DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 12, 2017

BIOMERIEUX, INC.
KAREN RUSSELL
STAFF REGULATORY AFFAIRS SPECIALIST
595 ANGLUM ROAD
HAZELWOOD MO 63042

Re: K161217
Trade/Device Name: VITEK 2 Gram Negative Ceftriaxone (≤0.25 - ≥64 µ/mL)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: II
Product Code: LON
Dated: December 22, 2016
Received: December 23, 2016

Dear Ms. Russell:

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 -A

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161217

Device Name
VITEK® 2 Gram Negative Ceftriaxone
(≤0.25 – ≥64 µg/mL)

Indications for Use *(Describe)*
VITEK® 2 Gram Negative Ceftriaxone is designed for antimicrobial susceptibility testing of Gram-negative bacilli. VITEK® 2 Gram Negative Ceftriaxone is a quantitative test 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. Ceftriaxone 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 clinical infections:

Enterobacter aerogenes	Escherichia coli	Klebsiella oxytoca
Klebsiella pneumoniae	Proteus mirabilis	Serratia marcescens

In vitro data available but clinical significance is unknown:

Citrobacter koseri (formerly Citrobacter diversus)	Citrobacter freundii	Shigella species
Providencia species (including Providencia rettgeri)	Salmonella species (including Salmonella typhi)	

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System 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., S. pneumoniae, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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VITEK® 2 AST-GN Ceftriaxone:
Section 028. 510(k) Summary

A. 510(k) Submission Information:

Submitter's Name: bioMérieux, Inc.

Address: 595 Anglum Road
Hazelwood, MO 63042

Contact Person: Karen Russell
Staff Regulatory Affairs Specialist
Phone Number: 314-731-8639
Fax Number: 314-731-8689

Date of Preparation: December 2, 2016

B. Device Name:

Formal/Trade Name: VITEK® 2 Gram Negative Ceftriaxone
(≤0.25 – ≥64 µg/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 Ceftriaxone

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

D. 510(k) Summary:

VITEK® 2 Gram Negative Ceftriaxone is designed for antimicrobial susceptibility testing of Gram-negative bacilli. VITEK® 2 Gram Negative Ceftriaxone is a quantitative test 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. Ceftriaxone 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 clinical infections:
Enterobacter aerogenes
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis

Serratia marcescens

In vitro data available but clinical significance is unknown:
Citrobacter koseri (formerly Citrobacter diversus)
Citrobacter freundii
Shigella species
Providencia species (including Providencia rettgeri)
Salmonella species (including Salmonella typhi)

The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to be used with the VITEK® 2 System 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., S. pneumoniae, 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 Ceftriaxone 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 Ceftriaxone.

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 Ceftriaxone 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 Ceftriaxone demonstrated acceptable performance of 97.5% overall Essential Agreement and 99.0% overall Category Agreement with the reference method. A performance limitation will be taken for *Proteus vulgaris*. Reproducibility and Quality Control demonstrated acceptable results.