July 3, 2018

bioMérieux SA
Asa Karlsson
Sr. Regulatory Affairs Manager
376 Chemin de l'Orme
Marcy L'Etoile, 69280 Fr

Re: K180936
Trade/Device Name: ETEST Telavancin (TLA) (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: April 9, 2018
Received: April 10, 2018

Dear Ms. Karlsson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

For
Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180936

Device Name
ETEST® Telavancin (TLA) (0.002 - 32 ug/mL)

Indications for Use *(Describe)*
ETEST® is a quantitative technique for determination of antimicrobial susceptibility of 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 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 isolates only)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**

**ETEST® Telavancin**

## A. 510(k) Submission Information:

| | |
|---|---|
| Submitter's Name: | bioMerieux SA |
| Address: | 376 Chemin de l'Orme<br>69280 Marcy-l'Etoile, FRANCE |
| Contact Person: | Asa Karlsson<br>Sr. Regulatory Affairs Manager |
| Phone Number: | +33 (0)6 48 61 68 49 |
| Date of Preparation: | July 2, 2018 |

## B. Device Name:

| | |
|---|---|
| Formal/Trade Name: | ETEST® Telavancin (TLA) (0.002 - 32 ug/mL) |
| Classification Name: | 21 CFR 866.1640<br>Manual Antimicrobial Susceptibility Test Systems<br>Product Code: JWY |
| Common Name(s): | ETEST® Telavancin; ETEST® TLA |

## C. Predicate Device:

ETEST® Ceftaroline (CPT) (0.002-32 μg/mL) (K151873)

## D. Device Description:

ETEST® is a thin, inert and non-porous plastic strip carrying on one side (A) the MIC reading scale in μg/mL, and on the other side (B) 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.

## E. Intended Use:

ETEST® is a quantitative technique for determination of antimicrobial susceptibility of 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 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 isolates only)

## F. Performance Overview

ETEST® Telavancin demonstrated substantially equivalent performance when compared with the CLSI M07-A10 January 2015 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-S27 January 2017.

This Premarket Notification (510[k]) presents data in support of ETEST® Telavancin for *Gram positive aerobic bacteria: Staphylococcus aureus* and *Enterococcus faecalis.* 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® Telavancin by comparing with the CLSI broth microdilution reference method.

ETEST® Telavancin demonstrated acceptable performance as presented in **Table 1** below:

**Table 1: Performance Characteristics for ETEST® Telavancin**

| | **% Essential Agreement** | **% Category Agreement** |
|---|---|---|
| | (EA) | (CA) |
| ***Staphylococcus aureus*** (including methicillin resistant isolates) | 98.4 | 97.9 |
| ***Enterococcus faecalis*** (vancomycin susceptible isolates only) | 91.6 | 97.6 |

Reproducibility and Quality Control demonstrated acceptable results.

## G. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. ETEST® Telavancin (0.002-32 μg/mL) is substantially equivalent to ETEST® Ceftaroline (0.002-32 μg/mL) (K151873).