DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 1 2005

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

Re: k052091
Trade/Device Name: Susceptibility Test Panel for Tigecycline 0.008-16µg/ml Gram Positive
Susceptibility Test Panel for Tigecycline 0.015-16µg/ml Gram Negative
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: JWY, LRG, LTT
Dated: July 29, 2005
Received: August 2, 2005

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,

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): K052091

Device Name: Susceptibility Test Panel for Tigecycline 0.008-16μg/ml for Gram Positive
Susceptibility Test Panel for Tigecycline 0.015-16μg/ml for Gram Negative

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 Tigecycline in the dilution range of 0.008 - 16 μg/ml for testing gram positive and 0.015-16μg/ml for testing gram negative isolates to the Sensititre 18 - 24 hour MIC panel. The approved primary "Indications for Use" and clinical significance of Tigecycline is for:

Aerobic facultative Gram-postive microorganisms
Enteroccus faecalis (vancomycin-susceptible isolates only)
Staphylococcus aureus (methicillin-susceptible and –resistant isolates)
Streptoccus agalactiae
Streptococcus pyogenes
***Aerobic and facultative Gram*-negative microorganisms**
Citrobacter freundii
Enterobacter cloacae
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae

In vitro data, without clinical correlation is provided for:

Aerobic and facultative Gram-postive microorganisms
Enterococcus avium
Enterococcus casseliflavus
Enterococcus faecalis (vancomycin-resistant isolates)
Enterococcus faecium (vancomycin-susceptible and –resistant isolates)
Enterococcus gallinarum
Staphylococcus epidermidis (methicillin-susceptible and –resistant isolates)
Staphylococcus haemolyticus
Aerobic and facultative Gram-negative microorganisms
Acinetobacter baumannii
Aeromonas hydrophila
Citrobacter koseri

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052091

Enterobacter aerogenes
Serratia marcescens
Stenotrophomonas maltophilia

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)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052091