K131069

 MAY 14 2014

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

Manufacturer & Submitter: Phamatech Inc.
10151 Barnes Canyon Road
San Diego, California 92121, USA

Contact: Carl A. Mongiovi
Vice President
Telephone 858 643 5555
Fax 858 635 5843

Date Prepared 5/08/2014

Proprietary Name: QuickScreen Drug Screening Test System

Common Name: Drug of Abuse Rapid Test System

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

Classification Names:

The applicant test system regulatory classification is Class II, Classification Panel is Clinical Toxicology (91). Regulatory information applicable to this test system is provided below:

21 CFR 862.3100 Amphetamine test system Product Code: DKZ

Predicate Device: QuikStrip OneStep Amphetamine Test – Syntron Bioresearch
Predicate 510(k) #: K971218

Intended Use:

QuickScreen™ Amphetamine 500 Test Model 9058 (dip card)

The QuickScreen Amphetamine 500 Test is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of Amphetamine in urine. The cut-off concentration is 500 ng/ml. It is intended for prescription point of care 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.

QuickScreen™ Amphetamine 500 Test Model 9054 (cassette)

The QuickScreen Amphetamine 500 Test is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of Amphetamine in urine. The cut-off concentration is 500 ng/ml. It is intended for prescription point of care 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.

QuickScreen™ Multi Drug Screening Test Model 9346T(dip card)

The QuickScreen™ Multi Drug Screening Test Model 9346T is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, oxycodone, PCP, Barbiturates, benzodiazepines, methadone and THC in urine. The test is available in any combination of the drugs or drug metabolites listed below. Tests for barbiturates, benzodiazepine and oxycodone cannot distinguish between abused drugs and certain prescribed medications. The test is intended for prescription point of care use only.

Amphetamine (d amphetamine) 500 ng/ml
Cocaine (benzoylecgonine) 150 ng/ml
Methamphetamine (d methamphetamine) 500 ng/ml
Opiates (morphine) 300 ng/ml
PCP (phencyclidine) 25 ng/ml
Barbiturates (Secobarbital) 300 ng/ml
Benzodiazepines (Oxazepam) 200 ng/ml
Methadone (Methadone) 300 ng/ml
Oxycodone (Oxycodone) 100 ng/ml
THC (Cannabinoids) 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.

QuickScreen™ Drug Cup Model 9346Z

The QuickScreen™ Drug Cup Model 9346Z is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, oxycodone, PCP, barbiturates, benzodiazepines, methadone and THC in urine at the cut-off concentrations listed below. The test is available in any combination of the drugs or drug metabolites listed below. Tests for barbiturates, benzodiazepine and oxycodone cannot distinguish between abused drugs and certain prescribed medications. The test is intended for prescription point of care use only.

Amphetamine (d amphetamine) 500 ng/ml
Cocaine (benzoylecgonine) 150 ng/ml
Methamphetamine (d methamphetamine) 500 ng/ml
Opiates (morphine) 300 ng/ml
PCP (phencyclidine) 25 ng/ml
Barbiturates (Secobarbital) 300 ng/ml
Benzodiazepines (Oxazepam) 200 ng/ml
Methadone (Methadone) 300 ng/ml
Oxycodone (Oxycodone) 100 ng/ml
THC (Cannabinoids) 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.

Similarities and differences to predicate device:

The QuickScreen Drug Screening Test system, 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 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.

	QuikStrip™ OneStep Amphetamine 500 Test	QuickScreen™ Drug Screening Test System
510(k) #	K971218	K131069
Format	Dip Card	Integrated Cup/Dip Card/Cassette
Intended Use	Detection of drugs of abuse	Detection of drugs of abuse
Specimen	Urine	Urine

Methodology	Lateral flow Immunoassay	Lateral flow Immunoassay
Qualitative	YES	YES
Antibodies	Monoclonal / Polyclonal	Monoclonal / Polyclonal
Analyte's detected	1	10
Cutoffs (ng/ml)	AMP 500	AMP 500 Cocaine: 150 THC: 50 Opiates: 300 PCP: 25 MET: 500 BZD: 200 Barb: 200 MTD: 300 OXY 100
Incubation	5 minutes	10 minutes
Control Features	Control Line Test Expired Indicator	Control Line Test Expired Indicator
End User	Point of Care Use	Point of Care Use

The QuickScreen Drug Testing System of this current 510(k) is similar to the version cleared in k103295, except for a change in amphetamine cutoff concentration. The cutoff concentration for amphetamine in k103295 was 1000 ng/ml. The cutoff concentration for amphetamine in this current 510(k) is 500 ng/ml. New performance studies for this current 510(k) were only conducted to support a 500ng/ml cutoff concentration for amphetamines. See k103295 for performance of all other analytes: barbiturates, benzodiazepines, cocaine, methadone, methamphetamines, opiates, oxycodone, phencyclidine and THC or their metabolites.

