February 25, 2022

BioMerieux, Inc.
Esther Hernandez
Regulatory Affairs Specialist
595 Anglum Road
Hazelwood, Missouri 63042

Re: K213241
Trade/Device Name: VITEK 2 AST-Yeast Fluconazole (<=0.5->=64 µg/mL), VITEK 2 AST-YS Fluconazole (<=0.5->=64 µg/mL), VITEK 2 AST-YS Fluconazole
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON
Dated: September 29, 2021
Received: September 30, 2021

Dear Esther Hernandez:

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)*

K213241

Device Name

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

Indications for Use *(Describe)*

VITEK® 2 AST-Yeast Fluconazole is designed for antifungal susceptibility testing of Candida species 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 antifungal agents. VITEK® 2 AST-Yeast Fluconazole is a quantitative test. Fluconazole has been shown to be active against most strains 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 VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an *in vitro* test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.

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-YS Fluconazole

A. 510(k) Submission Information:

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Esther Hernandez Regulatory Affairs Specialist
Phone Number:	314 -731-8841
Fax Number:	314-731-8689
Date of Preparation:	September 29, 2021

B. Device Name:

Formal/Trade Name:	VITEK® 2 AST-Yeast Fluconazole (≤ 0.5 – ≥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-YS Fluconazole

C. Predicate Device: VITEK® 2 AST-Yeast Fluconazole (K133817)

D. Device Description:

The principle of the VITEK® 2 AST cards is based on the microdilution minimum inhibitory concentration (MIC) technique reported by MacLowry and Marsh [(1)] and Gerlach [(2)]. The VITEK® 2 AST card is essentially a miniaturized, abbreviated and automated version of the doubling dilution technique [(3)].

Each VITEK® 2 AST card contains 64 wells. A control well which only contains microbiological culture media is resident on all cards. The remaining wells contain premeasured portions of a specific antibiotic combined with culture media. The bacterial or 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-YS Fluconazole has the following concentrations in the card: 2, 4, 8, 16, 32, and 64 (equivalent standard method concentration by efficacy in µg/mL).

E. Substantial Equivalence Information

The similarities and differences of the VITEK 2 AST-YS Fluconazole when compared to the predicate device, VITEK 2 AST-YS Fluconazole (K133817), are described in the following table. The only difference between both devices are the Indications for Use and the breakpoints used to analyze the data performance. The below table provides the similarities and differences:

Item	Device: VITEK® 2 AST-YS Fluconazole	Predicate: VITEK® 2 AST-GN Fluconazole (K133817)
	Similarities	
Intended Use	VITEK® 2 AST-Yeast Fluconazole is designed for antifungal susceptibility testing of Candida species 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 antifungal agents. VITEK® 2 AST-Yeast Fluconazole is a quantitative test. Fluconazole has been shown to be active against most strains 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 VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of	VITEK® 2 AST-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 AST-Yeast Fluconazole has been shown to be active against most strains 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*

	clinically significant yeasts to antifungal agents when used as instructed.	The VITEK® 2 Antimicrobial Susceptibility Test (AST) is intended to for use with the VITEK 2 Systems for the automated quantitative or qualitative susceptibility testing of isolated colonies for most clinically significant aerobic Gram-negative bacilli, Staphylococcus spp., Enterococcus spp., Streptococcus spp. and clinical significant yeast.
Test Methodology	Automated quantitative antimicrobial susceptibility test for use with the VITEK® 2 and VITEK® 2 Compact Systems to determine the *in vitro* susceptibility of yeast.	Same
Antimicrobial Agent	Fluconazole	Same
Inoculum	Saline suspension of organism	Same
Test Card	VITEK® 2 Yeast (AST) Susceptibility Test Card	Same
Analysis Algorithms	Discriminant Analysis	Same
Instrument	VITEK® 2 and VITEK® 2 Compact Systems	Same
Concentrations	2, 4, 8, 16, 32, 64	Same
Differences		
Indications for Use	*Candida albicans* *Candida parapsilosis* *Candida tropicalis*	*Candida albicans* *Candida parapsilosis* *Candida tropicalis* *Candida dubliniensis* *Candida guilliermondii* *Candida lusitaniae*
Breakpoints for *Candida* spp.	*Candida albicans:* ≤2 (S), 4 (I), ≥8 (R) *Candida parapsilosis:* ≤2 (S), 4 (I), ≥8 (R) *Candida tropicalis:* ≤2 (S), 4 (I), ≥8 (R)	*Candida* spp.: ≤8 (S), 16-32 (I), ≥64 (R)

