June 20, 2018

bioMerieux, Inc.
Jolyn Tenllado
Regulatory Affairs Expert
595 Anglum Rd.
Hazelwood, Missouri 63042

Re: K181368
Trade/Device Name: VITEK 2 AST-YS Micafungin (≤0.06 - ≥8 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: NGZ, LRG, LTT, LTW
Dated: May 22, 2018
Received: May 23, 2018

Dear Jolyn Tenllado:

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 Part 801 and Part 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181368

Device Name
VITEK® 2 AST-YS Micafungin (≤0.06 – ≥8 µg/mL)

Indications for Use *(Describe)*
VITEK® 2 Yeast Micafungin is designed for antifungal susceptibility testing of Candida species. VITEK® 2 Yeast Micafungin 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. VITEK® 2 Yeast Micafungin 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 clinical infections:
Candida albicans
Candida glabrata
Candida guilliermondii
Candida krusei
Candida parapsilosis
Candida tropicalis

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., 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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510(k) SUMMARY

VITEK 2 AST-YS Micafungin
Special 510(k): Device Modification

510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jolyn Tenllado RA Expert, Global Regulatory Affairs Microbiology
Phone Number:	314 -731-8386
Fax Number:	314-731-8689
Date of Preparation:	May 22, 2018

B. Device Name:

Formal/Trade Name:	VITEK 2 AST-Yeast Micafungin (≤0.06 – ≥8 µg/mL)
Classification Name:	Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645
Common Name:	VITEK 2 AST-YS Micafungin

C. Predicate Device: VITEK 2 AST-YS Micafungin (K151923)

D. 510(k) Summary:

VITEK® 2 Yeast Micafungin is designed for antifungal susceptibility testing of Candida species. VITEK® 2 Yeast Micafungin 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. VITEK® 2 Yeast Micafungin 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 clinical infections:
Candida albicans
Candida glabrata
Candida guilliermondii
Candida krusei
Candida parapsilosis
Candida tropicalis

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., *S. pneumoniae*, and clinically significant yeast.

The intended use of the VITEK 2 AST-YS Micafungin, as described in its labeling (package insert), has not changed as a result of this modification to change the expected QC range for QC organism *C. parapsilosis* ATCC 22019 from 0.5-2 µg/mL to 0.25-1 µg/mL based on a completed CLSI M23 study to establish the new QC range. This modification does not affect the fundamental scientific technology of this device. The device design was not altered in any way.

The VITEK 2 AST-YS Micafungin modified device, to change the QC organism *C. parapsilosis* ATCC 22019 expected QC range from 0.5-2 µg/mL to 0.25-1 µg/mL, demonstrated acceptable performance during risk assessment validation studies. Validation of the modified QC range and QC performance with the modified range has now been established. This Special 510(k) Device Modification presents data in support of the VITEK AST-YS Micafungin QC organism expected range change, and corresponding labeling changes, allowing a substantial equivalence decision when compared with the VITEK 2 AST-YS Micafungin unmodified device cleared under K151923.