITEK 2 AST-Gram Negative Delafloxacin is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK 2 and VITEK 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK 2 AST-Gram Negative Delafloxacin is a quantitative test. Delafloxacin has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

   Active both *in vitro* and in clinical infections
   Escherichia coli
   Enterobacter cloacae
   Klebsiella pneumoniae
   Pseudomonas aeruginosa

   The VITEK 2 Gram-negative Susceptibility Card is intended to for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   VITEK 2 and VITEK 2 Compact Systems using VITEK 2 Systems 9.02 software

I. Device Description:

The VITEK 2 AST card is a miniaturized, abbreviated and automated version of the doubling dilution technique for determining the minimum inhibitory concentration (MIC). Each VITEK 2 AST card contains 64 wells. A control well(s) which contain only nutrient medium is resident on all cards. The remaining wells contain premeasured portions of antimicrobials combined with the nutrient media. The isolate to be tested is diluted to a standardized concentration with 0.45% to 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System will automatically dilute the bacterial suspension to prepare an inoculum for susceptibility cards. Then the VITEK 2 will fill, seal and place the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing, and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time (up to 24 hours for *Streptococcus* species). The analysis program determines when a well demonstrates growth based on attenuation of light measured by an optical scanner. This data is used to determine the minimum inhibitory concentration or "MIC" values for the anti-microbial agent. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK 2 AST-GN Delafloxacin has the following concentrations in the card: 0.06, 0.25, 0.5, and 2 µg/mL (equivalent standard method concentration by efficacy in µg/mL). The Delafloxacin MIC result ranges for the VITEK 2 are:

- ≤ 0.06 – ≥ 4 µg/mL for *Enterobacteriaceae*
- ≤ 0.125 - ≥ 4 µg/mL for *Pseudomonas aeruginosa*

J. Substantial Equivalence Information:

1. Predicate device name(s):

   VITEK 2 AST-GN Amikacin

2. Predicate 510(k) number(s):

   K172731

3. Comparison with predicate:

Table 1: Comparison with Predicate Device

Similarities		
Item	**Device: VITEK 2 AST-GN Delafloxacin (K183524)**	**Predicate Device: VITEK 2 AST-GN Amikacin (K172731)**
Intended Use	The VITEK 2 Gram-negative Susceptibility Card is intended to for use with the VITEK 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant aerobic Gram-negative bacilli to antimicrobial agents when used as instructed.	The VITEK 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus* spp., *Enterococcus* spp., *Streptococcus* spp. and clinically significant yeast.
Test Method	Automated quantitative antimicrobial susceptibility test for use with the VITEK 2 and VITEK 2 Compact Systems to determine the *in vitro* susceptibility of Gram negative bacilli	Same
Inoculum	Standardized saline suspension of test organism	Same
Test Card	VITEK 2 Gram Negative Susceptibility Test Card	Same
Instrument	VITEK 2 and VITEK 2 Compact Systems	Same
Analysis Algorithm	Growth pattern analysis	Same
Differences		
Antimicrobial Agent	Delafloxacin	Amikacin
Antimicrobial Concentrations	0.06, 0.25, 0.5, and 2 µg/mL	2, 4, 16, and 48 µg/mL
Reporting Range	*Enterobacteriaceae:* ≤ 0.06 – ≥ 4 µg/mL *P. aeruginosa:* ≤ 0.125 - ≥ 4 µg/mL	*Enterobacteriaceae* and *P. aeruginosa:* ≤ 1 – ≥ 64 µg/mL *Acinetobacter* spp.: ≤ 2 – ≥ 64 µg/mL

K. Standard/Guidance Documents Referenced (if applicable)

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

- CLSI M07-A10, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard-Ninth Edition" Vol. 35 No. 2 (January 2015)

- CLSI M100, "Performance Standards for Antimicrobial Susceptibility Testing"; Twenty-eighth Edition (January 2018)

