November 26, 2019

BioMerieux SA
Sophie Quiblier
Regulatory Affairs Specialist
376, Chemin de L'Orme
Marcy L'Etoile, 69280 Fr

Re: K192738
Trade/Device Name: ETEST Delafloxacin (DFX) (0.002-32 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: September 26, 2019
Received: September 27, 2019

Dear Sophie Quiblier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Chief, General Bacteriology and Antimicrobial
Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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

A. 510(k) Submission Information:

Submitter's Name:	bioMerieux SA
Address:	376 Chemin de l'Orme
	69280 Marcy-l'Etoile, FRANCE
Contact Person:	Sophie Quiblier
	Regulatory Affairs Specialist
Phone Number:	+33 (0)4 78 87 75 71
Date of Preparation:	September 26th, 2019

B. Device Name:

Formal/Trade Name:	ETEST® Delafloxacin (DFX)
	(0.002 – 32 µg/mL)
Classification Name:	21 CFR 866.1640
	Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name(s):	ETEST® Delafloxacin; ETEST® DFX

C. Predicate Device: ETEST® Telavancin (TLA) (0.002 – 32 µg/mL) (K180936)

D. Device Description:

ETEST® is a thin, inert and non-porous plastic strip carrying on one side the MIC reading scale in µg/mL, and on the other side a predefined antibiotic gradient.

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.

E. Intended 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*

F. Summary of the technological characterictics of the new device in comparison to those of the predicate device.

The similarities and differences of ETEST® Delafloxacin (DFX) when compared to the predicate device, ETEST® Telavancin (TLA)(K180936) are described in the table below:

	Test Device	**Predicate Device**
	Similarities	
	ETEST® Delafloxacin (DFX) **(0.002-32 µg/mL)**	**ETEST® Telavancin (TLA)** **(0.002-32 µg/mL)**
Intended 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	ETEST® is a quantitative technique for determination of antimicrobial susceptibility of both non-fastidious Gram-negative and Gram-positive aerobic bacteria such as *Enterobacteriaceae, Pseudomonas, Staphylococcus,* and *Enterococcus species* and fastidious bacteria, such as *anaerobes, N. gonorrhoeae, S. pneumoniae, Streptococcus* and *Haemophilus species*. The system comprises a predefined antibiotic gradient which is

	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:** • *Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible strains) • *Staphylococcus haemolyticus* • *Staphylococcus lugdunensis* • *Enterococcus faecalis* • *Pseudomonas aeruginosa*	used to determine the Minimum Inhibitory Concentration (MIC), in µg/mL, of different antimicrobial agents against microorganisms as tested on agar media using overnight incubation. Telavancin has been shown to be active against the Gram-positive aerobic microorganisms listed below according to the FDA label for this antimicrobial agent. **Active both *in vitro* and in clinical infections:** • *Staphylococcus aureus* (including methicillin resistant isolates) • *Enterococcus faecalis:* (vancomycin-susceptible only)

Clinical & Challenge Performance Data	Acute Bacterial Skin and Skin Structure Infections (ABSSSI) indication *Staphylococcus aureus* (methicillin resistant and methicillin-susceptible isolates): EA = 96.5% CA = 93.0% *Staphylococcus haemolyticus:* EA = 100% CA = 93.5% *Staphylococcus lugdunensis* EA = 100% CA : Not applicable *Enterococcus faecalis:* EA = 100% CA = 96.1%	*Staphylococcus aureus:* EA = 98.4% CA = 97.9% • *Enterococcus faecalis:* (vancomycin-susceptible only) EA = 91.6% CA = 97.6%

	Pseudomonas aeruginosa: EA = 98.5% CA = 95.5% Community Acquired Bacterial Pneumonia (CABP) indication *Staphylococcus aureus* (methicillin-susceptible isolates): EA = 97.3% CA = 91.8% *Pseudomonas aeruginosa:* EA = 98.5% CA = 95.5%	
Reproducibility	Best-case: 100% Worst-case: 100%	Best-case: 100% Worst-case: 100%
Quality Control	Results within range > 95% of the times tested.	Results within range > 95% of the times tested.
Meets Guidance Document Performance Requirements	Yes	Yes

	Differences	
Antimicrobial Agent	Delafloxacin	Telavancin
Claimed species	• *Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible strains) • *Staphylococcus haemolyticus* • *Staphylococcus lugdunensis* • *Enterococcus faecalis* • *Pseudomonas aeruginosa*	• *Staphylococcus aureus* (including methicillin resistant isolates) • *Enterococcus faecalis:* (vancomycin-susceptible only)

G. Performance Overview

ETEST® Delafloxacin (DFX) (0.002-32 µg/mL) demonstrated substantially equivalent performance when compared with the CLSI M07-A11 January 2018 broth microdilution reference method, following rules as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA, issued on August 28, 2009 and following specifications as defined in CLSI M100-S29 January 2019.

This Premarket Notification (510[k]) presents data in support of ETEST® Delafloxacin (DFX) (0.002-32 µg/mL) for*: Staphylococcus aureus* (including methicillin-resistant and methicillin-susceptible strains), *Staphylococcus haemolyticus*, *Staphylococcus lugdunensis*, *Enterococcus faecalis* and *Pseudomonas aeruginosa*.

External evaluations were conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to establish the performance of ETEST® Delafloxacin (DFX) (0.002-32 µg/mL) by comparing with the CLSI broth microdilution reference method.

ETEST® Delafloxacin (DFX) (0.002-32 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for ETEST® Delafloxacin

	% Essential Agreement (EA)[a)]	% Category Agreement (CA)
Staphylococcus aureus (methicillin resistant and methicillin-susceptible isolates) [b), c)]	96.5	93.0
Staphylococcus haemolyticus [b)]	100.0	93.5
Staphylococcus lugdunensis [b)]	100.0	Not applicable [d)]
Enterococcus faecalis [b), c)]	100.0	96.1
Pseudomonas aeruginosa [b)]	98.5	95.5

Reproducibility and Quality Control demonstrated acceptable results.

Notes:

a) EA = % of MIC values within ± 1 dilution of the reference method.

b) 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.

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

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

Conclusion:

The performance data presented in this submission support a substantial equivalence decision. ETEST® Delafloxacin (DFX) (0.002-32 µg/mL) is substantially equivalent to ETEST® Telavancin (TLA) (0.002-32 µg/mL) (K180936).