K070098

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

DEC 07 2007

Identification: QuickScreen™ Barbiturates Test: Models 9019, 9018

Description: Immunoassay for the qualitative detection of Barbiturates in urine

Name Of Manufacturer:

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

Intended Use: The QuickScreen™ Barbiturates Test is a rapid, qualitative immunoassay for the detection of Barbiturates in urine. The cutoff concentration for this test is 300 ng/ml. This assay is intended for professional use.

Technology: The QuickScreen™ Barbiturates Test, like many commercially available barbiturate screening test kits, qualitatively measures the presence of Barbiturates by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the ABMC RapidOne BZD test (Kinderhook, NY). These devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / target analyte / antibody / complexes.

Performance: The product performance characteristics of the QuickScreen™ Barbiturates Test were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the QuickScreen™ Barbiturates Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of Barbiturates in urine. Laboratory studies, using clinical specimens, produced a **97.9%** correlation when compared to the predicate devices.

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

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

Identification: QuickScreen Multi Drug Screening Test: Model 9317T and 9187Z

Description: Immunoassay for the qualitative detection, Amphetamine, THC, Cocaine, PCP, Barbiturates, Benzodiazepines, Methadone, Opiates and Methamphetamine in urine

Name Of Manufacturer:

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

Intended Use: QuickScreen Multi Drug Screening Test 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
Barbiturates; 300 ng/ml
Benzodiazepines; 200 ng/ml
Cocaine; 300 ng/ml
Methadone 300 ng/ml
Methamphetamine; 1000 ng/ml
Opiates; 2000 ng/ml.
Phencyclidine (PCP) 25 ng/ml
THC; 50 ng/ml

This assay is intended to assist in the prevention of drug abuse

Technology: The QuickScreen Multi Drug Screening Test, 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 QuickScreen At Home Drug Test and the Phamatech QuickScreen 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 QuickScreen Multi Drug Screening Test were evaluated in a clinical sample correlation study and a blind labeled spiked study. The results of these studies demonstrate the Phamatech QuickScreen Multi Drug Screening Test 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 Behring EMIT II (Cupertino, CA 95014) and GC/MS methodology. Clinical studies, performed at two independent laboratories, were also performed. In them the Phamatech QuickScreen™ exhibited excellent overall accuracy (>97%) in the hands of professional users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech QuickScreen Multi Drug Screening Test is substantially equivalent to a variety of detection tests currently in commercial distribution and is safe

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 07 2007

Phamatech, Inc.
c/o Mr. Carl Mongiovi
Vice President
10151 Barnes Canyon Road
San Diego, CA 92121

Re: k070098
Trade/Device Name: Phamatech QuickScreen™ Barbiturates Test Models 9019, 9018, Phamatech Quick Screen™ Pro Multi Drug Screening Test Model 9317T and 9187Z
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system.
Regulatory Class: Class II
Product Code: DIS
Dated: October 30, 2007
Received: November 1, 2007

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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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 070098** .

Device Name: Phamatech QuickScreen™ Barbiturates Test Models 9019 , 9018

Indications for Use:

The QuickScreen Barbiturates Test is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of Barbiturates in urine. Tests for barbiturates cannot distinguish between abused drugs and certain prescribed medications. The cut-off concentration will be 300 ng/ml (secobarbital). It is intended for professional use only.

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

Prescription Use:____X____ AND/OR (Part 21 CFR 801 Subpart D

Over the Counter Use:_____ (21 CFR 807 Subpart C)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K070098

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): **K 070098 .**

Device Name: Phamatech QuickScreen™ Pro Multi Drug Screening Test Model 9317T

Indications for Use:

An invitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, Barbiturates, benzodiazepines, methadone and THC in urine. Tests for prescription drugs cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

Amphetamine	1000 ng/ml
Cocaine	300 ng/ml
Methamphetamine	1000 ng/ml
Opiates	2000 ng/ml
PCP	25 ng/ml
Barbiturates (Secobarbital)	300 ng/ml
Benzodiazepines	200 ng/ml
Methadone	300 ng/ml
THC	50 ng/ml

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

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

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Device Evaluation and Safety

510(k) K070098

INDICATIONS FOR USE

Applicant: Phamatech

510 (k) Number (if known): K 070098 .

Device Name: Phamatech QuickScreen™ Pro Drug Cup Model 9187Z

Indications for Use:

An invitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, Barbiturates, benzodiazepines, methadone and THC in urine. Tests for prescription drugs cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

Amphetamine	1000 ng/ml
Cocaine	300 ng/ml
Methamphetamine	1000 ng/ml
Opiates	2000 ng/ml
PCP	25 ng/ml
Barbiturates (Secobarbital)	300 ng/ml
Benzodiazepines	200 ng/ml
Methadone	300 ng/ml
THC	50 ng/ml

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

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

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