L. Test Principle:

The VITEK 2 and VITEK 2 Compact Systems utilize automated growth-based detection using attenuation of light measured by an optical scanner. The optics in the systems uses visible light to directly measure organism growth within each of the 64 micro-wells. Transmittance optics is based on an initial light reading of a well before significant growth has begun. Every 15 minutes throughout the incubation cycle (defined period of time based on the VITEK 2 card), light transmittance readings of each well measures organism growth by the amount of light that is prevented from passing through the well. At the completion of the incubation period, the MIC values and their associated interpretive category results for each antimicrobial on the test card are displayed in an automatically generated report.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   A reproducibility study for the VITEK 2 AST-GN card with Delafloxacin was conducted at three external clinical sites using a panel of ten isolates of Gram-negative bacilli consistent with the indications for use. Testing was performed on three separate days and in triplicate for a total of 270 data points. The isolates tested in the reproducibility study included five *Klebsiella pneumoniae pneumoniae*, two *E. cloacae*, and three *P. aeruginosa* isolates. Inocula were prepared using both the auto-dilution and manual dilution methods for testing in the VITEK 2 System. In addition, inocula were prepared by the manual dilution method only for use with the VITEK 2 Compact. The mode MIC value was determined and the reproducibility was calculated based on MIC values that fell within +/- one doubling dilution from the mode MIC value. The majority of data points were on-scale and within ± one doubling dilution agreement as compared to the mode MIC. Two data points were off-scale when tested by the VITEK 2 and the VITEK 2 Compact. The data was analyzed taking into consideration best case and worst case scenarios as described in the Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems. The reproducibility performance is shown in Table 2.

Table 2: Reproducibility Performance

	VITEK 2		VITEK 2 Compact
	Auto-Dilution	**Manual Dilution**	**Manual Dilution**
Best Case	100%	99.63%	100%
Worst Case	100%	99.63%	99.63%

The combined reproducibility results for all three sites were acceptable.

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Quality Control (QC) Testing
The CLSI recommended QC organisms (*E. coli* ATCC 25922 and *Pseudomonas aeruginosa* ATCC 27853) were tested using both the VITEK 2 card and the reference method at each site. Both the automatic dilution and manual dilution methods were used for the VITEK 2 and the manual dilution method was used for the VITEK 2 Compact.

As shown in Table 3, both the auto-dilution and the manual dilution methods for VITEK 2 and the manual dilution for VITEK 2 Compact were within the expected range >95% of the time.

Table 3: Quality Control Summary Results for VITEK 2 (Auto-Dilution and Manual Dilution Methods) and VITEK 2 Compact (Manual Dilution Method)

Delafloxacin		**VITEK 2**				**VITEK 2 Compact Manual Dilution**	
		Auto-Dilution		**Manual Dilution**			
Organism	**Conc. (µg/mL)**	**Reference**	**Test**	**Reference**	**Test**	**Reference**	**Test**
E. coli ATCC 25922 FDA/CLSI Expected Range 0.008 – 0.03 µg/mL (VITEK 2: ≤0.06 µg/mL)	≤0.004						
	0.008						
	0.015	35		30		30	
	0.03	80		60		60	
	0.06						
	≤0.06*		115		90		90
	0.12						
	0.25						
	≥0.5						
P. aeruginosa ATCC 27853 FDA/CLSI Expected Range 0.12 - 0.5µg/mL (VITEK 2: 0.12 – 0.5 µg/mL)	≤0.015						
	0.03						
	0.06						
	0.12	10		7		7	
	≤0.12**		0		0		0
	0.25	102	100	82	87	82	89
	0.5	4	16	3	4	3	3
	1						
	2						
	≥4				1		

* The lowest dilution of the VITEK 2 Delafloxacin MIC range is ≤0.06 µg/mL for *Enterobacteriaceae*. Obtaining this value was considered an indicator that the quality control test results were acceptable.
** The lowest dilution of the VITEK 2 Delafloxacin MC range is ≤0.12 µg/mL for *P. aeruginosa*. Obtaining this value was considered an indicator that the quality control results were acceptable.

The CLSI Delafloxacin expected ranges for *E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853 are 0.008 – 0.03 and 0.12 – 0.5 µg/mL respectively. However, the VITEK 2 MIC reporting range is ≤0.06 – ≥4 µg/mL (MIC results: ≤0.06, 0.12, 0.25, 0.5, 1, 2, ≥4 µg/mL) for *Enterobacteriaceae* and ≤0.12 – ≥4 µg/mL (MIC results: ≤0.12, 0.25, 0.5, 1, 2, ≥4 µg/mL) for *P. aeruginosa.* The two recommended QC strains tested provided off-scale with the VITEK 2 card as the acceptable ranges are lower than the lowest concentration on the card (0.06 µg/mL for *Enterobacteriaceae* and 0.12 µg/mL for *P. aeruginosa*). The quality control test results were considered acceptable for both QC strains when the MIC value of ≤0.06 µg/mL was obtained for *E. coli* ATCC 25922 and ≤0.12 µg/mL for *P. aeruginosa* ATCC 27853. Given this, bioMérieux included the following footnote indicating that QC for delafloxacin is off-scale:

> *VITEK 2 AST-GN Delafloxacin does not include the full CLSI/FDA recommended dilution range for QC testing with this organism.*

However, during this study, all VITEK QC results for *P. aeruginosa* ATCC 27853 were either at 0.5 or 0.25 µg/mL and none gave a value of ≤0.12µg/mL (See Table 3). In addition, bioMérieux includes the CLSI broth microdilution expected range in the labeling when the VITEK 2 system range is not aligned with that of the FDA/CLSI range. The additional information is acceptable.

