April 30, 2025

bioMerieux, SA
Sophie Quiblier
Regulatory Affairs Specialist
376 Chemin de l'Orme
Marcy L'Etoile, 69280
France

Re: K250274
Trade/Device Name: ETEST Imipenem/Relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: January 30, 2025
Received: January 30, 2025

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250274

Device Name
ETEST Imipenem/Relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL)

Indications for Use *(Describe)*
ETEST is a manual, quantitative technique for the 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.
Testing with ETEST Imipenem/Relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL) is indicated for Pseudomonas aeruginosa, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).
The ETEST Imipenem/Relebactam P. aeruginosa (IRPA) (0.008/4-128/4 µg/mL) demonstrated acceptable performance with the following microorganism:
• Pseudomonas aeruginosa

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.

ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 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:	Sophie QUIBLIER
	Regulatory Affairs Specialist
Phone Number:	(314) 731-8666
Date of Preparation:	April 28th, 2025

B. Device Name:

Formal/Trade Name:	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL)
Classification Name:	21 CFR 866.1640
	Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name(s):	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) ETEST® (IRPA)

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

D. Device Description:

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

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 *P. aeruginosa* (IRPA) with a concentration range of 0.008/4-128/4 µg/mL is specially designed and formulated for testing *P. aeruginosa.*

E. Intended Use:

ETEST® is a manual, quantitative technique for the 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.

Testing with ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) is indicated for *Pseudomonas aeruginosa*, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC).

The ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) demonstrated acceptable performance with the following microorganism:

- *Pseudomonas aeruginosa*

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

The similarities and differences of ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) when compared to the predicate device, ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) (K183031), are described in the table below:

Item	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) (K183031)
General Device Characteristic Similarities		
Intended Use	ETEST® is a manual, quantitative technique for the 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. Testing with ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) is indicated for *Pseudomonas aeruginosa*, as recognized by the FDA	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. Meropenem/Vaborbactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial

Item	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) (K183031)
	Susceptibility Test Interpretive Criteria (STIC). The ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) demonstrated acceptable performance with the following microorganism: • *Pseudomonas aeruginosa*	agent; ETEST® MEV can be used to determine the MIC of Meropenem/Vaborbactam against indicated organisms (as listed in differences section)
Test Methodology	Quantitative antimicrobial susceptibility test to determine the in vitro susceptibility of microorganisms	Same
Inoculum	Suspension of organism	Same
Type of test	Quantitative	Same
Clinical & Challenge Performance Data	*Pseudomonas aeruginosa* EA = 97.7% CA = 91.1%	Enterobacteriaceae (excluding *Proteus mirabilis*) EA=95.8% CA=99.3%

Item	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) (K183031)
Reproductibility	Best case: 99.6% Worst Case: 99.6%	Best case: 99,6% Worst Case: 99,6%
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	Imipenem/Relebactam	Meropenem/Vaborbactam
Concentrations	Imipenem: 0.008 to 128 µg/mL Relebactam: 4 µg/mL	Meropemen: 0.004 to 64 µg/mL Vaborbactam: 8 µg/mL
Indicated organisms	Testing with ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) is indicated for *Pseudomonas aeruginosa*, as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC). The ETEST Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) demonstrated acceptable performance with the following microorganism:	Meropenem/Vaborbactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent; ETEST® MEV can be used to determine the MIC of Meropenem/Vaborbactam against the following microorganisms. Active both in vitro and in clinical infections:

Item	ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8 µg/mL) (K183031)
	• *Pseudomonas aeruginosa*	○ *Enterobacter cloacae* complex species ○ *Escherichia coli* ○ *Klebsiella pneumoniae* In vitro data are available for the following microorganisms, but clinical significance is unknown: ○ *Citrobacter freundii* ○ *Citrobacter koseri* ○ *Klebsiella aerogenes* ○ *Klebsiella oxytoca* ○ *Morganella morganii* ○ *Providencia spp.* ○ *Serratia marcescens*
Breakpoints	*P.aeruginosa:* (S/I/R) ≤2/4/≥8	Enterobacterales: (S/I/R) ≤4/8/≥16

G. Performance Overview

ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) demonstrated substantially equivalent performance when compared with the CLSI M07-11th Ed (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 34th Ed. (February 2024).

This Premarket Notification (510[k]) presents data in support of ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) for *P. 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 *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) by comparing with the CLSI broth microdilution reference method.
ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA)

	Strains (N)	**% Essential Agreement** (EA)[a)]	**% Category Agreement** (CA)
Pseudomonas aeruginosa	437	97.7	91.1

Notes:

- a) EA = % of MIC values within ± 1 dilution of the reference method.
- b) In the ETEST® Imipenem/Relebactam clinical studies, swabs were used for plate inoculation/streaking and forceps were used for ETEST® strip application. Testing with the optional Inoculator RETRO C80™, Vacuum Pen NEMA C88™ and Applicator SIMPLEX C76™ was not evaluated during the clinical studies.

Reproducibility and Quality Control demonstrated acceptable results.

Conclusion:

The performance data presented in this submission support a substantial equivalence decision. ETEST® Imipenem/Relebactam *P. aeruginosa* (IRPA) (0.008/4-128/4 µg/mL) is substantially equivalent to ETEST® Meropenem/Vaborbactam (MEV) (0.004-64/8µg/mL) (K183031).