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

## I Background Information:

### A 510(k) Number

K192738

### B Applicant

bioMérieux SA

### C Proprietary and Established Names

ETEST Delafloxacin (DFX) (0.002-32 µg/mL)

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| JWY | Class II | 21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder | MI - Microbiology |

## II Submission/Device Overview:

### A Purpose for Submission:

To obtain a substantial equivalence determination for delafloxacin at concentrations of 0.002 – 32 µg/mL for susceptibility testing of Gram-negative and Gram-positive aerobic organisms with ETEST.

### B Measurand:

Delafloxacin 0.002 – 32 µg/mL

### C Type of Test:

Quantitative Antimicrobial Susceptibility Test growth-based detection

## III Intended Use/Indications for Use:

### A Intended Use(s):

See Indications for Use below.

### B Indication(s) for Use:

ETEST is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory Concentration (MIC, in μg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation.

Delafloxacin has been shown to be active against the aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.

ETEST DFX can be used to determine the MIC of Delafloxacin against the following microorganisms:

Active both *in vitro* and in clinical infections:

Gram-positive bacteria:
*Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible strains)
*Staphylococcus haemolyticus*
*Staphylococcus lugdunensis*
*Enterococcus faecalis*

Gram-negative bacteria:
*Pseudomonas aeruginosa*

### C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

### D Special Instrument Requirements:

Manual reading only

## IV Device/System Characteristics:

### A Device Description:

The ETEST gradient technology is based on a combination of the concepts of dilution and diffusion principles for susceptibility testing.

The ETEST consists of a thin, inert, nonporous plastic strip that is used to determine the antimicrobial susceptibility of bacteria. One side of the strip has the minimum inhibitory

concentration (MIC) reading scale expressed in µg/mL. The other side of the strip contains a predefined continuous exponential gradient of antibiotic concentrations.

When the strip is applied to an inoculated agar surface, the preformed antibiotic gradient immediately transfers into the agar matrix, then forming a stable, continuous and exponential gradient of antibiotic concentrations directly underneath the strip. Bacterial growth becomes visible during incubation, and a symmetrical inhibition ellipse centered along the strip appears. The MIC value is read from the scale in terms of µg/mL at complete inhibition of bacterial growth, where the pointed end of the ellipse intersects the strip.

ETEST Delafloxacin contains a range of delafloxacin from 0.002 to 32 µg/mL.

### B Principle of Operation:

When the ETEST strip is applied to an inoculated agar surface, the preformed antibiotic gradient immediately transfers into the agar matrix, then forming a stable, continuous and exponential gradient of antibiotic concentrations directly underneath the strip. Bacteria growth becomes visible during incubation, and a symmetrical inhibition ellipse centered along the strip appears. After incubation, the MIC value is read from the scale in terms of µg/mL at complete inhibition of bacterial growth, where the pointed end of the ellipse intersects the strip. Since ETEST generates MIC values which fall between two-fold dilutions for interpretation, the MIC value read must be recorded to the next two-fold dilution.

## V Substantial Equivalence Information:

### A Predicate Device Name(s):

ETEST Telavancin (TLA) (0.002-32 µg/mL)

### B Predicate 510(k) Number(s):

K180936

### C Comparison with Predicate(s):

| **Device & Predicate Device(s):** | **K192738** (device) | **K180936** (predicate) |
|---|---|---|
| Device Trade Name | **ETEST Delafloxacin** | **ETEST Telavancin** |
| **General Device Characteristic Similarities** | | |
| Intended Use/Indications for Use | ETEST is a manual, quantitative technique for determination of antimicrobial susceptibility of non-fastidious Gram-negative and Gram-positive aerobic bacteria and fastidious bacteria. The system comprises a predefined antibiotic gradient which is used to determine the Minimum Inhibitory | Same |

| Device & Predicate Device(s): | K192738 (device) | K180936 (predicate) |
|---|---|---|
| | Concentration (MIC, in µg/mL) of different antimicrobial agents against microorganisms tested on agar media after overnight incubation. | |
| Test Design | Predefined exponential gradient of the dried and stabilized antibiotic covers a continuous concentration range across 15 two-fold dilutions of a conventional MIC method | Same |
| Antimicrobial Concentration Range | 0.002 – 32 µg/mL | Same |
| Inoculum | Isolated colonies from culture | Same |
| Incubation | 35º ± 2º C for 16 – 20 hours | Same |
| Result | MIC in µg/mL | Same |
| **General Device Characteristic Differences** | | |
| Claimed Organisms | • *Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible strains)<br>• *Staphylococcus haemolyticus*<br>• *Staphylococcus lugdunensis*<br>• *Enterococcus faecalis*<br>• *Pseudomonas aeruginosa* | • *Staphylococcus aureus* (including methicillin-resistant isolates)<br>• *Enterococcus faecalis* (vancomycin-susceptible isolates only) |
| Antibiotic | Delafloxacin | Telavancin |

## 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 document M07, 11th ed., "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard, 2018".
- CLSI M100, 29th ed., "Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Ninth Informational Supplement, January 2019".