Inoculum Density Control
The DensiCHEK Plus was used to standardize the inoculum to a 0.5 McFarland standard. The instrument was standardized daily with all results recorded at each site. Calibration values were within the expected range.

Purity Check
A purity check of all organisms was performed on the dilution tube used to prepare the VITEK 2 card inoculum. Only those cultures that were pure were evaluated in the study.

Growth Failure Rate
There was one isolate that failed to grow in the VITEK 2 card in the clinical study. Complete test results were available for 403 isolates from a total of 404 clinical isolates. The growth failure rate was 0.25% and was acceptable.

A challenge set of 206 isolates was evaluated at one site. All 206 challenge organisms grew in the VITEK 2 GN card with Delafloxacin using both the auto-dilution and manual dilution methods for the VITEK 2 and manual inoculation for the VITEK 2 Compact System.

A total of 609 VITEK 2 AST results were available.

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:

Testing of delafloxacin on the VITEK 2 AST-Gram Negative card was performed at three external sites and on internal site using VITEK 2 Systems (PC) version 9.02. Results obtained with the bioMérieux VITEK 2 AST-Gram Negative card with Delafloxacin were compared to results obtained with the CLSI broth microdilution reference panel. The following concentrations of Delafloxacin are contained in the VITEK 2 AST-GN test card: 0.06, 0.25, 0.5, and 2 µg/mL. However, the reporting range is ≤ 0.06 – ≥4 µg/mL for *Enterobacteriaceae* and ≤ 0.12 – ≥4 µg/mL for *Pseudomonas aeruginosa*. The reference panel contained two-fold serial dilutions with a range of ≤ 0.0039 to ≥16 µg/mL. The testing conditions for the reference method consisted of the following:

- Medium – Mueller Hinton broth with appropriate dilutions of antimicrobial solution added
- Inoculum – Direct colony suspension
- Incubation – 35°C ambient air incubator; 16-20 hours

The VITEK 2 AST cards were inoculated with test organisms using the auto-dilution method (VITEK 2 System) and using the manual dilution method (VITEK 2 System and VITEK 2 Compact). All test inocula used for the VITEK 2 AST cards and the reference method were standardized using the DensiCHEK Plus instrument.

A total of 404 clinical isolates were evaluated at three sites with VITEK 2 AST – Gram Negative cards inoculated by automatic dilution and interpreted using the VITEK 2 instrument. There was one isolate that did not grow in the studies and was excluded from the study. The no growth rate was 0.25% (1/404). Most isolates were recently isolated from clinical specimen (270 isolates, 66.8%). The remainder were stock isolates (134 isolates, 33.2%). The clinical study included several species within *Enterobacteriaceae* that were not indicated in the FDA drug label for delafloxacin.

A total of 206 challenge organisms (147 *Enterobacteriaceae* and 59 *P. aeruginosa*)

were evaluated at one site. The challenge set was tested with the auto-dilution and manual dilution options of the VITEK 2 System and with the manual dilution method on the VITEK 2 Compact System. Challenge isolates included *E. cloacae* (18 isolates), *E. coli* (12 isolates), *K. pneumoniae pneumoniae* (14 isolates), *K. pneumoniae* (103 isolates), and *P. aeruginosa* (59 isolates).

The combined data set of clinical and challenge isolates included 609 AST results (428 *Enterobacteriaceae* and 181 *P. aeruginosa*). A total of 289 (47.4%) resistant isolates were tested among the clinical (n=130) and challenge (n=159) isolates. A sufficient number of resistant isolates from the indicated species were included.

The overall performance using the auto-dilution method of the VITEK 2 System demonstrated an EA of 98.0% and a CA of 95.9%. There were two major errors (2/291 susceptible isolates, 0.7% error rate) and 23 minor errors (23/609 total isolates, 3.7% error rate). The major error and minor error rates were acceptable. With *Enterobacteriaceae* isolates, performance was acceptable with an EA of 98.6% and a CA of 96.0%. With *P. aeruginosa* isolates, performance was acceptable with an EA of 96.7% and a CA of 95.6%. The performance based on combined clinical and challenge data was acceptable. The overall performance is shown in Table 4. In addition, there was no significant difference in performance between indicated organisms only when compared to performance of all *Enterobacteriaceae* isolates tested (Tables 4.1 and 4.2).

