

JUN 16 1998

510k Submission for

* 981197

One Step™ Urine Drug of Abuse Amphetamine Test
Technical Chemicals & Products, Inc.

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Revision A -3/15/98 Printed (3/31/98)

Statement of Safety and Effectiveness

The sponsor, Technical Chemicals and Products, Inc. (3340 S.W. 15th Street, Pompano Beach, Florida, 33069), has developed, manufactured and tested under GMP/GLP guidelines a device for the qualitative testing of urine for the presence of Amphetamine and its metabolites in a screening format. This summary was originally written in May of 1995 and has been updated as of March, 1998.

The trade name of the device is One Step™ Urine Drug of Abuse Amphetamine Test having a designated common name of Amphetamine Test System and a classification as a Class II device per 21 CFR ¶ 862.3100. This device is intended for professional medical/forensic screening of urine for Amphetamine.

TCPI's One Step™ Urine Drug of Abuse Amphetamine 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 500 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.

The sponsor tested the product in laboratory studies against GC/MS. The accuracy of this 260 sample population was 99.62%. Subsequent clinical trials on 300 patient samples yielded a calculated accuracy of 96.00%. When the results of all testing is combined the total number of comparisons was 560 and the calculated accuracy was found to be 97.68%. If the 12 ephedrine positive samples are dropped the accuracy of the TCPI test is 99.82%. The comparison of results clearly demonstrated no difference between the TCPI One Step™ Urine Drug of Abuse Amphetamine Test and other screening tests as noted in the presentation of results. Like all of the screening methods tested TCPI's will report false positives when ephedrine and phenyl propanolamine are present.

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

JUN 16 1998

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

Re: K981197
One Step™ Urine Drug of Abuse Amphetamine Test
Regulatory Class: II
Product Code: DKZ
Dated: March 31, 1998
Received: April 2, 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 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 (Pre-market 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 pre-market 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.

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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): As Yet to be Assigned

Device Name: One Step™ Urine Drug of Abuse Amphetamine Test

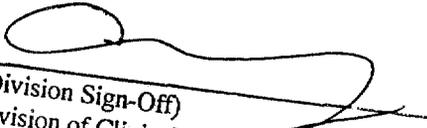
Indications For Use:

INTENDED USE

The TCPI One Step™ Urine Drug of Abuse Amphetamine Test is a rapid, qualitative, competitive binding immunoassay for the determination of Amphetamine in urine. 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 indicated⁶. The TCPI One Step™ Urine Drug of Abuse Amphetamine assay is not intended to monitor drug levels, but only to screen urines for the presence of amphetamine and its metabolites.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981197

Perscription Use: 
(Per 21 CFR 801.109)

or

Over The Counter Use: "
(Optional Format 1-2-96)