Summary of Safety and Effectiveness

The sponsor, Technical Chemicals and Products, Inc. (3341 SW 15th St., Pompano Beach, Fl. 33069), has developed, manufactured, and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Benzodiazepine and its metabolites in a screening format.

The trade name of the device is One Step™ Urine Drug of Abuse: Benzodiazepine Test having a designated common name of Benzodiazepine Test System and a classification as a Class II device per 21 CFR ¶ 862.3170. This device is intended for the medical/forensic screening of urine.

Technical Chemicals and Products, Inc.'s One Step™ Urine Drug of Abuse: Benzodiazepine Test, consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the free drug in the specimen forming an antibody:antigen complex. This complex competes with immobilized antigen conjugate in the positive reaction zone and will not produce a magenta color band when the drug is above the detection level of 200 ng/ml. Unbound dye conjugate binds to the reagent in the control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly.

In-house testing of Technical Chemicals and Products, Inc.'s One Step™ Urine Drug of Abuse: Benzodiazepine Test yielded an agreement within positive samples of 1.000 and an agreement within negative samples of 0.9740 and an accuracy of 98.54% when tested against Syva EMIT $II_{(200)}$ ® on samples documented to be positive by $GC/MS_{(200)}$. A clinical trial consisting of 303 samples was run and the combined data yielded an agreement within positives of 100%, an agreement within negatives of 95.42% with an accuracy of 97.69% when compared to Emit $II_{(200)}$ ® run at 200 ng/ml. By non-parametric testing, the results are significantly different from one another. Emit II® yielded 7 false positives. $GC/MS_{(200)}$ results indicated the presence of drugs, but at a level below the cutoff of 200 ng/ml.

All positive samples by either screening method were confirmed by $GC/MS_{(200)}$. The testing performed by both the Sponsor and the Clinical Trial site did find 2 and 7 respectively false positives and no false negatives in the samples tested. $GC/MS_{(200)}$ confirmed the presence of benzodiazepines, but at levels below the cutoff of 200 ng/ml.

Additional information on this submission may be obtained by contacting Dr. Cleve W. Laird, President, Drial Consultants, Inc. at 805-522-6223(Ca) or by fax at 805-522-1526.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 29 1998

Technical Chemicals & Products, Inc.
C/O Cleve W. Laird, Ph.D.
Drial Consultants, Inc.
1420 Los Angeles Avenue, Suite 201
Simi Valley, California 93065

Re: K980776
One-Step™ Urine Drug of Abuse: Benzodiazepine Assay
Regulatory Class: II
Product Code: JXM
Dated: February 25, 1998
Received: March 2, 1998

Dear Dr. Laird:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known): **Not yet Assigned**

Device Name: **One Step™ Urine Drug of Abuse: Benzodiazepine assay**

Indications For Use:

INTENDED USE

Technical Chemicals and Products, Inc.'s One Step™ Urine Drug of Abuse: Benzodiazepine assay is a rapid, qualitative, competitive binding immunoassay for the determination of Benzodiazepine in urine at the cutoff level of 200 ng/ml. **The test provides only preliminary data that should be confirmed by other methods such as gas chromatography/mass spectrophotometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated[6]. Technical Chemicals and Products, Inc.'s One Step™ Urine Drug of Abuse: Benzodiazepine Test is not intended to monitor drug levels, but only to screen urine for the presence of Benzodiazepine and its metabolites.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k980776

Prescription Use: ✓ **or** **Over The Counter Use:** _____
(Per 21 CFR 801.109 **(Optional Format 1-2-96)**