



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Cynthia C. Knapp  
Director Lab Services  
TREK Diagnostic Systems, Inc.  
29299 Clemens Road, Suite 1-K  
Westlake, OH 44145

NOV - 9 2006

Re: k062839

Trade/Device Name: Sensititre<sup>®</sup> *Haemophilus influenzae*/*Streptococcus pneumoniae* (HP)  
MIC Susceptibility Plates, for Tetracycline (0.5-8 µg/ml),  
Trimethoprim/Sulphamethoxazole (0.5/9.5-4/76 µg/ml),  
Vancomycin (0.5-4 µg/ml)

Regulation Number: 21 CFR 866.1640

Regulation Name: Antimicrobial Susceptibility Test Powder

Regulatory Class: Class II

Product Code: JWY, LRG

Dated: September 19, 2006

Received: September 27, 2006

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).

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, appearing to read "Sally A. Hojvat", with a long horizontal flourish extending to the right.

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):

K062839

**Device Name:** Sensititre® Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC Susceptibility Plates.  
Tetracycline (0.5-8µg/ml), Trimethoprim/Sulphamethoxazole (0.5/9.5-4/76 µg/ml), Vancomycin (0.5-4 µg/ml)

**Indications For Use:**

The Sensititre® Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC Susceptibility plate is an *in vitro* diagnostic product for clinical susceptibility testing of *Haemophilus influenzae*; *Streptococcus pneumoniae* and *Streptococcus species*.

**This 510(k) is for the addition of *Streptococcus spp*s to Tetracycline (0.5 –8 ug/mL), Trimethoprim/Sulphamethoxazole (0.5/9.5-4/76 ug/mL), Vancomycin (0.5-4 ug/mL) for use with the Sensititre® Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC Susceptibility Plates.**

**Tetracycline is for:**

- Streptococcus pneumoniae*
- Streptococcus agalactiae*
- Streptococcus pyogenes*
- Viridans group streptococci
- Streptococcus* (beta-hemolytic group )

**Trimethoprim/Sulphamethoxazole is for**

- Streptococcus pneumoniae*

**Vancomycin is for:**

- Streptococcus pneumoniae*
- Streptococcus pyogenes*
- Viridans group streptococci
- Streptococcus agalactiae*
- Streptococcus* (beta-hemolytic group )

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)

*Frederic M. Poole*  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K062839