October 18, 2018

Phamatech Inc.
% Korina Akhondzadeh
Sr. Regulatory Consultant to Phamatech
Kara & Associates
6965 El Camino Real, Suite 105-428
Carlsbad, CA 92009

Re: k181945
Trade/Device Name: QuickScreen Pro Multi Drug Screening Test, Model 9395Z
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, JXM, DJC, LFG, DIS, DIO, DJR, LDJ, LCM, DJG
Dated: July 16, 2018
Received: July 20, 2018

Dear Korina Akhondzadeh:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k181945

Device Name
QuickScreen Pro Multi Drug Screening Test Model 9395Z

Indications for Use *(Describe)*
The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a screening test for the qualitative detection of amphetamines, barbiturates, benzodiazepines, cocaine, ecstasy, methadone, methamphetamine, opiates, oxycodone, phencyclidine, marijuana, tricyclic antidepressants (imipramine) and buprenorphine in urine at the cut-off concentrations listed below. Test for barbiturates, benzodiazepine, oxycodone, buprenorphine and tricyclic antidepressants (imipramine) cannot distinguish between abused drugs and certain prescription medications. The test is intended for professional use only.

Analyte	Abbreviation	Cut-off Concentration (ng/ml)
Amphetamines	AMP	1000
Barbiturates	BAR	200
Benzodiazepines	BZD	200
Cocaine	COC	300
Ecstasy	MDMA	500
Methadone	MTD	300
Methamphetamine	MET	500
Opiates	OPI	300
Oxycodone	OXY	100
Phencyclidine	PCP	25
Marijuana	THC	50
Tricyclic Antidepressants (Imipramine)	TCA (Imipramine)	1000
Buprenorphine	BUP	10

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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PHAMATECH
LABORATORIES & DIAGNOSTICS

k181945

510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTER

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Date Prepared: October 15, 2018

II. DEVICE

Device Name: QuickScreen Pro Multi Drug Screening Test, Model 9395Z
Common/Usual Name: Multi-Drug Urine Test Panel
Class: II

Product Code and Regulation:

Product Code	Regulation Number	Regulation Description
DKZ	862.3100	Amphetamine test system
DIS	862.3150	Barbiturate test system
JXM	862.3170	Benzodiazepine test system
DIO	862.3250	Cocaine and cocaine metabolite test system
DJC	862.3610	Methamphetamine test system
DJR	862.3620	Methadone test system
DJG	862.3650	Opiate test system
LCM	Unclassified	Phencyclidine
LDJ	862.3870	Cannabinoid test system
LFG	862.3910	Tricyclic antidepressant drugs test system

III. PREDICATE DEVICE

Primary Predicate Device
At Home Drug Test 12: Model 9308Z, K070009

The predicate device has not been subject to a recall.

IV. DEVICE DESCRIPTION

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a screening test for the rapid detection of the following drugs in urine at the cut-off concentrations listed in Table 1. It is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a single-use device utilizing a cup format.

The device is based upon the Phamatech At Home 12 Drug Test Models 9308Z cleared in K070009 for home use for the detection of amphetamines(AMP), barbiturates (BAR), benzodiazepines (BZD), cocaine (COC), ecstasy (MDMA), methadone (MTD), methamphetamine(MET), opiates (OPI), oxycodone (OXY), phencyclidine (PCP) and marijuana (THC) in urine samples. The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z adds testing for tricyclic antidepressants (TCA) (imipramine) and buprenorphine (BUP).

The QuickScreen Pro Multi-Drug Screening Test System is intended for use in prescription point-of-care settings.

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a chromatographic absorbent device in which drugs or drug metabolites in a urine sample compete with drug / protein conjugate immobilized on a porous membrane of the test device for a limited number of antibody / dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify drugs of abuse in urine. The test device also contains a self-timer that indicates when test results are ready to be interpreted.

V. INDICATIONS FOR USE

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a screening test for the qualitative detection of amphetamines, barbiturates, benzodiazepines, cocaine, ecstasy, methadone, methamphetamine, opiates, oxycodone, phencyclidine, marijuana, tricyclic antidepressants (imipramine) and buprenorphine in urine at the cut-off concentrations listed below. Test for barbiturates, benzodiazepine, oxycodone, buprenorphine and tricyclic antidepressants (imipramine) cannot distinguish between abused drugs and certain prescription medications. The test is intended for professional use only.

Analyte	Abbreviation	Cut-off Concentration (ng/ml)
Amphetamines	AMP	1000
Barbiturates	BAR	200
Benzodiazepines	BZD	200
Cocaine	COC	300
Ecstasy	MDMA	500
Methadone	MTD	300
Methamphetamine	MET	500
Opiates	OPI	300
Oxycodone	OXY	100
Phencyclidine	PCP	25
Marijuana	THC	50
Tricyclic Antidepressants (Imipramine)	TCA (Imipramine)	1000
Buprenorphine	BUP	10

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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is substantially equivalent to the predicate At Home Drug Test 12: Model 9308Z based upon the same technological characteristics identified in Table 5-1 Comparison of the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z to the Predicate Device and as discussed below

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Comparison of Technological Characteristics

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z and its predicate device, At Home Drug Test 12: Model 9308Z, are qualitative lateral flow immunoassays based upon the principle of antigen and antibody immunochemistry for the detection of the identified drug analytes. Both devices test in urine using a cup format.