## VII Performance Characteristics (if/when applicable):

### A. Analytical Performance:

1. Precision/Reproducibility:

Reproducibility testing was conducted at three sites over three days using a twelve-organism panel that included six *Staphylococcus aureus* [4 methicillin-susceptible (MSSA) and 2 methicillin-resistant (MRSA)], two *Staphylococcus haemolyticus*, two *Enterococcus faecalis* and two *Pseudomonas aeruginosa* isolates. The mode of MIC values was determined for each isolate and the reproducibility was calculated based on the number of MIC values that fell within ±1 doubling dilution of the mode.

The overall reproducibility results were acceptable at 100%.

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   **Inoculum Density Check**. Inoculum density checks were performed for all quality control and for 10% of the suspensions prepared for susceptibility testing of the contemporary clinical isolates. Inoculum density checks were also performed on reproducibility organism suspensions.

   The overall mean inoculum densities in colony forming units per milliliter (CFU/mL) for isolates tested with the reference method ranged from $4.33 \times 10^5$ to $5.65 \times 10^5$ CFU/mL. The overall mean inoculum densities for isolates tested with the ETEST ranged from $8.66 \times 10^7$ to $1.51 \times 10^8$ CFU/mL.

   The inoculum densities were acceptable.

   **Purity Check**. Verification of isolate purity was conducted on all clinical, challenge and quality control organism suspensions for each ETEST inoculum and from each growth control well of the broth microdilution (BMD) reference panel.

   **Growth or Device Failure**. Growth was observed for all organisms and no device failures occurred in the ETEST Delafloxacin clinical trial.

   **Quality Control Testing.** The CLSI recommended QC strains (*Enterococcus faecalis* ATCC 29212, *Pseudomonas aeruginosa* ATCC 27853 and *Staphylococcus aureus* ATCC 29213) were tested at least 20 times per site at four sites using both ETEST and BMD reference methods. The results are summarized in **Table 1.**

**Table 1. ETEST Delafloxacin QC Results**

| QC Organism | Delafloxacin Expected Range | Delafloxacin MIC (µg/mL) | Reference (BMD) Results | ETEST Results |
|---|---|---|---|---|
| *E. faecalis* ATCC 29212 | 0.016 – 0.12 µg/mL | <0.016 | | |
| | | 0.016 | | |
| | | 0.03 | 16 | |
| | | 0.06 | 44 | 68 |
| | | 0.12 | 20 | 12 |

| QC Organism | Delafloxacin Expected Range | Delafloxacin MIC (µg/mL) | Reference (BMD) Results | ETEST Results |
|---|---|---|---|---|
| | | >0.12 | | |
| *P. aeruginosa* ATCC 27853 | 0.12 – 0.5 µg/mL | <0.12 | | |
| | | 0.12 | 19 | 4 |
| | | 0.25 | 53 | 72 |
| | | 0.5 | 8 | 4 |
| | | >0.5 | | |
| *S. aureus* ATCC 29213 | 0.001 – 0.008 µg/mL | <0.001 | | |
| | | 0.002 | 41 | |
| | | 0.004 | 24 | 48 |
| | | 0.008 | 14 | 32 |
| | | >0.008 | 1[a] | |

[a] Out-of-range reference result from a single day at one site (internal). The other three *S. aureus* ATCC 29213 QC tested that day gave results within the CLSI expected range. Therefore, QC was considered acceptable for that day.

The Quality Control results were within the recommended range > 95% of the time which is acceptable.