To address testing of non-indicated species the sponsor included the following statement in the Precautions section of the device labeling:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

Table 4. Performance of Clinical and Challenge Isolates, VITEK 2 Auto-Dilution Method

Organism Type	EA Total	EA N	EA %	Eval EA Total	Eval EA N	Eval EA %	CA N	CA %	#R	Min	Maj	Vmj
Enterobacteriaceae												
Clinical	281	275	97.9	136	130	95.6	267	95.0	72	12	2	0
Challenge	147	147	100	31	31	100	144	98.0	129	3	0	0
Combined	**428**	**422**	**98.6**	**167**	**161**	**96.4**	**411**	**96.0**	**201**	**15**	**2**	**0**
P. aeruginosa												
Clinical	122	117	95.9	68	63	92.6	115	94.3	58	7	0	0
Challenge	59	58	98.3	30	29	96.7	58	98.3	30	1	0	0
Combined	**181**	**175**	**96.7**	**98**	**92**	**93.9**	**173**	**95.6**	**88**	**8**	**0**	**0**
All species												
Clinical	403	392	97.3	204	193	94.6	382	94.8	130	19	2	0
Challenge	206	205	99.5	61	60	98.4	202	98.1	159	4	0	0
Combined	**609**	**597**	**98.0**	**265**	**253**	**95.5**	**584**	**95.9**	**289**	**23**	**2**	**0**

EA – Essential Agreement (± 1 dilution)
CA – Category Agreement
Eval – Evaluable isolates
R – Resistant isolates
Min – minor discrepancies
Maj – major discrepancies
Vmj – very major discrepancies

Essential agreement (EA) occurs when the result of the reference method and that of the VITEK card are within plus or minus one serial two-fold dilution of the antibiotic. Evaluable results are those that are on scale for both the reference method and the VITEK card. Category agreement (CA) occurs when the interpretation of the result of the reference method agrees exactly with the interpretation provided by the VITEK card.

Table 4.1: Performance of *Enterobacteriaceae* Species (Indicated Species Only), Auto-dilution Method

Delafloxacin	EA Tot	EA N	EA %	Eval EA Tot	Eval EA N	Eval EA %	CA N	CA %	#R	Min	Maj	Vmj
Enterobacter cloacae												
Clinical	10	10	100	9	9	100	9	100	0	0	0	0
Challenge	18	18	100	9	9	100	17	94.4	13	1	0	0
Combined	28	28	100	18	18	100	27	96.4	13	1	0	0
Escherichia coli												
Clinical	97	97	100	15	15	100	92	94.8	38	5	0	0
Challenge	12	12	100	3	3	100	12	100	10	0	0	0
Combined	109	109	100	18	18	100	104	95.4	48	5	0	0
Klebsiella pneumoniae pneumoniae												
Clinical	4	4	100	2	2	100	4	100	1	0	0	0
Challenge	14	14	100	7	7	100	13	92.9	9	1	0	0
Combined	18	18	100	9	9	100	17	94.4	10	1	0	0
Klebsiella pneumoniae												
Clinical	52	47	90.4	31	26	83.9	50	96.2	14	1	1	0
Challenge	103	103	100	12	12	100	102	99.0	97	1	0	0
Combined	155	150	96.8	43	38	88.4	152	98.1	111	2	1	0
***Enterobacteriaceae* (all)**												
Clinical	163	158	96.9	57	52	91.2	156	95.7	53	6	1	0
Challenge	147	147	100	31	31	100	144	98.0	129	3	0	0
Combined	310	305	98.4	88	83	94.3	300	96.8	182	9	[1]	0

Table 4.2: Performance of Delafloxacin, Comparison Between Indicated Species and All Species within *Enterobacteriaceae*

	EA Total	EA#	EA%	Eval EA Tot	Eval EA#	Eval EA%	CA#	CA %	#R	Min	Maj	Vmj
Indicated Species	310	305	98.4	88	83	94.3	300	96.8	182	9	1	0
All Species within *Enterobacteriaceae*	428	422	98.6	167	161	96.4	411	96.0	201	15	2	0

Challenge Data – Auto and Manual Dilution

The challenge data set was evaluated at one site with both the auto-dilution and manual dilution options of the VITEK 2 System and with the manual dilution method on the VITEK 2 Compact System. The performance was acceptable. Overall performance is shown in Table 5, and performances with *P. aeruginosa* and *Enterobacteriaceae* isolates are shown in Table 6 and Table 7, respectively.

