Summary of Safety and Effectiveness

The Sponsor, TCPI, Inc. (3341 S.W. 15th Street, 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 Phencyclidine (PCP) and its metabolites in a screening format. The trade name of the device is One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test, having a designated common name of Phencyclidine (PCP) Test System and a classification as a Class II device per FDA..

TCPI's One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip is a rapid, qualitative, competitive binding immunoassay for the determination of Phencyclidine (PCP) in urine. The One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip is intended to be used in professional laboratories (medical & forensic) where preliminary screening is essential. The test provides only preliminary data which should be confirmed by other methods: in particular, preliminary positive results must be substantiated with an approved confirmatory method, such as gas chromatography/mass spectrometry (GC/MS) Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are positive. This test is not intended to be used for monitoring drug levels, but only to screen urines for the presence of Phencyclidine (PCP)

TCPI's One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip is 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 a limited number of antibody binding sites. As a test sample flows up through the absorbent device, labeled antibody-dye conjugate binds to free drug in the specimen, forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the Test Zone of the strip, and will not produce a magenta color band when the drug concentration in the specimen is above the detection level of 25 ng/ml. Unbound dye conjugate binds to the reagent in the Control Zone of the strip, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **negative** specimen produces two distinct color bands, one in the Test Zone and one in the Control Zone A **positive** specimen produces only one color band in the Control Zone.

TCPI's One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip was tested in-house on 227 individual urine samples, and was subsequently tested in a clinical trial on 286 individual urine samples which were submitted to a NIDA certified laboratory. In both studies, the laboratories used Emit® II Phencyclidine (PCP) as their screening procedure, with a cutoff of 25 ng/ml. The accuracy of the One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip was 513/513 or 100%, when compared to Emit® II. Compared to Emit® II, the relative sensitivity or agreement between positive samples was 223/223 or 100%, and the relative specificity or agreement between negative samples was 290/290 or 100%. All 223 samples which tested positive by either screening method (Emit® II or One Step Urine Drug of Abuse Phencyclidine™ (PCP) Test Strip) were confirmed by GC/MS. When compared to GC/MS, the Emit® II screening method reported two (2) false positives and the One Step strip reported two (2) false positives GC/MS results for these samples indicated that they contained phencyclidine levels of 21 and 23 ng/ml.

Additional information on this submission may be obtained by contacting Dr. Jeffrey Bolts, Technical Chemicals and Products, Inc., at 954-979-0400 (FL) or by fax at 954-979-0009.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 22 1998

Dr. Jeffrey Bolts
Director of Quality Assurance
Technical Chemicals & Products, Inc.
P.O. Box 8726
Ft. Lauderdale, FL 33310

Re: K981363
Trade Name: One Step Urine Drug of Abuse: Phencyclidine (PCP) Test
Regulatory Class: II
Product Code: LCM
Dated: November 20, 1998
Received: November 27, 1998

Dear Dr. Bolts:

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 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). 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 at (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 Issued

Device Name: One Step™ Urine Drug of Abuse: Phencyclidine (PCP) Test

Indications For Use:

INTENDED USE

TCPI's One Step™ Urine Drug of Abuse: Phencyclidine (PCP) Test is a rapid, qualitative, competitive binding immunoassay for the determination of Phencyclidine (PCP) in urine at the cutoff level of 25 ng/ml. **The test provides only preliminary data which 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]. TCPI's One Step™ Urine Drug of Abuse: Phencyclidine (PCP) Test is not intended to monitor drug levels, but only to screen urines for the presence of Phencyclidine (PCP) 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 K981363

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