



Food and Drug Administration
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April 15, 2016

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

Re: K152075

Trade/Device Name: VITEK[®] 2 AST - Gram Negative Ertapenem (≤ 0.12 - ≥ 8 $\mu\text{g/mL}$)

Regulation Number: 21 CFR 866.1645

Regulation Name: Fully automated short-term incubation cycle antimicrobial susceptibility system

Regulatory Class: II

Product Code: LON, LTW, LTT

Dated: February 29, 2016

Received: March 1, 2016

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)
K152075

Device Name
VITEK® 2 AST-Gram Negative Ertapenem ($\leq 0.12 - \geq 8$ µg/mL)

Indications for Use (Describe)

VITEK® 2 Gram Negative Ertapenem is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK® 2 and VITEK® 2 Compact Systems as a laboratory aid in the determination of in vitro susceptibility to antimicrobial agents. VITEK® 2 Gram Negative Ertapenem is a quantitative test. Ertapenem has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active in vitro and in clinical infections:

Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis

In vitro data available but clinical significance is unknown:

Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca (excluding ESBL producing isolates)
Morganella morganii
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Serratia marcescens

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp. and clinically significant yeast.

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

VITEK[®] 2 AST-GN Ertapenem

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 24, 2015

B. Device Name:

Formal/Trade Name: VITEK[®] 2 AST-Gram Negative Ertapenem
($\leq 0.12 - \geq 8$ $\mu\text{g/mL}$)
Classification Name: 21 CFR 866.1645
Fully Automated Short-Term Incubation Cycle
Antimicrobial Susceptibility System
Product Code LON
Common Name: VITEK[®] 2 AST-GN Ertapenem

C. Predicate Device: VITEK[®] 2 AST-GN Doxycycline (K121546)

D. 510(k) Summary:

VITEK[®] 2 Gram Negative Ertapenem is designed for antimicrobial susceptibility testing of Gram negative bacilli and is intended for use with the VITEK[®] 2 and VITEK[®] 2 Compact Systems as a laboratory aid in the determination of *in vitro* susceptibility to antimicrobial agents. VITEK[®] 2 Gram Negative Ertapenem is a quantitative test. Ertapenem has been shown to be active against most strains of the microorganisms listed below, according to the FDA label for this antimicrobial.

Active in vitro and in clinical infections:
Escherichia coli

Klebsiella pneumoniae
Proteus mirabilis

In vitro data available but clinical significance is unknown:

Citrobacter freundii
Citrobacter koseri
Enterobacter aerogenes
Enterobacter cloacae
Klebsiella oxytoca (excluding ESBL producing isolates)
Morganella morganii
Proteus vulgaris
Providencia rettgeri
Providencia stuartii
Serratia marcescens

The VITEK[®] 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK[®] 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for the most clinically significant aerobic gram-negative bacilli, *Staphylococcus spp.*, *Enterococcus spp.*, *Streptococcus spp.* and clinically significant yeast.

The antimicrobial presented in VITEK[®] 2 AST-GN Cards is in concentrations equivalent by efficacy to standard method concentrations in mcg/ml. The VITEK[®] 2 AST Cards are essentially miniaturized versions of the doubling dilution technique for determining the minimum inhibitory concentration (MIC) microdilution methodology.

The isolate to be tested is diluted to a standardized concentration in 0.45 - 0.50% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK[®] 2 automatically fills, seals and places the card into the incubator/reader. The VITEK[®] 2 Compact has a manual filling and sealing operation. The VITEK[®] 2 monitors the growth of each well in the card over a defined period of time (up to 18 hours). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antimicrobial contained on the card.

VITEK[®] 2 AST-GN Ertapenem 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 VITEK[®] 2 AST-GN Ertapenem. 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 VITEK[®] 2 AST-GN Ertapenem by comparing its performance with the CLSI broth microdilution reference method incubated at 16-20 hrs. The data is representative of

performance on both the VITEK[®] 2 and VITEK[®] 2 Compact instrument platforms. VITEK[®] 2 AST-GN Ertapenem demonstrated acceptable performance of 97.9% overall Essential Agreement and 97.9% overall Category Agreement with the reference method. Reproducibility and Quality Control demonstrated acceptable results.