F. Intended Use:

VITEK® 2 AST-Yeast Fluconazole is designed for antifungal susceptibility testing of Candida species 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 antifungal agents. VITEK® 2 AST-Yeast Fluconazole is a quantitative test. Fluconazole has been shown to be active against most strains 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 VITEK® 2 Fungal Susceptibility Card is intended for use with the VITEK® 2 Systems in clinical laboratories as an in vitro test to determine the susceptibility of clinically significant yeasts to antifungal agents when used as instructed.

G. Performance Overview:

VITEK® 2 AST-YS Fluconazole 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 (Special 510[k]) presents data in support of VITEK® 2 AST-YS Fluconazole. 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-YS Fluconazole by comparing its performance with the CLSI broth microdilution reference method incubated at 24 hours (or up to 48 hours for isolates that are not growing well at 24 hours). The data is representative of performance on both the VITEK® 2 and VITEK® 2 Compact instrument platforms.

VITEK® 2 AST-YS Fluconazole demonstrated acceptable performance of 96.2% overall Essential Agreement and 93.7% overall Category Agreement with the reference method when testing *C. albicans, C. parapsilosis*, and *C. tropicalis*.

Antimicrobial	Anti-microbial Code	Antibiotic Version	Bp[1]	Comment	Essential Agreement				Category Agreement				%Repro-ducibility
					% Error				% Error				
					% EA	VME	ME	mE	% CA	VME	ME	mE	
Fluconazole	FLU	flu02n	CLSI (FDA)	#, E,	(425/442) 96.2	N/A	N/A	N/A	(414/442) 93.7	(2/26) 7.7	(12/398) 3.0	(14/442) 3.2	100
					An overall essential agreement rate of 99.1% and an overall category agreement rate of 94.5% were observed for *Candida parapsilosis* when tested with VITEK 2 Fluconazole. Compared to the reference broth microdilution, two of 14 results for *Candida parapsilosis* (one of which was in essential agreement) resulted in very major errors. VITEK 2 Fluconazole MIC values tended to be in exact agreement or at least one doubling dilution higher when testing *C. albicans, C parapsilosis,* and *C. tropicalis* compared to the broth microdilution reference method.								

[1]Abbreviations – Bp = breakpoint committee; EA = essential agreement; CA = category agreement; VME = Very Major Error (susceptible result with resistant reference result); ME Major Error (resistant result with susceptible reference result); mE = minor Error (susceptible or resistant result with an intermediate reference result, or an intermediate result with a susceptible or resistant reference result)
# = US Food and Drug Administration 510(k) cleared
CLSI = Clinical and Laboratory Standards Institute
E = External performance data
N/A = Not applicable

Reproducibility and Quality Control demonstrated acceptable results.

H. Conclusion:

The performance data presented in this submission support a substantial equivalence decision. VITEK® 2 AST-Yeast Fluconazole (≤ 0.5 – ≥64 µg/mL) is substantially equivalent to VITEK® 2 AST-Yeast Fluconazole (K133817).

References:

1. MacLowry, J.D. and Marsh, H.H., Semi-automatic Microtechnique for Serial Dilution Antibiotic Sensitivity Testing in the Clinical laboratory, Journal of Laboratory Clinical Medicine, 72:685-687, 1968.
2. Gerlach, E.H., Microdilution 1: A Comparative Study, p. 63-76. Current Techniques for Antibiotic Susceptibility Testing. A. Balows (ed.), Charles C. Thomas, Springfield, IL, 1974.
3. Barry, A.L., The Antimicrobic Susceptibility Test, Principles and Practices, Lea and Febiger, Philadelphia, PA, 1976.