



Food and Drug Administration
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May 31, 2017

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

Re: K170670

Trade/Device Name: Etest Ceftolozane/ Tazobactam (0.016-256 µg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: JWY
Dated: March 3, 2017
Received: March 6, 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

Indications for Use

510(k) Number (if known)

K170670

Device Name

Etest® Ceftolozane / Tazobactam (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.

Etest® Ceftolozane / Tazobactam has been shown to be active against the Gram negative aerobic microorganisms listed below, according to the FDA label for this antimicrobial agent:

Active both in vitro and in clinical infections:

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

Morganella morganii

Proteus vulgaris

Providencia rettgeri

Providencia stuartii

Serratia liquefaciens

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.

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510(k) SUMMARY

Etest® Ceftolozane / Tazobactam

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, SA
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:	March 03, 2017

B. Device Name:

Formal/Trade Name:	Etest® Ceftolozane / Tazobactam (0.016 - 256 ug/ml)
Classification Name:	21 CFR 866.1640 Manual Antimicrobial Susceptibility Test Systems Product Code: JWY
Common Name:	Etest® Ceftolozane / Tazobactam

C. Predicate Device: Etest® Ceftaroline (0.002 - 32ug/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 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.

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Klebsiella pneumoniae

Proteus mirabilis

Pseudomonas aeruginosa

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Morganella morganii

Proteus vulgaris

Providencia rettgeri

Providencia stuartii

Serratia liquefaciens

Serratia marcescens

F. Performance Overview

Etest® Ceftolozane / Tazobactam 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® Ceftolozane / Tazobactam 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® Ceftolozane / Tazobactam by comparing with the CLSI broth microdilution reference method.

Etest[®] Ceftolozane/Tazobactam demonstrated acceptable performance of 97.2% overall Essential Agreement and 98.6% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.

G. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. The Etest[®] Ceftolozane/Tazobactam is substantially equivalent to the Etest[®] Ceftaroline (K151873).