Indications for Use

510(k) Number (if known): k040846

Device Name: Sensititre Haemophilus/Streptococcus pneumoniae (HP) MIC Susceptibility Plate For Ertapenem 0.008-16µg/ml

Indications For Use:

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

This 510(k) is for the addition of Ertapenem in the dilution range of 0.008-16µg/ml to the Sensititre Haemophilus/Streptococcus pneumoniae (HP) MIC Susceptibility plate for testing Haemophilus/Streptococcus pneumoniae isolates. The approved primary "Indications for Use" and clinical significance for Ertapenem is for: Streptococcus pneumoniae (penicillin susceptible strains only) and Haemophilus influenzae (Beta-lactamase negative strains only). In vitro data, without clinical correlation is provided for: Streptococcus pneumoniae (penicillin-intermediate strains only) and Haemophilus influenzae (Beta-lactamase positive strains)

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

k040846

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1 2004

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

Re: k040846
Trade/Device Name: Sensititre Haemophilus/Streptococcus pneumoniae (HP) MIC Susceptibility Plate for Ertapenem 0.008-16µg/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: JWY
Dated: March 31, 2004
Received: April 1, 2004

Dear Ms. Knapp:

This letter corrects our substantially equivalent letter of April 26, 2004, regarding the change of address.

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.

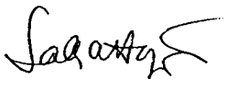
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 (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