DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

MAR 2 0 2008

Re: k073653
Trade/Device Name: The Sensititre® 18-24 MIC or BP Susceptibility System with Dtest 1 and 2 (1 contains erythromycin at 4µg/ml and clindamycin at 0.5µg/ml and 2 contains erythromycin at 8µg/ml and clindamycin 1.5µg/ml) broth test for Staphylococcus spp.
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial susceptibility test powder
Regulatory Class: Class II
Product Code: JWY, LRG
Dated: March 13, 2008
Received: March 14, 2008

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 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" (21CFR 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): k073653

Device Name:
The "Sensititre® 18-24 hour MIC or BP Susceptibility Test System" with Dtest 1 and 2 (1 contains erythromycin at 4ug/ml and clindamycin at 0.5ug/ml and 2 contains erythromycin at 8ug/ml and clindamycin at 1.5ug/ml) broth test for *Staphylococcus* spp.

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

This 510(k) is for the addition of: "Dtest"
The Dtest for Broth Microdilution Test is for *Staphylococcus* spp. resistant to (MIC's $\geq$ 8ug/ml) erythromycin and susceptible or intermediate (MIC's $\leq$ 2ug/ml) to clindamycin. With these isolates a Dtest 1 (4/0.5 ug/ml) or 2 (8/1.5 ug/ml) or both 1 and 2 are positive (growth) the test should be reported as inducible clindamycin resistance. If with these isolates there is no growth in both Dtest 1 and 2 the isolates should be reported as negative for inducible resistance.

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)
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k073653