October 5, 2023

bioMérieux
Sophie Quiblier
Regulatory Affairs Specialist
376 Chemin de l'Orme
Marcy-l'Etoile, 69280
France

Re: K232395
Trade/Device Name: ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL), ETEST® SUD
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: August 8, 2023
Received: August 9, 2023

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 -S

Ribhi Shawar, Ph.D. D(ABMM), F(AAM)
Branch 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

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)*
K232395

Device Name

ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 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.
Sulbactam/Durlobactam has been shown to be active against the Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.
ETEST® SUD can be used to determine the MIC of Sulbactam/Durlobactam against the following microorganisms:

• *Acinetobacter baumannii-calcoaceticus* complex

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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ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 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:	+33 (0)4 78 87 75 71
Date of Preparation:	August 8th , 2023

B. Device Name:

Formal/Trade Name:	ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL)
Classification Name:	21 CFR 866.1640
	Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name(s):	ETEST® Sulbactam/Durlobactam; ETEST® SUD

C. Predicate Device: (K183031) ETEST® Meropenem/Vaborbactam (0.004/8-64/8 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® Sulbactam/Durlobactam contains a range of Sulbactam from 0.004 to 64 µg/mL, overlaid with a fixed concentration of 4 µg/mL of Durlobactam.

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.

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

ETEST® SUD can be used to determine the MIC of Sulbactam/Durlobactam against the following microorganisms:

Active both in vitro and in clinical infections:

- *Acinetobacter baumanii-calcoaceticus* complex

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

The similarities and differences of ETEST® Sulbactam/Durlobactam (SUD) when compared to the predicate device, ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL) (K183031), are described in the table below:

	Test Device	Predicate Device
	Similarities	
	ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL) (K183031)
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. Sulbactam/Durlobactam has been shown to be active against the aerobic microorganisms listed below according to the	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

	Test Device	Predicate Device
	FDA label for this antimicrobial agent. ETEST® SUD can be used to determine the MIC of Sulbactam/Durlobactam against the following microorganisms: Active both in vitro and in clinical infections: ○ *Acinetobacter baumanii-calcoaceticus* complex	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: ○ *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*
Clinical &	*Acinetobacter baumanii-*	*Enterobacteriaceae*:*

	Test Device	Predicate Device
Challenge Performance Data	*calcoaceticus* complex EA = 97.7% CA = 98.4%	EA = 95.8% CA = 99.3% *Excluding *P.mirabilis*

Reproducibility	Best-case: 99.5% Worst-case: 99.5%	Best-case: 99.6% Worst-case: 99.6%
Quality Control	Results within expected range > 95% of the time.	Results within expected range > 95% of the time.
Meets Guidance Document Performance Requirements	Yes	Yes
	Differencies	
Name	ETEST®Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL)	ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL) (K183031)
Antimicrobial Agent	Sulbactam/Durlobactam	Meropenem/Vaborbactam
Claimed species	*Acinetobacter baumanii-calcoaceticus* complex	○ *Enterobacter cloacae* complex species ○ *Escherichia coli* ○ *Klebsiella pneumoniae*
Product scale	(0.004/4-64/4 µg/mL)	(0.004/8-64/8 µg/mL)

G. Performance Overview

ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 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 33rd. (March 2023).

This Premarket Notification (510[k]) presents data in support of ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL) for *Acinetobacter baumanii-calcoaceticus* complex.

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® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL) by comparing with the CLSI broth microdilution reference method.
ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for ETEST® Sulbactam/Durlobactam

	Strains (N)	**% Essential Agreement** (EA)[a)]	**% Category Agreement** (CA)
Acinetobacter baumanii-calcoaceticus complex	562	97.7%	98.4%

Notes:

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

b) In the ETEST® Sulbactam/Durlobactam 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.

Limitation:

Due to the occurrence of a Very Major Error with Sulbactam/Durlobactam (1/43 resistant isolates), isolates of *Acinetobacter baumannii-calcoaceticus* complex that provide an MIC of 4 µg/mL should be retested by an alternate method, if critical to patient care.

Reproducibility and Quality Control demonstrated acceptable results.

Conclusion:

The performance data presented in this submission support a substantial equivalence decision. ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL) is substantially equivalent to ETEST® Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL) (K183031).