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

BIOMERIEUX, INC.
JOCELYN JENNINGS, M.S., R.A.C.
SENIOR MANAGER, REGULATORY AFFAIRS August 5, 2014
100 RODOLPHE ST
DURHAM NC 27712

Re: K133817
Trade/Device Name: VITEK 2 AST - Yeast Fluconazole
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: II
Product Code: NGZ
Dated: July 17, 2014
Received: July 18, 2014

Dear Ms. Jennings:

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,

Uwe Scherf -S for

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

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)*
K133817

Device Name
VITEK® 2 AST-YS Fluconazole (≤ 0.5 – ≥ 64 µg/mL)

Indications for Use *(Describe)*
VITEK® 2 Yeast Fluconazole is designed for antifungal susceptibility testing of Candida species and 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 antifungal agents. VITEK® 2 Yeast Fluconazole has been shown to be active against most isolates of the microorganisms listed below, according to the FDA label for this antifungal.

Active in vitro and in clinical infections
Candida albicans
Candida parapsilosis
Candida tropicalis

The following in vitro data are available, but their clinical significance is unknown.
Candida dubliniensis
Candida guilliermondii
Candida lusitaniae

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ribhi Shawar -S
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Section 8. 510(k) SUMMARY

VITEK® 2 AST- *Yeast* Fluconazole

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	100 Rodolphe Street Durham, NC 27712
Contact Person:	Jocelyn Jennings Senior Manager, Regulatory Affairs
Phone Number:	919-620-2894
Fax Number:	919-620-2548
Date of Preparation:	December 13, 2013

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST - *Yeast* Fluconazole
Classification Name:	21 CFR 866.1640 Antimicrobial Susceptibility Test Powder Susceptibility Test Plate, Antifungal Product Code NGZ
Common Name:	VITEK® 2 AST - *Yeast* Fluconazole

C. Predicate Device: VITEK® 2 AST - *Yeast* Voriconazole (K092454)

D. 510(k) Summary:

VITEK 2 AST - *Yeast* Fluconazole is designed for an antifungal susceptibility testing of *Candida* species and 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 antifungal agents. The antimicrobial presented in VITEK 2 AST 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 yeast isolate to be tested is diluted to a standardized concentration with 0.45 - 0.5% saline before being used to rehydrate the antimicrobial medium within the card. The VITEK 2 System automatically fills, seals and places the card into the incubator/reader. The VITEK 2 Compact has a manual filling, sealing and loading operation. The VITEK 2 Systems monitor the growth of each well in the card over a defined period of time. At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antibiotic contained on the card.

VITEK 2 AST - *Yeast* Fluconazole for *Candida* species demonstrated substantially equivalent performance when compared with the CLSI broth microdilution reference method, as defined in the *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 - *Yeast* Fluconazole for *Candida* species. An external evaluation was conducted with fresh and stock clinical isolates and stock challenge strains. The external evaluations were designed to confirm the acceptability of VITEK AST - *Yeast* Fluconazole for *Candida* species by comparing its performance with the CLSI broth microdilution reference method. The data is representative of performance on both the VITEK 2 and VITEK 2 Compact instrument platforms, as evidenced in the AST equivalency study presented in the VITEK 2 Compact 510(k), k050002. VITEK 2 AST - *Yeast* Fluconazole for *Candida* species demonstrated acceptable performance of 96.0% overall Essential Agreement and 94.6% overall Category Agreement. Due to performance obtained for Fluconazole with *C. glabrata* the following limitation will appear on the second page of the package insert:

> "Perform an alternative method of testing prior to reporting of results for the following antibiotic/organism combination(s)":
>
> - Fluconazole: *C. glabrata, C. kefyr*

Reproducibility and Quality Control demonstrated acceptable results.