DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

TREK Diagnostic Systems
c/o Cynthia C. Knapp
Director of U.S. Regulatory and Global Affairs
982 Keynote Circle, Suite 6
Cleveland, OH 44131

NOV 16 2011

Re: K112276
Trade/Device Name: The Sensititre ® Vizion®
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY
Dated: October 12, 2011
Received: October 24, 2011

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.

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) 796-7100 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

K112276

INDICATIONS FOR USE STATEMENT
Vizion®

510(k) Number

Device Name:
The "Sensititre® Vizion®

Indications for Use:

The Sensititre® Vizion® is intended for use with the Sensititre® MIC or BP Susceptibility Test System. The "Sensititre® Vizion® is an instrument that takes a digital image of a Sensititre® susceptibility plate and magnifies it through the use of a dedicated software and a monitor. The Sensititre® Vizion® is an alternate manual reading method for the Sensititre® MIC plates for non-fastidious Gram positive, Gram negative and fastidious organisms comprising of *Haemophilus influenzae, Streptococci pneumoniae* and *Streptococci* other than *S. pneumoniae* and *Candida* spp.

NOTE: Please refer to the Sensititre® 18-24 hour MIC or Breakpoint Susceptibility System package insert and the YeastOne package insert for additional instructions, limitations, and references.

This 510(k) is for the addition of: "Vizion® for reading Sensititre YeastOne Plates"
The Vizion® captures an image of a Sensititre 96 well micro-titre susceptibility plate and projects it onto a touch screen monitor. The user determines the MIC by visually looking for the color change as indicated in the YeastOne technical insert.

The "Vizion" can be used as an alternate method where the user manually reads the MIC result on the Sensititre System.

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)

Freddie M. Poole

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K112276