Ms. Lorna Gamboa  
Regulatory Affairs Manager  
Varian, Inc.  
Consumable Products  
25200 Commercentre Drive  
Lake Forest, CA 92630

Re:  k033659  
Trade/Device Name: OnTrak Test Tcups® and OnTrak Test Tstik®  
Regulation Number: 21 CFR 862.3100  
Regulation Name: Amphetamine Test System  
Regulatory Class: Class II  
Product Code: DKZ, DIO, DJG, LDJ, LCM, LDJ, JXM, DIS  
Dated: November 19, 2003  
Received: November 21, 2003

Dear Ms. Gamboa:

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 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

510(k) Number: K033659

Device Name: OnTrak Testcup and OnTrak Teststik

Indications for Use:

OnTrak Testcup and OnTrak Teststik products, as listed below, are in vitro diagnostics tests intended for professional use for the qualitative detection of drugs in urine at or above the stated cutoff concentrations.

OnTrak Testcup Products:
- OnTrak Testcup 4
- OnTrak Testcup 5
- OnTrak Testcup 5 M2K
- OnTrak Testcup 501
- OnTrak Testcup PRO-5

OnTrak Teststik Products:
- OnTrak Teststik AMP
- OnTrak Teststik BAR
- OnTrak Teststik BNZ
- OnTrak Teststik COC
- OnTrak Teststik MET
- OnTrak Teststik MOR
- OnTrak Teststik PCP
- OnTrak Teststik THC
- OnTrak Teststik 2 COC/THC
- OnTrak Teststik 3 COC/MOR/THC

Cutoff Concentrations:

- Amphetamines: 1000 ng/mL
- Barbiturates: 200 ng/mL
- Benzodiazepines: 100 ng/mL
- Cocaine metabolite: 300 ng/mL
- Methamphetamine: 500 ng/mL
- Morphine: 300 ng/mL
- Morphine (M2K): 2000 ng/mL
- Phencyclidine (PCP): 25 ng/mL
- Tetrahydrocannabinols (THC): 50 ng/mL

OnTrak Testcup and OnTrak Teststik products provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.

Conurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033659

Prescription Use (Per 21 CFR 801.109) OR Over-the-Counter Use

(Optional Format 1-2-96) CONFIDENTIAL