SEP 1 0 2004

K041518

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

Identification: Phamatech QuickScreen™ Models 9177X and 9178X

Description: Immunoassay for the qualitative detection, Amphetamine, THC, Cocaine, Opiates and PCP (9177X) or Methamphetamines (9178X) in urine.

Name Of Manufacturer:

Phamatech, Inc.
10151 Barnes Canyon Road
San Diego, California 92121, USA

Intended Use: Phamatech QuickScreen™ Model 9177X & 9178X is a rapid, qualitative immunoassay for the detection of the target drugs/drug metabolites in urine. The cut-off concentrations of this test are as follows: amphetamine; 1000 ng/ml, THC; 50 ng/ml, cocaine; 300 ng/ml, PCP 25 ng/ml, opiates; 2000 ng/ml, methamphetamines; 500 ng/ml. This assay is intended to assist in the prevention of drug abuse

Technology: The Phamatech QuickScreen™ Model 9177X & 9178X, 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 Phamatech At Home™ DrugTest and the Phamatech QuickScreen Pro Multi Drug Screening Test. 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 Phamatech QuickScreen™ Models 9177X & 9178X was evaluated in a clinical sample correlation. The results of these studies demonstrate the Phamatech QuickScreen™ Model 9177X & 9178X 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. Correlation studies, using clinical specimens, produced a >98% correlation when compared to the QuickScreen™ in the hands of professional users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen™ Model 9177X & 9178X is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe in the hands of the professional user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 0 2004

Mr. Carl A. Mongiovi
Vice President
Phamatech
10151 Barnes Canyon Road
San Diego, CA 92121

Re: k041578
Trade/Device Name: Phamatech QuickScreen™ Model 9177X
Phamatech QuickScreem™ Model 9178X
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: LCM, DKZ, DJC, DIO, DJG, LDJ
Dated: July 28, 2004
Received: September 2, 2004

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).

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
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): K 041578

Device Name: Phamatech QuickScreen™ Model 9177X

Indications for Use:

An in vitro diagnostic test for the qualitative identification of amphetamine, cocaine, opiates, PCP and THC in urine. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

Prescription Use: ✓ AND/OR Over the Counter Use: _____
(Part 21 CFR 801 Subpart D (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of the CDRH Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K041578

Device Name: Phamatech QuickScreen™ Model 9178X

Indications for Use:

An in vitro diagnostic test for the qualitative identification of amphetamine, cocaine, opiates, methamphetamines and THC in urine. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

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(Part 21 CFR 801 Subpart D (21 CFR 807 Subpart C)

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