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

**B. Comparison Studies:**

1. Method Comparison with Predicate Device:

   Results obtained with ETEST Delafloxacin were compared to results obtained with the CLSI broth microdilution (BMD) reference panel. The reference panel, prepared and interpreted according to recommendations outlined in the CLSI M07 11th ed., contained two-fold serial dilutions of delafloxacin with a concentration range of 0.002 – 32 µg/mL. At the end of incubation, the MIC value obtained from the ETEST (where the complete inhibition of growth intersects the strip) was compared to MIC results obtained with the reference method. The testing conditions for ETEST consisted of the following:

   - Inoculum: Direct colony suspension to achieve a suspension equivalent to a 0.5 McFarland standard suspension
   - Medium: Cation-adjusted Mueller Hinton broth or agar
   - Incubation: 35° C ± 2 for 16-20 hours

   Clinical testing for ETEST Delafloxacin was evaluated at three external sites (two located within the United States and one located outside the United States). Each clinical isolate was tested one time by ETEST and BMD using the same initial standardized inoculum prepared in 0.85% saline. A total of 538 clinical isolates were tested which included 120 *E. faecalis,*

240 *S. aureus*, 31 *S. haemolyticus*, 27 *S. lugdunensis* and 120 *P. aeruginosa.* Of the tested clinical isolates, 71.0% (382/538) were considered contemporary (i.e., tested within six months of the organism's original isolation from clinical culture) and 29.0% (156/538) were considered stock (i.e., no time limit on time from isolation prior to testing).

Challenge testing was performed at one internal site using ETEST and BMD. A total of 87 challenge isolates were tested which included 7 *E. faecalis*, 47 *S. aureus* (27 MRSA and 20 MSSA), 15 *S. haemolyticus*, 5 *S. lugdunensis* and 13 *P. aeruginosa.*

In total, the comparative study included 625 clinical and challenge isolates.

**Overall Performance**

ETEST Delafloxacin performance observed for clinical and challenge isolates is provided below by clinical indication: Acute Bacterial and Skin Structure Infections (**Table 2**) and Community Acquired Bacterial Pneumonia (**Table 3**).

**Table 2: Performance of Clinical and Challenge Isolates using Breakpoints for Acute Bacterial Skin and Skin Structure Infections (ABSSSI)**

| Delafloxacin | Total | EA N | EA % | Eval. Total | Eval. EA N | Eval. EA % | CA N | CA % | #R | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Enterococcus faecalis*** | | | | | | | | | | | | |
| Clinical | 120 | 120 | 100 | 120 | 120 | 100 | 115 | 95.8 | 34 | 5 | 0 | 0 |
| Challenge | 7 | 7 | 100 | 7 | 7 | 100 | 7 | 100 | 1 | 0 | 0 | 0 |
| Combined | 127 | 127 | 100 | 127 | 127 | 100 | 122 | 96.1 | 35 | 5 | 0 | 0 |
| ***Staphylococcus aureus* (MRSA)** | | | | | | | | | | | | |
| Clinical | 150 | 145 | 96.7 | 139 | 134 | 96.4 | 134 | 89.3 | 4 | 16 | 0 | 0 |
| Challenge | 27 | 25 | 92.6 | 24 | 22 | 91.7 | 25 | 92.6 | 18 | 2 | 0 | 0 |
| Combined | 177 | 170 | 96.0 | 163 | 156 | 95.7 | 159 | 89.8 | 22 | 18 | 0 | 0 |
| ***Staphylococcus aureus* (MSSA)** | | | | | | | | | | | | |
| Clinical | 90 | 89 | 98.9 | 60 | 59 | 98.3 | 89 | 98.9 | 1 | 1 | 0 | 0 |
| Challenge | 20 | 18 | 90.0 | 20 | 18 | 90.0 | 19 | 95.0 | 6 | 1 | 0 | 0 |
| Combined | 110 | 107 | 97.3 | 80 | 77 | 96.3 | 108 | 98.2 | 7 | 2 | 0 | 0 |
| ***Staphylococcus aureus* (MRSA and MSSA combined)** | | | | | | | | | | | | |
| Clinical | 240 | 234 | 97.5 | 199 | 193 | 97.0 | 223 | 92.9 | 5 | 17 | 0 | 0 |
| Challenge | 47 | 43 | 91.5 | 44 | 40 | 90.9 | 44 | 93.6 | 24 | 3 | 0 | 0 |
| Combined | 287 | 277 | 96.5 | 243 | 233 | 95.9 | 267 | 93.0 | 29 | 20 | 0 | 0 |
| ***Staphylococcus haemolyticus*** | | | | | | | | | | | | |
| Clinical | 31 | 31 | 100 | 27 | 27 | 100 | 28 | 90.3 | 1 | 3 | 0 | 0 |
| Challenge | 15 | 15 | 100 | 15 | 15 | 100 | 15 | 100 | 8 | 0 | 0 | 0 |
| Combined | 46 | 46 | 100 | 42 | 42 | 100 | 43 | 93.5 | 9 | 3 | 0 | 0 |
| ***Staphylococcus lugdunensis*** [a] | | | | | | | | | | | | |
| Clinical | 27 | 27 | 100 | 26 | 26 | 100 | n/a | n/a | n/a | n/a | n/a | n/a |
| Challenge | 5 | 5 | 100 | 5 | 5 | 100 | n/a | n/a | n/a | n/a | n/a | n/a |
| Combined | 32 | 32 | 100 | 31 | 31 | 100 | n/a | n/a | n/a | n/a | n/a | n/a |
| ***Pseudomonas aeruginosa*** | | | | | | | | | | | | |
| Clinical | 120 | 118 | 98.3 | 112 | 110 | 98.2 | 114 | 95.0 | 25 | 6 | 0 | 0 |
| Challenge | 13 | 13 | 100 | 11 | 11 | 100 | 13 | 100 | 5 | 0 | 0 | 0 |
| Combined | 133 | 131 | 98.5 | 123 | 121 | 98.4 | 127 | 95.5 | 30 | 6 | 0 | 0 |

