August 22, 2019

bioMérieux SA
Marine Taravant
Regulatory Affairs Specialist
376, Chemin de L'Orme
Marcy L'Etoile, 69280 Fr

Re: K191953
Trade/Device Name: ETEST Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: July 19, 2019
Received: July 22, 2019

Dear Marine Taravant:

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® Imipenem/Relebactam (IPR) (0.002/4-32/4 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:	Marine Taravant
	Regulatory Affairs Specialist
Phone Number:	+33 (0)4 78 87 21 26
Date of Preparation:	July 19th, 2019

B. Device Name:

Formal/Trade Name:	ETEST® Imipenem/Relebactam (IPR)
	(0.002/4 – 32/4 µg/mL)
Classification Name:	21 CFR 866.1640
	Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name(s):	ETEST® Imipenem/Relebactam; ETEST® IPR

C. Predicate Device: ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL) (K183031)

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® Imipenem/Relebactam contains a range of imipenem from 0.002 to 32 µg/mL, overlaid with a fixed concentration of 4µg/mL of relebactam.

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.

Imipenem/Relebactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.

ETEST® IPR can be used to determine the MIC of Imipenem/Relebactam against the following microorganisms:

Active both in vitro and in clinical infections:

- *Citrobacter freundii*
- *Enterobacter cloacae*
- *Escherichia coli*
- *Klebsiella aerogenes*
- *Klebsiella oxytoca*
- *Klebsiella pneumoniae*
- *Pseudomonas aeruginosa*

F. Performance Overview

ETEST® Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL) 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-S28 January 2018.

This Premarket Notification (510[k]) presents data in support of ETEST® Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL) for *Gram negative aerobic bacteria: Enterobacteriaceae* 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® Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL) by comparing with the CLSI broth microdilution reference method.

ETEST® Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for ETEST® Imipenem/Relebactam

	% Essential Agreement	**% Category Agreement**
	(EA)	(CA)
Enterobacteriaceae	95.8	98.1
Pseudomonas aeruginosa	96.0	96.0

Reproducibility and Quality Control demonstrated acceptable results.

Notes:

- *EA = % of MIC values within ± 1 dilution of the reference method.*
- *The performance data presented for Enterobacteriaceae include Citrobacter freundii (30), Klebsiella aerogenes (30), Enterobacter cloacae (33), Enterobacter cloacae complex (70), Escherichia coli (165), Klebsiella oxytoca (32) and Klebsiella pneumoniae (117).*

- *The optional inoculator and ETEST® strip applicator were used for plate inoculation and applying ETEST® strips onto agar media. In the 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.*
- *ETEST® Imipenem/Relebactam MIC values tended to be in exact agreement or at least one doubling dilution higher when testing Enterobacteriaceae and Pseudomonas aeruginosa compared to the reference broth microdilution method.*
- *The percentage of Very Major Errors of 2.3% for Enterobacteriaceae (1/44 resistant Enterobacteriaceae isolates) was only due to one Very Major Error with an E. coli isolate. Repeat testing of both ETEST® Imipenem/Relebactam and the reference method with this isolate showed acceptable category agreement between the two tests.*

Limitations

- Perform an alternative method of testing for isolates of *Morganella morganii*, *Citrobacter koseri*, *Serratia marcescens*, *Providencia rettgeri* and *Providencia stuartii*.
- The ability of ETEST® Imipenem/Relebactam to detect resistant isolates is unknown for *Citrobacter freundii*, *Klebsiella aerogenes*, *Enterobacter cloacae/E. cloacae complex* and *Klebsiella oxytoca* because an insufficient number of resistant strains were available at the time of comparative testing. Isolates yielding Imipenem/Relebactam results suggestive of a resistant category, should be submitted to a reference laboratory for further testing.

G. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. ETEST® Imipenem/Relebactam (IPR) (0.002/4-32/4 µg/mL) is substantially equivalent to ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL).