K121002

BIOMÉRIEUX

OCT 12 2012

510(k) SUMMARY

Etest® Ceftaroline

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jennifer Chia-Hsuan Lin Regulatory Affairs Specialist
Phone Number:	314 -731-8639
Fax Number:	314-731-8689
Date of Preparation:	March 30, 2012

B. Device Name:

Formal/Trade Name:	Etest® Ceftaroline
Classification Name:	21 CFR 866.1640 Antimicrobial Susceptibility Test (AST) Powder Product Code - JWY
Common Name:	Antimicrobial susceptibility test

C. Predicate Device: Etest® Tobramycin (K102668)

D. 510(k) Summary:

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.

This submission is for the addition of the antimicrobial ceftaroline at concentrations of 0.002 – 32 µg/mL to the Etest® products. Ceftaroline has been shown to be active in vitro against most strains of the microorganism listed below, as described in the FDA-approved label for this antimicrobial agent.

Active *in vitro* and in clinical infections

Skin Infections
Staphylococcus aureus (including methicillin-susceptible and –resistant isolates)

Etest® Ceftaroline demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the FDA Class II Special Controls

Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued August 28, 2009.

The Premarket Notification (510[k]) presents data in support of Etest® Ceftaroline. An external evaluation was conducted with fresh and stock clinical isolates, as well as a set of challenge strains. The external evaluations were designed to confirm the acceptability of Etest® Ceftaroline by comparing its performance with the CLSI broth microdilution reference method incubated at 16 - 20 hrs. Etest® Ceftaroline demonstrated acceptable performance of 99.8% overall Essential Agreement (EA) and 99.8% overall Category Agreement (CA) with the reference method for Staphylococcus aureus during the trial. Reproducibility and Quality Control demonstrated acceptable results. Details can be found in the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

bioMérieux, Inc.
c/o Jennifer CH Lin
Specialist, Regulatory Affairs
595 Anglum Road
Hazelwood, MO 63042

OCT 12 2012

Re: K121002
Trade Name: Etest®Ceftaroline (0.002 - 32µg/mL)
Regulation Number: 21 CFR §866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: October 4, 2012
Received: October 5. 2012

Dear Lin:

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.

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); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, 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): k121002

Device Name: Etest® Ceftaroline (0.002 – 32 µg/mL)

Indications For 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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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k121002