November 12, 2021

bioMerieux SA
Marine Taravant
Regulatory Affairs Specialist
376, chemin de l'Orme
Marcy-l'Etoile, 69280
France

Re: K210757
Trade/Device Name: ETEST Fosfomycin (FO) (0.032-512 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: March 12, 2021
Received: March 15, 2021

Dear Marine Taravant:

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, Ph.D. (ABMM)
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K210757

Device Name
ETEST® Fosfomycin (FO) (0.032-512 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.

Fosfomycin has been shown to be active against the Gram-positive and Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.

ETEST® (FO) can be used to determine the MIC of Fosfomycin against the following microorganisms:

Active both in vitro and in clinical infections:
- *Escherichia coli*
- *Enterococcus faecalis*

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**ETEST® FOSFOMYCIN (FO) (0.032-512 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: | Marine Taravant |
| | Regulatory Affairs Specialist |
| Phone Number: | +33 (0)4 78 87 21 26 |
| Date of Preparation: | March 12th, 2021 |

## B. Device Name:

| | |
|---|---|
| Formal/Trade Name: | ETEST® FOSFOMYCIN (FO) (0.032–512 µg/mL) |
| Classification Name: | 21 CFR 866.1640 |
| | Manual Antimicrobial Susceptibility Test Systems<br>Product Code: JWY |
| Common Name(s): | ETEST® FOSFOMYCIN; ETEST® FO |

**C. Predicate Device:** (K192050) ETEST® ERAVACYCLINE (ERV) (0.002-32 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® Fosfomycin contains a range of fosfomycin from 0.032 to 512 µg/mL.

## 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.

Fosfomycin has been shown to be active against the Gram-positive and Gram-negative aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.

ETEST® FO can be used to determine the MIC of Fosfomycin against the following microorganisms:

Active both *in vitro* and in clinical infections:

- *Escherichia coli*
- *Enterococcus faecalis*

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

The similarities and differences of ETEST® Fosfomycin (FO) when compared to the predicate device, ETEST® Eravacycline (ERV) (K192050) are described in the table below:

| | Test Device | Predicate Device |
|---|---|---|
| | **Similarities** | |
| | **ETEST® Fosfomycin (FO) (0.032-512 µg/mL)** | **ETEST® Eravacycline (ERV) (0.002-32 µg/mL) (K192050)** |
| 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.<br><br>Fosfomycin has been shown to be active against the aerobic microorganisms listed below according to the FDA label for this antimicrobial agent.<br><br>ETEST® FO can be used to determine the MIC of fosfomycin against 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.<br><br>Eravacycline has been shown to be active against most isolates of the bacteria listed below according to the FDA label for this antimicrobial agent;<br><br>ETEST® ERV can be used to determine the MIC of Eravacycline against the |

| | Test Device | Predicate Device |
|---|---|---|
| | following microorganisms:<br><br>Active both in vitro and in clinical infections:<br><br>o *Escherichia coli*<br>o *Enterococcus faecalis* | following microorganisms.<br><br>Active both in vitro and in clinical infections:<br><br>• Aerobes:<br>o Gram-negative: *Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae.*<br>o Gram-positive: *Enterococcus faecalis, Enterococcus faecium.*<br><br>In vitro data are available for the following microorganisms, but clinical significance is unknown:<br><br>• *Citrobacter koseri*<br>• *Klebsiella aerogenes* |
| Clinical & Challenge Performance Data | *Enterococcus faecalis:*EA = 97.9%<br>CA = 93.7%<br><br>*Escherichia. coli:*<br>EA= 90.8%<br>CA= 99.2% | *Enterobacteriaceae:*<br>EA = 99.4%<br>CA = 98.0%<br><br>*Enterococcus faecalis* and *Enterococcus faecium*<br>EA= 100%<br>CA= 94.9% |

| | | |
|---|---|---|
| Reproducibility | Overall reproducibility results > 95% | Overall reproducibility results > 95% |
| 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** | |
| | **ETEST® Fosfomycin (FO) (0.032-512 µg/mL)** | **ETEST® Eravacycline (ERV) (0.002-32 µg/mL) (K192050)** |
| Antimicrobial Agent | Fosfomycin | Eravacycline |
| Product scale | 0.032-512 µg/mL | 0.002-32 µg/mL |

## G. Performance Overview

ETEST® Fosfomycin (FO) (0.032-512 µg/mL) demonstrated substantially equivalent performance when compared with the CLSI M07-A11 January 2018 agar 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 30th Ed. (January 2020).

This Premarket Notification (510[k]) presents data in support of ETEST® Fosfomycin (FO) (0.032-512 µg/mL) for *Escherichia coli* and *Enterococcus faecalis*.

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® Fosfomycin (FO) (0.032-512 µg/mL) by comparing with the CLSI agar microdilution reference method.

ETEST® Fosfomycin (FO) (0.032-512 µg/mL) demonstrated acceptable performance as presented in **Table 1** below:

**Table 1: Performance Characteristics for ETEST® Fosfomycin**

| | **Strains** (N) | **% Essential Agreement** (EA)[a)] | **% Category Agreement** (CA) |
|---|---|---|---|
| *Enterococcus faecalis*[b)] | 191 | 97.9 | 93.7 |
| *Escherichia coli*[b)c)] | 238 | 90.8 | 99.2 |

**Notes:**

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

b) The optional Inoculator RETRO C80™ and Applicator SIMPLEX C76™ can be used to inoculate plates and apply ETEST® strips to agar media. In the ETEST® Fosfomycin clinical studies, swabs were used for plate inoculation/ streaking, and forceps and the Vacuum Pen NEMA C88™ were used for ETEST® strip application

c) ETEST® Fosfomycin MIC values tended to be in exact agreement or at least one doubling dilution lower when testing *Escherichia coli* compared to the reference agar dilution method.

Reproducibility and Quality Control demonstrated acceptable results.

**Conclusion:**

The performance data presented in this submission support a substantial equivalence decision. ETEST® Fosfomycin (FO) (0.032-512 µg/mL) is substantially equivalent to ETEST® Eravacycline (ERV) (0.002-32 µg/mL) (K192050).