



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 27 2004

Ms. Cynthia C. Knapp  
Director Lab Services  
TREK Diagnostic Systems, Inc.  
982 Keynote Circle, Suite 6  
Cleveland, OH 44131

Re: k041534  
Trade/Device Name: Sensititre<sup>®</sup> Haemophilus/Streptococcus pneumoniae (HP)  
MIC/Susceptibility Plate and Test Panel for Telithromycin  
0.002-16µg/ml  
Regulation Number: 21 CFR 866.1640  
Regulation Name: Antimicrobial Susceptibility Test Powder  
Regulatory Class: Class II  
Product Code: JWY, LRG  
Dated: June 8, 2004  
Received: June 8, 2004

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.

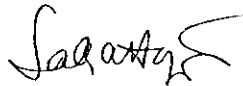
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.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): K041534

Device Name: Sensititre® Haemophilus/Streptococcus pneumoniae (HP) MIC/ Susceptibility Plate and Susceptibility Test Panel for: Telithromycin 0.002-16µg/ml

### Indications For Use:

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

The Sensititre 18 - 24 hour MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of gram positive organisms.

**This 510(k) is for the addition of Telithromycin in the dilution range of 0.002-16µg/ml to the Sensititre Haemophilus/Streptococcus pneumoniae (HP) MIC Susceptibility plate for testing Haemophilus/Streptococcus pneumoniae and the Sensititre 18 - 24 hour MIC panel for testing gram positive isolates. The approved primary "Indications for Use" and clinical significance for Telithromycin is for: Streptococcus pneumoniae (including multi-drug resistant isolates [MDRSP]), Haemophilus influenzae, and Staphylococcus aureus (methicillin and erythromycin susceptible isolates only). In vitro data, without clinical correlation is provided for: Streptococcus pyogenes (erythromycin susceptible isolates only).**

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)

Freddie M. Poole  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

K041534