K092454

BIOMÉRIEUX

510(k) SUMMARY

VITEK® 2 Yeast Voriconazole

510(k) Submission Information:

MAY 21 2010

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Nancy Weaver Associate Director, Regulatory Affairs
Phone Number:	314 -731-8695
Fax Number:	314-731-8689
Date of Preparation:	August 06, 2009

B. Device Name:

Formal/Trade Name:	VITEK® 2 Yeast Voriconazole
Classification Name:	21 CFR 866.1640 Antimicrobial Susceptibility Test Product Code NGZ
Common Name:	VITEK® 2 AST-YS Voriconazole

C. Predicate Device: VITEK® 2 Yeast Fluconazole (K061945)

D. 510(k) Summary:

VITEK® 2 Yeast Voriconazole is designed for antifungal susceptibility testing of *Candida* species. VITEK® 2 Yeast Voriconazole 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. Voriconazole has been shown to be active against most strains of the following microorganisms listed below according to the FDA label for the antifungal.

Candida albicans	*Candida tropicalis*
Candida krusei	*Candida lusitaniae*
Candida parapsilosis	*Candida guilliermondii*

The antifungal 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 isolate to be tested is diluted to a standardized concentration in 0.45% saline before being used to rehydrate the antifungal 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 36 hours for

yeast). At the completion of the incubation cycle, a report is generated that contains the MIC value along with the interpretive category result for each antifungal contained on the card.

VITEK® 2 Yeast Voriconazole demonstrated substantially equivalent performance when compared with the CLSI reference method, as defined in the FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA. Issued Feb. 5, 2003.

The Premarket Notification (510[k]) presents data in support of VITEK® 2 Yeast Voriconazole. 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® 2 Yeast Voriconazole by comparing its performance with the CLSI reference method incubated at 24 and at 48 hrs. 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 Yeast Voriconazole demonstrated acceptable performance of 99.2% overall Essential Agreement and 99.2% overall category agreement with the reference method incubated for 24 hrs. With the reference method incubated 48 hrs the overall Essential Agreement was 96.9% and overall category agreement was 98.7%. Reproducibility and Quality Control demonstrated acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Biomerieux, Inc.
c/o Nancy Weaver
Associate Director, Regulatory Affairs
595 Anglum Rd.
Hazelwood, Missouri 63042

MAY 2 1 2010

Re: k092454

Trade/Device Name:	Vitek ® 2 Yeast Voriconazole
Regulation Number:	21CFR §866.1640
Regulation Name:	Antifungal susceptibility of Candida species to Voriconazle
Regulatory Class:	Class II
Product Code:	NGZ
Dated:	May 10, 2010
Received:	May 11, 2010

Dear Ms. Weaver:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such 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. This letter will allow you to begin marketing your device as described in your Section

510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K09 2454

Device Name: VITEK® 2 Yeast Voriconazole (0.12 – 8 µg/ml)

Indications For Use:

VITEK® 2 Yeast Voriconazole is designed for antifungal susceptibility testing of *Candida* species. VITEK 2 Yeast Voriconazole 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. Voriconazole has been shown to be active against most strains of the following microorganisms listed below according to the FDA label for the antifungal.

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

Active *in vitro* but their clinical significance is uknown:
Candida lusitaniae
Candida guilliermondii

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie K. Poole
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K09 2454