DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

FEB 25 2010

Ms. Cindy Knapp
Director, Lab Services
TREK Diagnostics Systems, Inc.,
982 Keynote Circle, Suite 6
Cleveland, OH 44131

Re: k093741
Trade/Device Name: Sensititre® *Haemophilus influenza/Streptococcus pneumoniae* (HP) MIC susceptibility plates, Tigecycline (0.004 - 8µg/mL)
Regulation Number: 21 CFR § 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: II
Product Code: JWY, LRG
Dated: December 2, 2009
Received: December 4, 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).

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) 276-0484. 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/industry/support/index.html

Sincerely yours,

Freddie M. Poole
for

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): K093741

Device Name: **Sensititre® *Haemophilus influenza/Streptococcus pneumoniae* (HP) MIC susceptibility plates, Tigecycline (0.004 – 8µg/mL)**

Indications for Use:

The Sensititre® *Haemophilus influenza/Streptococcus pneumoniae* (HP) MIC susceptibility plates and JustOne® are *in vitro* diagnostic products for quantitatively and or qualitative susceptibility testing of isolated colonies of *Haemophilus influenzae, Streptococcus pneumoniae* and *Streptococcus* species from clinical specimens.

Plates can either be read manually or automatically on the Sensititre Autoreader and/or ARIS with *Streptococcus pneumoniae* and *Streptococcus* species and manually with *H. influenzae.* The JustOne® strip can only be read manually.

This 510(k) is for the addition of Tigecycline in the dilution range of 0.004 - 8 µg/ml for testing *Streptococcus pneumoniae* isolates on the Sensititre® (HP) MIC susceptibility system. The additional approved primary "Indications for Use" and clinical significance of Tigecycline is for:

Aerobic facultative Gram-positive microorganisms
*Streptococcus pneumoniae (*Penicillin susceptible stains 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)

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

Lucinda A. Pook
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K093741