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

MAY 2 4 2013

The Assigned 510(k) number is: k121065

Date of Summary: May 15, 2013

Common Name: Drugs of Abuse Screening Device

Regulatory Information:

1. Regulation section: 21 CFR part 862 (PCP), 862.3870 (THC), 862.3250 (COC), 862.3640 (MOR), 862.3100 (AMP), 862.3170 (BZO), 862.3610 (MDMA), Drugs of Abuse
2. Classification: Class II
3. Product Codes: LDJ (THC), DIO (COC), LCM (PCP), DNK (MOR), DKZ (AMP), JXM (BZO), DJC (MDMA), Drugs of Abuse
4. Panel: Toxicology (91)

Applicant and Initial Importer:

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Contact Persons:

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Identification / Product Name:

Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device

Description:
One-step, colloidal gold based chromatographic immunoassay for the rapid, qualitative detection of Marijuana, Cocaine, Phencyclidine, Morphine, Amphetamine, Benzodiazepines, and MDMA (Ecstasy) in human urine.

Intended Use:
The Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device are rapid chromatographic immunoassays for the qualitative and simultaneous detection of one to seven of the following drugs in a variety of combinations in human urine. The cutoff concentrations and direct calibrator for these drugs are as follows:

Analyte	**Abbreviation**	**Direct Calibrator**	**Cutoff (ng/ml)**
Amphetamine	AMP	Amphetamine	1000
Benzodiazepines	BZO	Oxazepam	300
Cocaine	COC	Benzoylecgonine	300
Marijuana	THC	11-nor-Δ9-THC9-COOH	50
Morphine	MOR	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Ecstasy	MDMA	3,4-Methylenediioxy-MET	500

For prescription use in central laboratories only. This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

Predicate Kit:
ACON One Step Drug Screen Tests are used as predicate device for Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device to compare their performance with the GC/MS and/or LC/MS confirmed clinical urine specimens.

510(k) numbers for predicate devices are:

Amphetamine	k011673
Benzodiazepine	k012300
Cocaine	k010841
MDMA	k022589
Morphine 2000	k011353
PCP	k011730
THC	k003557

Similarities		
Item	The Polymed Therapeutics' Fastep Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep Dipcard Drugs of Abuse Screen Device	Acon Predicate Devices
Intended Use	Qualitative detection of amphetamine, benzodiazepines, cocaine, THC, morphine, PCP, and MDMA	Same
Sample Type	Urine	Same
Methodology	Qualitative lateral flow chromatographic immunoassay	Same
Assay Cutoffs (ng/mL)	Amphetamine 1000 Benzodiazepines 300 Cocaine 300 THC 50 Morphine 2000 2000 PCP 25 MDMA 500	Same
Read Time Window	5 – 10 minutes	Same
Storage	2 – 30° C	Same
Differences		
Item	Device	Predicate
Intended Users	Prescription use in central laboratories only	Point of care use

Performance:
The product performance characteristics of Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device were evaluated in the blind-labeled clinical specimen correlation study and in the blind-labeled spiked control studies including accuracy, precision, specificity, and interference studies. Results of these studies demonstrate substantial equivalence between Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device and performance characteristics of GC/MS and/or LC/MS methodology as well as ACON's One Step DOA Test Panels.

Conclusion:
Results of Accuracy, Precision, Specificity, and Interference studies demonstrate substantial equivalence between Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device and the ACON One Step DOA Screen Test panels. Results also demonstrate that Polymed Therapeutics' Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics' Fastep™ Dipcard Drugs of Abuse Screen Device are safe and effective in detecting Amphetamine, Benzodiazepines, Cocaine, Marijuana, Morphine, Phencyclidine, and Ecstasy in human urine specimen, for prescription use in central laboratories.

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

Polymed Therapeutics, Inc.
C/O J.J. Xia
LSI Consulting Inc.
12828 Doe Lane
GAITHERSBURG MD 20878

May 24, 2013

Re: K121065
Trade/Device Name: Polymed Therapeutics Fastep Dipstick Drugs of Abuse Screen Device,
Polymed Therapeutics Fastep Dipcard Drugs of Abuse Screen Device
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, JXM, DIO, LDJ, DJC, LCM, DNK
Dated: May 20, 2013
Received: May 23, 2013

Dear J.J. Xia:

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Katherine Serrano

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

Indications for Use

510(k) Number (if known): k121065

Device Name: Polymed Therapeutics Fastep™ Dipstick Drugs of Abuse Screen Device and Polymed Therapeutics Fastep™ Dipcard Drugs of Abuse Screen Device

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k121065