



Food and Drug Administration
10903 New Hampshire Avenue
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October 7, 2015

BIOMERIEUX SA
CLAIRE DUMAS
REGULATORY AFFAIRS SENIOR SPECIALIST
5, RUE DES AQUEDUCS
CRAPONNE 69290
FRANCE

Re: K151873
Trade/Device Name: Etest[®] Ceftaroline (0.002 - 32µg/ml)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: JWY
Dated: June 30, 2015
Received: July 9, 2015

Dear Ms. Dumas:

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)

K151873

Device Name

Etest® Ceftaroline (0.002 – 32 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.

This submission is for additional indications for the antimicrobial Etest® Ceftaroline at concentrations of 0.002 – 32 µg/mL. Etest® Ceftaroline has been shown to be active in vitro against fastidious strains of the microorganisms listed below, according to the FDA label for this antimicrobial agent:

Streptococcus pneumoniae,
Streptococcus agalactiae,
Haemophilus influenzae.

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[®] Ceftaroline

A. 510(k) Submission Information:

Submitter's Name: bioMérieux SA
Address: 5 rue des Aqueducs
69290 CRAPONNE, France
Contact Person: Claire Dumas
Senior Regulatory Affairs Specialist
Phone Number: +33 (0) 4 78 87 75 22
Fax Number: +33 (0) 4 78 87 76 65
Date of Preparation: June 30, 2015

B. Device Name:

Formal/Trade Name: Etest[®] Ceftaroline
(0.002 – 32 µg/mL)
Classification Name: 21 CFR 866.1640
Antimicrobial Susceptibility Test (AST) Powder
Product Code - JWY
Common Name: Manual Antimicrobial Susceptibility Test
Systems

C. Predicate Device: Etest[®] Ceftaroline (K121002)
(0.002 – 32 µg/mL) - Product code: CPT

D. Device Description

The Etest gradient technology is based on a combination of the concepts of dilution and diffusion principles for susceptibility testing.

The Etest consists of a thin, inert, nonporous plastic strip that is used to determine the antimicrobial susceptibility of bacteria. One side of the strip carries



the minimum inhibitory concentration (MIC) reading scale expressed in $\mu\text{g/mL}$. The other side of the strip contains a predefined continuous exponential gradient of antibiotic concentrations.

When the Etest strip is applied to an inoculated agar surface, an immediate and effective transfer of the preformed antibiotic gradient on the plastic carrier surface into the agar matrix occurs. Following incubation, a symmetrical inhibition ellipse centered along the strip is seen. The MIC value is read from the scale in term of $\mu\text{g/mL}$ where the ellipse edge 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 $\mu\text{g/mL}$, of different antimicrobial agents against microorganisms as tested on agar media using overnight incubation.

This submission is for additional indications for the antimicrobial Etest[®] Ceftaroline at concentrations of 0.002 – 32 $\mu\text{g/mL}$. Etest[®] Ceftaroline has been shown to be active *in vitro* against fastidious strains of the microorganisms listed below, according to the FDA label for this antimicrobial agent:

Streptococcus pneumoniae,
Streptococcus agalactiae,
Haemophilus influenzae.

Note: Etest[®] Ceftaroline (0.002 – 32 $\mu\text{g/mL}$) is already cleared for *in vitro* activity against *Staphylococcus aureus* (including methicillin-susceptible and – resistant isolates) (510(k) K121002 - Oct 2012).

F. Comparison of the technological characteristics of the device compared to the predicate device

This submission is for additional indications for the antimicrobial Etest[®] Ceftaroline at concentrations of 0.002 – 32 $\mu\text{g/mL}$. Etest[®] Ceftaroline has been shown to be active *in vitro* against *Streptococcus pneumoniae*, *Streptococcus agalactiae*, *Haemophilus influenzae* in addition to *Staphylococcus aureus*



(including methicillin-susceptible and – resistant isolates) which claim has already been 510(k) cleared (K121002 - Oct 2012).

The technological characteristics between the two devices are exactly the same (same design, same development, same antimicrobial with same concentrations, same features, storage, handling, intended users and environment of use).

G. Performance data

Etest[®] Ceftaroline demonstrated substantially equivalent performance when compared with the CLSI M07-A9 January 2012 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-S24 January 2014.

This Premarket Notification (510[k]) presents data in support of Etest[®] Ceftaroline for *Streptococcus pneumoniae*, *Streptococcus agalactiae*, *Haemophilus influenzae*. 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[®] Ceftaroline by comparing with the CLSI broth microdilution reference method read at 18 hrs (following recommendation of Antimicrobial agent package insert) and at 23h (following CLSI recommendation of 20-24h).

Etest[®] Ceftaroline demonstrated acceptable performance for overall Essential Agreement (EA) and for overall Category Agreement (CA) with the reference method read at 18h and 23h for each strain. Reproducibility and Quality Control demonstrated acceptable results. Details can be found in the submission.

Performance details:

FDA Breakpoints. Broth Microdilution Reading at 18 hr. Clinical and Challenge Combined

Organism Group	Total Tested	# EA	% EA	# CA	% CA
<i>S. pneumoniae</i>	283	269	95.1%	283	100.00%
<i>S. agalactiae</i>	276	259	93.8%	276	100.00%
<i>H. influenzae</i>	285	265	93.0%	285	100.00%
All Organisms	844	793	94.0%	844	100.00%

FDA Breakpoints. Broth Microdilution Reading at 23 hr. Clinical and Challenge Combined



Organism Group	Total Tested	# EA	% EA	# CA	% CA
<i>S. pneumoniae</i>	283	272	96.1%	283	100.00%
<i>S. agalactiae</i>	276	269	97.5%	276	100.00%
<i>H. influenzae</i>	285	270	94.7%	285	100.00%
All Organisms	844	811	96.1%	844	100.00%

H. Conclusion

The performance data presented in this submission support a substantial equivalence decision. The Etest[®] Ceftaroline is substantially equivalent to the Etest[®] Ceftaroline (K121002).