The predicate device, At Home Drug Test 12: Model 9308Z, tests for the same drugs as the subject device, QuickScreen™ Pro Multi Drug Screening Test Model 9395Z with the exception of buprenorphine and tricyclic antidepressants (imipramine).

VII. PERFORMANCE DATA

Performance testing was conducted for the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z. Studies focused on performance testing for the addition of the TCA and BUP tests. Performance testing for the other drugs was reported in K070009 (Phamatech At Home Drug Test 12: Model 9308Z).

Performance testing was conducted to establish the substantial equivalence of the device:

- Method Comparison Studies
- Assay Interference Studies
- Assay Precision/Sensitivity Studies
- Prozone Response
- Sample pH
- Read Time
- Sample Temperature
- Specific Gravity

VIII. CONCLUSIONS

The testing conducted supports the safety and effectiveness of the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z and demonstrates the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z performs as intended. The performance testing conducted demonstrates that the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z performs substantially equivalent to the predicate device. Both the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z and the predicate device have the same intended use and technological characteristics.

Table 5-1 Comparison of the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z to the Predicate Device

Feature	QuickScreen™ Pro Multi Drug Screening Test Model 9395Z	At Home Drug Test 12: Model 9308Z (K070009) Predicate Device
Indications for Use	The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is an screening test for the qualitative detection of amphetamines, barbiturates, benzodiazepines, cocaine, ecstasy, methadone, methamphetamine, opiates, oxycodone, phencyclidine, marijuana, (imipramine) antidepressants and buprenorphine in urine at the cut-off concentrations listed.	The Phamatech At Home 12 Drug Test: Model 9308Z for amphetamines (AMP), barbiturates (BAR), benzodiazepines (BZD), cocaine (COC), ecstasy (MDMA), methadone (MTD), methamphetamine (MET), opiates (OPI), oxycodone (OXY), phencyclidine (PCP) and marijuana (THC) is a screening test for the rapid detection of the drugs listed above in urine.
Intended Use	Professional	OTC
510(k) Number	N/A	K070009

Feature	QuickScreen™ Pro Multi Drug Screening Test Model 9395Z	At Home Drug Test 12: Model 9308Z (K070009) Predicate Device
Classification	Class II	Class II
Product Code Regulation No. Drug	DKZ 862.3100 (AMP) DIS 862.3150 (BAR) JXM 862.3170 (BZD) DIO 862.3250 (COC) DJC 862.3610 (MET/MDMA) DJR 862.3620 (MTD) DJG 862.3650 (OPI/BUP/OXY) LCM Pre-amendment (PCP) LDJ 862.3870 (THC) LFG 862.3910 (TCA)	DKZ 862.3100 (AMP/MDA) DIS 862.3150 (BAR) JXM 862.3170 (BZD) DIO 862.3250 (COC) DJC 862.3610 (MET/MDMA) DJR 862.3620 (MTD) DJG 862.3650 (OPI/OXY) LCM Pre-amendment (PCP) LDJ 862.3870 (THC)
Methodology	Lateral flow immunoassay based on the principle of antigen and antibody immunochemistry	Lateral flow immunoassay based on the principle of antigen and antibody immunochemistry
Results	Qualitative	Qualitative
Analyte Cut-off	Amphetamines (AMP): 1000 ng/ml Barbiturates (BAR): 200 ng/ml Benzodiazepines: (BZD): 200 ng/ml Cocaine (COC): 300 ng/ml Ecstasy (MDMA): 500 ng/ml Methadone (MTD): 300 ng/ml Methamphetamine (MET): 500 ng/ml Opiates (OPI): 300 ng/ml Oxycodone (OXY): 100 ng/ml Phencyclidine (PCP): 25 ng/ml Marijuana (THC): 50 ng/ml Tricyclic Antidepressants (TCA) (Imipramine): 1000 ng/ml Buprenorphine (BUP): 10 ng/ml	Amphetamines (AMP): 1000 ng/ml Barbiturates (BAR): 200 ng/ml Benzodiazepines: (BZD): 200 ng/ml Cocaine (COC): 300 ng/ml Ecstasy (MDMA): 500 ng/ml Methadone (MTD): 300 ng/ml Methamphetamine (MET): 500 ng/ml Opiates (OPI): 300 ng/ml Oxycodone (OXY): 100 ng/ml Phencyclidine (PCP): 25 ng/ml Marijuana (THC): 50 ng/ml
Configuration	Cup	Cup
Specimen Type	Urine	Urine
Use	Single-use	Single-use