n/a: Not applicable due to the lack of breakpoints

[a] Category agreement and error calculations were not made because Delafloxacin breakpoints for *S. lugdunensis* were not established by the FDA.

**EA** – Essential Agreement
**CA** – Category Agreement
**EVAL** – Evaluable isolates
**NS** – Non-susceptible isolates
**min** – minor errors
**maj** – major errors
**vmj** – very major errors

Essential Agreement (EA) is when the ETEST result agrees exactly or within one doubling dilution of the reference broth microdilution result. Category Agreement (CA) is when the ETEST result interpretation agrees exactly with the reference broth microdilution result interpretation.

**Table 3: Performance of Clinical and Challenge Isolates using Breakpoints for Community Acquired Bacterial Pneumonia (CABP)[a]**

| Delafloxacin | Total | EA N | EA % | Eval. Total | Eval. EA N | Eval. EA % | CA N | CA % | #R | min | maj | vmj |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ***Staphylococcus aureus* (MSSA [a])** | | | | | | | | | | | | |
| Clinical | 90 | 89 | 98.9 | 60 | 59 | 98.3 | 82 | 91.1 | 2 | 8 | 0 | 0 |
| Challenge | 20 | 18 | 90.0 | 20 | 18 | 90.0 | 19 | 95.0 | 6 | 1 | 0 | 0 |
| Combined | 110 | 107 | 97.3 | 80 | 77 | 96.3 | 101 | 91.8 | 8 | 9 | 0 | 0 |
| ***Pseudomonas aeruginosa* [b]** | | | | | | | | | | | | |
| Clinical | 120 | 118 | 98.3 | 112 | 110 | 98.2 | 114 | 95.0 | 25 | 6 | 0 | 0 |
| Challenge | 13 | 13 | 100 | 11 | 11 | 100 | 13 | 100 | 5 | 0 | 0 | 0 |
| Combined | 133 | 131 | 98.5 | 123 | 121 | 98.4 | 127 | 95.5 | 30 | 6 | 0 | 0 |

[a] Data was analyzed using CABP breakpoints for MSSA only. Breakpoints are not established for MRSA for this indication.
[b] Performance for testing *P. aeruginosa* was identical for ABSSSI and CABP. Breakpoints for *P. aeruginosa* for both ABSSSI and CABP indications are the same.

ETEST Delafloxacin performance for each organism group was acceptable with both essential agreement and categorical agreement >90% and zero major or very major errors.

According to the FDA drug label, delafloxacin is active both *in vitro* and in clinical infections against *S. lugdunensis.* At the time of testing, breakpoints for delafloxacin and *S. lugdunensis* had not been established; therefore, categorical agreement could not be determined. The following statement is included in the device labeling as a footnote to the performance table:

*Category Agreement is not calculated because Delafloxacin breakpoints for S. lugdunensis were not established by the FDA.*

To address testing and reporting of non-indicated species, the following statement is included in the Warnings and 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.*

**Inoculator and ETEST Strip Applicator Options**

Culture media plates for ETEST can be inoculated and streaked by swabs manually or with the RETRO C80 inoculator. ETEST strips can be applied onto inoculated media using forceps or the NEMA C88 vacuum pen.

The ETEST Delafloxacin studies used both inoculation and strip application methods. The following statement is included as a footnote to the performance table in the device labeling:

> *The optional inoculator and ETEST strip applicator can be used for plate inoculation and applying ETEST strips onto agar media. In the ETEST Delafloxacin clinical studies, swabs and the Inoculator RETRO C80 were used for plate inoculation/streaking and forceps and the Vacuum Pen NEMA C88 were used for ETEST strip application.*

**Trending**

A trending analysis was conducted using the combined data (clinical and challenge) for each organism species and group. This trending calculation analyzes device MIC values that are determined to be one or more doubling dilutions lower or higher than the reference method. MIC values that are off-scale for both the reference and device are not considered in the trending analysis.

