



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Cythina C. Knapp  
Director Lab Services  
Trek Diagnostic System Inc  
982 Keynote Circle Suite 6  
Cleveland, OH 44131

**MAR 6 2009**

Re: k081063  
Trade/Device Name: Sensititre<sup>®</sup> YeastOne<sup>®</sup> Susceptibility plates  
Regulation Number: 21 CFR 866.1640  
Regulation Name: Antimicrobial Susceptibility Test Powder  
Regulatory Class: Class II  
Product Code: NGZ  
Dated: February 19, 2009  
Received: February 20, 2009

Dear Ms Knapp:

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.

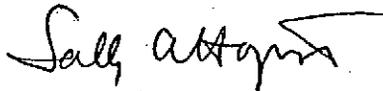
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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), 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" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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): K081063

Device Name: Sensititre® YeastOne® Susceptibility System with Voriconazole (0.008 - 16µg/ml) for *Candida* spp.

Indications for Use: The Sensititre® YeastOne® Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of *Candida* spp.

**This 510(k) is for voriconazole in the dilution range of 0.008 - 16µg/ml for testing *Candida* spp. on the Sensititre® YeastOne® Susceptibility system. The approved primary "Indications for Use" and clinical significance of voriconazole is for:**

*Candida albicans*  
*Candida krusei*  
*Candida parapsilosis*  
*Candida tropicalis*

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)

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

  
\_\_\_\_\_  
Division Sign-Off

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K081063