

K061945



SEP 19 2006

510(k) SUMMARY

VITEK[®] 2 Yeast Fluconazole

510(k) Submission Information:

Submitter's Name: bioMérieux, Inc.
Address: 595 Anglum Road
Hazelwood, MO 63042
Contact Person: Nancy Weaver
Staff Regulatory Affairs Specialist
Phone Number: 314 -731-8695
Fax Number: 314-731-8689
Date of Preparation: July 6, 2006

B. Device Name:

Formal/Trade Name: VITEK[®] 2 Yeast Fluconazole
Classification Name: 21 CFR 866.1640
Antimicrobial Susceptibility Test
Common Name: VITEK 2 AST-YS Fluconazole

C. Predicate Device:

YEASTONE[®](K0991810) Fluconazole

D. 510(k) Summary:

VITEK[®] 2 Yeast Fluconazole is designed for antifungal susceptibility testing of *Candida* species. It is intended for use with the VITEK 2 System as a laboratory aid in the determination of *in vitro* susceptibility to antifungal agents. The antifungal presented in the VITEK 2 AST Cards is in concentrations equivalent by efficacy to standard method concentrations in µg/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 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 monitors the growth of each well in the card over a defined period of time (up to 36 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 antifungal contained on the card.

bioMérieux, Inc.

595 Anglum Road, Hazelwood, Missouri 63042-2320, USA Phone: 314/731-8500 800/638-4835 Fax: 314/731-8700
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VITEK 2 Yeast Fluconazole 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 Fluconazole. 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 Fluconazole by comparing its performance with the CLSI reference method incubated at 24 and at 48 hrs. VITEK 2 Yeast Fluconazole demonstrated acceptable performance of 97.6% overall Essential Agreement with the reference method incubated for 24 hrs; and 97.1 % overall Essential Agreement with the reference method incubated for 48 hrs. Reproducibility and Quality Control demonstrated acceptable results.



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Ms. Nancy Weaver
Staff Regulatory Affairs Specialist
BioMérieux, Inc.
595 Anglum Road
Hazelwood, MO 63042-2320

Re: k061945
Trade/Device Name: VITEK[®] 2 Yeast Fluconazole (1 - 64 µg/ml)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully automated short-term incubation cycle antimicrobial
susceptibility system
Regulatory Class: Class II
Product Code: NGZ
Dated: July 6, 2006
Received: July 10, 2006

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 either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Sally A. Hojvat". The signature is written in a cursive style with a long, sweeping horizontal line extending to the right from the end of the name.

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): K061945

Device Name: VITEK[®] 2 Yeast Fluconazole (1 – 64 µg/ml)

Indications For Use:

VITEK[®] 2 Yeast Fluconazole is designed for antifungal susceptibility testing of *Candida* species. VITEK 2 Yeast Fluconazole is a quantitative test. It is intended for use with the VITEK 2 System as a laboratory aid in the determination of *in vitro* susceptibility to antifungal agents.

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
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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