Trending results were stratified by species to determine if species-related trends were observed (**Table 4**). Species for which the difference between the percentage of isolates with higher versus lower MIC values was ≥30% and for which the confidence interval was determined to be statistically significant were considered to have evidence of trending and is addressed in labeling.

**Table 4. Trending by Species (clinical and challenge isolates combined)**

| Organism | Total Evaluable for Trending | ≥1 dil. Lower # (%) | Exact # (%) | ≥1 dil. Higher # (%) | Percent Difference (95% CI) | Trending Noted |
|---|---|---|---|---|---|---|
| *Enterococcus faecalis* | 127 | 4 (3.15) | 68 (53.54) | 55 (43.31) | 40.16% (30.64 to 49.06) | yes |
| *Staphylococcus aureus* | 280 | 9 (3.21) | 80 (28.57) | 191 (68.21) | 65.00% (58.69 to 70.39) | yes |
| *Staphylococcus haemolyticus* | 45 | 4 (8.89) | 29 (64.44) | 12 (26.67) | 17.78% (1.81 to 33.12) | no |
| *Staphylococcus lugdunensis* | 31 | 2 (6.45) | 27 (87.10) | 2 (6.45) | 0% (-15.01 to 15.01) | no |
| *Pseudomonas aeruginosa* | 127 | 6 (4.72) | 80 (62.99) | 41 (32.28) | 27.56% (18.43 to 36.48) | no |

As noted above, a trend toward higher MIC values was observed with *S. aureus* and *E. faecalis*. The following statement is included as a footnote to the performance table in the device labeling:

> *ETEST Delafloxacin MIC values tended to be in exact agreement or at least one doubling dilution higher when testing Staphylococcus aureus and Enterococcus faecalis compared to the CLSI reference broth microdilution method.*

**Resistance Markers**

Resistance markers for clinical isolates were identified by whole genome sequencing analysis. They consisted of genetic markers that encode β-lactam resistance (*mecA, mecC, pdc, oxa, veb, lcr-nps*), mutations in defined regions of targeted bacterial enzymes that promote quinolone resistance (MexR, MexT, MexS, GyrA, ParC, ParE) or genetic markers that encode glycopeptides (*vanB*).

2. Matrix Comparison:

Not applicable

## C. Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

## D. Clinical Cut-Off:

Not applicable

## E. Expected Values/Reference Range:

The FDA-identified susceptibility interpretive criteria for delafloxacin for Acute Bacterial Skin and Skin Structure Infections are listed in **Table 5.** The FDA-identified susceptibility interpretive criteria for delafloxacin for Community Acquired Bacterial Pneumonia are listed in **Table 6**.

**Table 5: FDA-Identified Interpretive Criteria for Delafloxacin for Acute Bacterial Skin and Skin Structure Infections (µg/mL) [a]**

| Organism | Susceptible | Intermediate | Resistant |
|---|---|---|---|
| *Enterococcus faecalis* | ≤0.12 | 0.25 | ≥0.5 |
| *Staphylococcus aureus* (methicillin-resistant and methicillin-susceptible isolates) | ≤0.25 | 0.5 | ≥1 |
| *Staphylococcus haemolyticus* | ≤0.25 | 0.5 | ≥1 |
| *Staphylococcus lugdunensis* [b] | n/a | n/a | n/a |
| *Pseudomonas aeruginosa* | ≤0.5 | 1 | ≥2 |

[a] According to FDA STIC Website

[b] *Category Agreement is not calculated because Delafloxacin breakpoints for S. lugdunensis were not established by the FDA.*

**Table 6: FDA-Identified Interpretive Criteria for Delafloxacin for Community Acquired Bacterial Pneumonia (µg/mL)[a]**

| Organism | Susceptible | Intermediate | Resistant |
|---|---|---|---|
| *Staphylococcus aureus* (methicillin-susceptible isolates) | ≤0.12 | 0.25 | ≥0.5 |
| *Pseudomonas aeruginosa* | ≤0.5 | 1 | ≥2 |

[a] According to FDA STIC Website

## 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.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission included a breakpoint change protocol that was reviewed and accepted by FDA. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that bioMérieux intends to use to evaluate the ETEST Delafloxacin when revised breakpoints for delafloxacin are published on the FDA STIC webpage. The breakpoint change protocol included with the submission indicated that if specific criteria are met, bioMérieux will update the delafloxacin device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.