DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 2 2003

Nadine M. Sullivan, Ph.D.
Chief Science Officer
TREK Diagnostic Systems
982 Keynote Circle, Suite 6
Cleveland, OH 44131

Re: k032306
Trade/Device Name: VERSATREK
Regulation Number: 21 CFR 866.2560
Regulation Name: Microbial Growth Monitor
Regulatory Class: Class I
Product Code: MDB
Dated: July 17, 2003
Received: July 25, 2003

Dear Dr. Sullivan:

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). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT
VersaTREK Instrument

Blood Culture System (K921637/A): VersaTREK System is for cultivating and recovering microorganisms, especially bacteria and yeasts, from blood and other normally sterile body fluids.

Myco Detection (K972756): VersaTREK Myco, with VersaTrek Myco GS, and Either VersaTREK as or PVNA added is a selective growth medium for use with either VersaTREK or ESP II Culture system II for the culture recovery of mycobacteria from sterile body specimens and from digested-decontaminated clinical specimens.

Myco modification-Organism Identification (KK972772): Organism identification may be determined using nucleic acid probes (AccuProbe®) .

Mycobacterium tuberculosis susceptibility testing (K972772): The VersaTREK Myco Susceptibility Kit is intended for qualitative *in vitro* susceptibility testing of isolated colonies of *Mycobacterium tuberculosis* with Rifampin, Ethambutol, and Isoniazid on the VersaTREK instrument. Appropriate inoculum sources are prepared from growth on solid agar, such as Middlebrook 7H10 or Lowenstein-Jensen slants, or Middlebrook 7H9 broth.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

Division Sign-Off 8/20/03

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032306

Prescription Use √ OR Over-The-Counter Use _____
(Per 21CFR 801.109) (Optional Format 1-2-96)