DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2017

BIOMÉRIEUX, INC
CHERECE JONES
STAFF REGULATORY AFFAIRS SPECIALIST
595 ANGLUM RD.
HAZELWOOD MO 63042

Re: K172150
Trade/Device Name: Etest Ceftazidime/Avibactam (CZA) (0.016 - 256 µg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: JWY
Dated: July 13, 2017
Received: July 17, 2017

Dear Ms. Jones:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172150

Device Name
Etest® Ceftazidime/Avibactam (CZA) (0.016-256 µg/mL)

Indications for Use *(Describe)*

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 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.

Ceftazidime/Avibactam has been shown to be active against the Gram negative aerobic microorganisms listed below, according to the FDA label for this antimicrobial agent.

Etest® CZA can be used to determine the MIC of Ceftazidime/Avibactam against the microorganisms listed below:

Active both in vitro and in clinical infections:
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

The following in vitro data are available, but clinical significance is unknown:
Citrobacter koseri
Enterobacter aerogenes
Morganella morganii
Providencia rettgeri
Providencia stuartii
Serratia marcescens

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® Ceftazidime/Avibactam (CZA) (0.016-256 µg/mL)

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Cherece L. Jones Staff Regulatory Affairs Specialist
Phone Number:	314 -731-8684
Fax Number:	314-731-8689
Date of Preparation:	July 13, 2017

B. Device Name:

Formal/Trade Name:	Etest® Ceftazidime/Avibactam (CZA) (0.016-256 µg/mL)
Classification Name:	21 CFR 866.1640 Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name(s):	Etest® Ceftazidime/Avibactam; Etest® CZA

C. Predicate Device: Etest® Ceftolozane/Tazobactam (0.016-256 µg/ml) (K170670)

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 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 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.

Ceftazidime/Avibactam has been shown to be active against the Gram negative aerobic microorganisms listed below, according to the FDA label for this antimicrobial agent.

Etest® CZA can be used to determine the MIC of Ceftazidime/Avibactam against the microorganisms listed below:

Active both *in vitro* and in clinical infections:

Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Pseudomonas aeruginosa

The following *in vitro* data are available, but clinical significance is unknown:

Citrobacter koseri
Enterobacter aerogenes
Morganella morganii
Providencia rettgeri
Providencia stuartii
Serratia marcescens

F. Performance Overview

Etest® Ceftazidime/Avibactam 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-S26 January 2016.

This Premarket Notification (510[k]) presents data in support of Etest® Ceftazidime/Avibactam 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® Ceftazidime/Avibactam by comparing with the CLSI broth microdilution reference method.

Etest® Ceftazidime/Avibactam demonstrated acceptable performance as presented in **Table 1** below:

Table 1: Performance Characteristics for Etest® Ceftazidime/Avibactam

	% Essential Agreement	**% Category Agreement**
	(EA)	(CA)
Enterobacteriaceae*	99.1	99.6
Pseudomonas aeruginosa	99.3	99.3

*The overall very major error rate for *Enterobacteriaceae* was 4.4%. The two very major errors were one dilution apart from the reference method and as such fall within essential agreement. Based on the essential agreement, and the lack of an intermediate breakpoint for Ceftazidime/Avibactam, the adjusted very major rate is 0.0%.

Reproducibility and Quality Control demonstrated acceptable results.

G. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. The Etest® Ceftazidime/Avibactam (CZA) (0.016-256 μg/ml) is substantially equivalent to the Etest® Ceftolozane/Tazobactam (0.016-256 μg/ml) (K170670).