



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 16 2009

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

Re: K092445

Trade/Device Name: Sensititre 18-24 hour Susceptibility Plates
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Test Powder
Regulatory Class: Class II
Product Code(s): JWY
LRG
Dated: July 30, 2009
Received: August 10, 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 class II (Special Controls), 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.

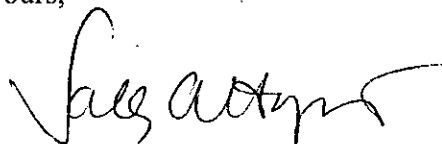
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, Ph.D.
Director, Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use

510(k) Number (if known): K092445

Device Name: The "Sensititre® 18 - 24 hour MIC or Breakpoint Susceptibility System" with Minocycline (0.03 - 32µg/ml) for Gram Negative and Gram Positive's

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 addition of Minocycline in the dilution range of 0.03 - 32µg/ml for testing gram negative and gram positive isolates on the Sensititre® 18 - 24 hour Susceptibility system. The approved primary "Indications for Use" and clinical significance of Minocycline is for:

Aerobic and facultative Gram-negative and Gram-positive microorganisms:

Escherichia coli

Klebsiella spp.

Enterobacter aerogenes

Acinetobacter spp.

Staphylococcus aureus*

*Minocycline is not the drug of choice in the treatment of any type of staphylococcal infection.

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)



Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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