

APR 14 2003

**510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)**

K030447

Identification: At Home Drug Cup (Model 9150X)

Description: Immunoassay for the qualitative detection of amphetamine, MDA, methamphetamine, MDMA, THC, cocaine and opiates in urine

Name Of Manufacturer: Phamatech
9530 Padgett Street, Suite 101
San Diego, California 92126, USA

Intended Use: The At Home Drug Cup is a rapid, qualitative immunoassay for the detection of the target drugs/drug metabolites in urine. The cut-off concentration for this test is as follows: amphetamine and MDA; 1000 ng/ml, methamphetamine and MDMA; 500 ng/ml, THC (or marijuana); 50 ng/ml, cocaine; 300 ng/ml, opiates; 300 ng/ml. This assay is intended for use in the home to assist in the prevention of drug abuse. This kit is designed to incorporate a mechanism for anonymous confirmation testing to be performed at a SAMHSA certified laboratory.

Technology: The At Home Drug Cup, like many commercially available drug screening test kits, qualitatively measures the presence of target drugs or their metabolites by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the QuickScreen At Home Drug Test (9150T) and the Applied Biotech SureStep Test (San Diego, CA 92121). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target drug / antibody / complexes.

Performance: The product performance characteristics of the At Home Drug Cup were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Phamatech At Home Drug Cup to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of the stated target drugs in urine. Correlations studies, using clinical specimens, produced a >98% correlation when compared to the Behring EMIT II (Cupertino, CA 95014) and GC/MS methodology. Clinical studies, performed at two independent laboratories, were also performed. In them the Phamatech At Home Drug Test™ exhibited excellent overall accuracy (>97%) in the hands of professional users. A consumer study was also performed. The At Home Drug Cup exhibited excellent overall accuracy (388/400 correct or 97%) in the hands of lay users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech At Home Drug Cup Model 9150X is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the lay user.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 14 2003

Mr. Carl Mongiovi
Vice President
Pharmatech, Inc.
9530 Padgett Street – Suite 101
San Diego, CA 92126

Re: k030447
Trade/Device Name: At Home Drug Cup (Model 9150X)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: MVO; LAF; DKZ; DIO; DJG; LDJ
Dated: March 17, 2003
Received: March 24, 2003

Dear Mr. Mongiovi:

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.

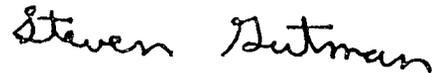
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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). You may obtain other general information on your responsibilities under the Act 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

Applicant: Phamatech

510 (k) Number (if known): K030447

Device Name: At Home Drug Cup (Model 9150X)

Indications for Use:

A home drug screening, and if needed, confirmation service. This kit provides a preliminary result for the detection/presence of the following drugs of abuse in urine: Amphetamine, MDA, Methamphetamine, MDMA, THC, Cocaine and Opiates.

PLEASE DO NOT WRITE BELOW THIS LINE

Concurrence of the CDRH Office of Device Evaluation (ODE)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K030447

Division Sign-off
Division of Clinical Laboratory Devices
510 (k) Number:

Prescription Use: _____ OR Over the Counter: ✓
Per 21 CFR 801.109