Table 5. Performance of Challenge Isolates, VITEK 2 and VITEK 2 Compact – All Organisms

Dilution	EA Total	EA N	EA %	Eval EA Total	Eval EA N	Eval EA %	CA N	CA %	#R	Min	Maj	Vmj
VITEK 2 System												
Auto	206	205	99.5	61	60	98.4	202	98.1	159	4	0	0
Manual	206	203	98.5	61	58	95.1	200	97.1	159	5	1	0
VITEK 2 Compact												
Manual	206	206	100	61	61	100	202	98.1	159	4	0	0

Table 6. Performance of Challenge Isolates, VITEK 2 and VITEK 2 Compact – *P. aeruginosa*

Dilution	EA Total	EA N	EA %	Eval EA Total	Eval EA N	Eval EA %	CA N	CA %	#R	Min	Maj	Vmj
VITEK 2 System												
Auto	59	58	98.3	30	29	96.7	58	98.3	30	1	0	0
Manual	59	57	96.6	31	29	93.5	57	96.6	30	2	0	0
VITEK 2 Compact												
Manual	59	59	100	31	31	100	58	98.3	30	1	0	0

Table 7. Performance of Challenge Isolates, VITEK 2 and VITEK 2 Compact - *Enterobacteriaceae*

Dilution	EA Total	EA N	EA %	Eval EA Total	Eval EA N	Eval EA %	CA N	CA %	#R	Min	Maj	Vmj
VITEK 2 System												
Auto	147	147	100	31	31	100	144	98.0	129	3	0	0
Manual	147	146	99.3	30	29	96.7	143	97.3	129	3	1	0
VITEK 2 Compact												
Manual	147	147	100	30	30	100	144	98.0	129	3	0	0

MIC Trends:

An analysis of trending was conducted using the combined clinical and challenge data for each organism group. This trending calculation considers MIC values that are determined to be one or more doubling dilutions lower or higher compared to the reference method regardless of whether the device MIC values are on-scale. Results

that are not clearly at least one dilution lower, at least one dilution higher or in exact agreement with the CLSI reference method are not considered in the trending analysis.

Trending analysis results are shown in Table 8; results were stratified by species to assess species-related trends. Species for which the difference between the percentage of isolates with higher or lower readings was ≥30 with a statistically significant confidence interval were considered to show evidence of trending. Trending that provides higher or lower MIC values compared to the reference method is addressed in labeling.

There was no trending noted for *P. aeruginosa*, however, when *Enterobacteriaceae* species were analyzed separately and combined, trends for higher MIC values compared to the reference were observed (Table 8). The following footnote was added to the performance table in the package insert to address trending:

> *MIC values tended to be in exact agreement or at least one doubling dilution higher when Enterobacteriaceae isolates compared to the reference micro-dilution.*

Table 8. MIC Trending Analysis of All Organisms (Clinical and Challenge)

Organism	Total Evaluable For Trending	≥1 Dilution Lower No. (%)	Exact No. (%)	≥1 Dilution Higher No. (%)	Percent Difference* (95% CI)	Trending Noted
E. cloacae	18	1 (5.56)	7 (38.9)	10 (55.6)	50 (20.3 to 70.4)	Yes
E. coli	23	0 (0)	11 (47.8)	12 (52.2)	47.8 (24.3 to 67.0)	Yes
K. pneumoniae pneumoniae	10	0 (0)	7 (70)	3 (30)	30.0 (3.8 to 60.3)	Yes
K. pneumoniae	42	3 (7.1)	19 (45.2)	20 (47.6)	(21.9 to 55.9)	Yes
All Enterobacteriaceae	93	4 (4.3)	44 (47.3)	45 (48.4)	44.1 (32.4 to 54.4)	Yes
P. aeruginosa	102	11 (10.8)	64 (62.8)	27 (26.5)	15.7 (5.0 to 26.1)	No

***** A positive percent difference indicates a higher MIC value compared to the reference method. A negative percent difference indicates a lower MIC value compared to the reference method.

b. Matrix comparison:

Not applicable

3. Clinical studies:

   Not applicable

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

Table 6: Interpretive Criteria for Delafloxacin (FDA STIC Webpage*)

Organism	FDA Interpretive Criteria for Delafloxacin MIC (µg/mL)		
	S	**I**	**R**
Enterobacteriaceae	≤0.25	0.5	≥1
Pseudomonas aeruginosa	≤0.5	1	≥2

* FDA STIC Webpage
https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm

N. Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device

O. Conclusion:

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