The following laboratory performance studies were performed to determine substantial equivalence of the QuickScreen Drug Screening Test system to the predicate:

Performance of the QuickScreen Drug Screening Test System around the cutoff for amphetamine was evaluated by testing standard drug solutions diluted in drug free urine at 3 sites by 2 technicians in card, cup and cassette formats for a period of 20 days. The results are summarized below.

SENSITIVITY / PRECISION – Summary of all sites

Conc.	Multi-card		Cassette		Cup		Dipcard	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	60	0	60	0	60	0	60	0
100.86	60	0	60	0	60	0	60	0
211.2	60	0	60	0	60	0	60	0
286.22	60	0	60	0	60	0	60	0

Cutoff	10	50	38	22	38	22	38	22
583.3	0	60	0	60	0	60	0	60
878	0	60	0	60	0	60	0	60
1062	0	60	0	60	0	60	0	60
1361	0	60	0	60	0	60	0	60

METHOD COMPARISON – The performance of the QuickScreen Drug Screening Test System was evaluated at three locations by typical operators at each site. Operators tested 106 unaltered clinical samples. These samples were blinded and sufficiently randomized. Results were compared to GC/MS testing. Those results are presented below.

Candidate Device Result		Negative: NO DRUG	Negative <-50% of cutoff	Negative -50% to Cutoff	Positive Cutoff to +50%	High Positive
Dip	+	0	0	4	22	20
	-	23	19	18	0	0
Cassette	+	0	0	4	22	20
	-	23	19	18	0	0
Cup	+	0	0	4	22	20
	-	23	19	18	0	0
Multi drug dip	+	0	0	4	22	20
	-	23	19	18	0	0

Discordant Results

Sample ID	QuickScreen Test Result	GC/MS Test Result
18	Positive	421.6
1	Positive	440.2
12	Positive	450.1
73	Positive	454.6

Other technical performance tests include:

Assay Cross-reactivity:

The following cross reactivity by structurally related compounds was observed:

Substance	Concentration (ng/ml)	% Crossreactivity
d-amphetamine	500	N/A
L-amphetamine	10,000	5.0
Methylenedioxyamphetamine (MDA)	1000	50
Methylenedioxymethamphetamine (MDMA)	100,000	0

Norphedrin	>10,000	>5.0
Tyramine	5000	10

Assay Interference from structurally un-related compounds was not observed to concentrations of 100 μg/ml.

Effect of Sample pH
Samples with amphetamine concentrations of 250, 375, 625 and 750 ng/ml were tested in pH ranges of 4.5 to 8.5. No effect was observed by sample pH within these ranges.

Specific Gravity Effects
Samples with amphetamine concentrations of 250, 375, 625 and 750 ng/ml were tested In specific gravity ranges of 1.002 to 1.040. No effect was observed by sample specific gravity within these ranges.

Conclusion: For the reasons mentioned above, it may be concluded that Phamatech's QuickScreen Drug Test system is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 14, 2014

PHAMATECH INC.
CARL MONGIOVI
VICE PRESIDENT
10151 BARNES CANYON RD
SAN DIEGO CA 92121

Re: K131069
Trade/Device Name: Quickscreen™ Amphetamine 500 Test Model 9054 (cassette)
Quickscreen™ Multi Drug Screening Test Model 9346T
Quickscreen™ Drug Cup Model 9346Z
Quickscreen™ Amphetamine 500 Test Model 9058 (dip card)
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ
Dated: April 10, 2014
Received: April 10, 2014

Dear Mr. Carl 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k131069

Device Name
QuickScreen Amphetamine 500 Model 9058 (dip card)
QuickScreen Ampletamine 500 Test Model 9054 (cassette)
QuickScreen Multi Drug Screening Test Model 9346T (dip card)
QuickScreen Multi Drug Cup Model 9346Z

Indications for Use *(Describe)*

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Denise Johnson-lyles -S

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