



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

TREK Diagnostic Systems, Ltd.
C/o Cindy Knapp
Director of US Regulatory and Global Clinical Affairs
982 Keynote Circle, Suite 6
Cleveland OH 44131

NOV - 8 2011

Re: K111615

Trade/Device Name: Sensititre® 18-24 hour Susceptibility MIC Plates
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY, LRG
Dated: November 2, 2011
Received: November 4, 2011

Dear Cindy 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.

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

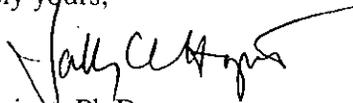
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FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally Hojvat, 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)

510(k) Number (if known):

Device Name: Sensititre® HP MIC Susceptibility Plate with Ceftaroline (0.015-32µg/ml) and The Sensititre® 18 - 24 hour MIC Susceptibility System Test Panel with Ceftaroline (0.015-64µg/ml)

Indications for Use: The Sensititre HP MIC Susceptibility plate with Ceftaroline (0.015-32µg/ml) and the Sensititre 18-24 hour MIC susceptibility System Test Panel with Ceftaroline (0.015-64µg/ml) are intended for use with the Sensititre MIC or BP Susceptibility System.

The Sensititre HP MIC Susceptibility plate is an *in vitro* diagnostic product for clinical susceptibility testing of fastidious isolates. The Sensititre 18 - 24 hour MIC or Breakpoint Susceptibility System is an *in vitro* diagnostic product for clinical susceptibility testing of non-fastidious isolates.

This 510(k) is for the addition of Ceftaroline in the dilution range of 0.015-32µg/ml to the Sensititre HP MIC Susceptibility plate for testing *Haemophilus influenzae* and the Sensititre 18 - 24 hour MIC panel in the dilution range of 0.015-64µg/ml for testing gram negative isolates.

The approved primary "Indications for Use" and clinical significance of Ceftaroline is for:

Facultative Gram-negative Microorganisms:

Escherichia coli
Klebsiella pneumoniae
Klebsiella oxytoca
Haemophilus influenzae

In vitro data, without clinical correlation is provided for:

Facultative Gram-Negative Microorganisms:

Citrobacter koseri
Citrobacter freundii
Enterobacter cloacae
Enterobacter aerogenes
Moraxella catarrhalis
Morganella morganii
Proteus mirabilis

Ceftaroline is not active against Gram negative bacteria producing extended spectrum beta-lactamases (ESBLs) from the TEM, SHV or CTX-M families, serine carbapenemases (such as KPC), class B metallo-beta-lactamases or class C (AmpC cephalosporinases).

Prescription Use X
(Part 21 CFR 801 Subpart D)

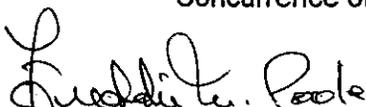
AND/OR

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)

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Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111615