K052197

JUN - 9 2006

510(k) Summary

Date of Summary: 30 May, 2005

Product Name
First Sign™ Drug of Abuse Urine Screening Tests

Sponsor and Manufacturer

WHPM, Inc.
9662 Telstar Avenue
El Monte, CA 91731

WHPM, Bioresearch and Technology Co. Ltd.
806 Taihong Mansion, No 44 Chongwai Street
Chongwai District
Beijing, China 100062

Product will be manufactured in both locations and distributed through the California site.

Correspondent

Fran White, President
MDC Associates, LLC
163 Cabot Street
Beverly, MA 01915

Substantial Equivalency
The First Sign™ Drug of Abuse Urine Screening Test is substantially equivalent to other tests currently on the market.

First Sign Test Analyte	Predicate Device Name	Predicate Device 510(k) #
Oxazepam	ACON BZO One Step Benzodiazepine Test Strip	K012300
Oxycodone	ACON OXY One Step Oxycodone Test Strip	K043507
Secobarbital	ACON BAR One Step Barbiturates Test Strip	K050593
Methadone	ACON MTD One Step Methadone test Strip	K012595
Nortriptyline	ACON TCA One Step Tricyclic Antidepressants	K021526
MDMA	ACON MDMA One Step Ecstasy Test Strip	K022589

Product Description
The First Sign Drug of Abuse Tests are rapid, chromatographic immunoassays for the qualitative detection of drugs-of-abuse in human urine.

Indications for Use
The First Sign Drug of Abuse Tests are rapid, chromatographic immunoassays for the qualitative detection of drugs-of-abuse in human urine. The tests may be run singly or in combinations of up to six drugs simultaneously. The cut-off concentrations for these drugs are as follows: Nortriptyline 1,000ng/mL, Secobarbital 300ng/mL, MDMA 500ng/mL, Oxazepam 300ng/mL, Methadone 300ng/mL, Oxycodone 100ng/mL.
For Professional Use Only.

Performance Characteristics

A clinical evaluation compared test results between the First Sign Drugs of Abuse Tests and GC/MS or HPLC results. The results are summarized below.

First Sign Test	Positive Agreement	Negative Agreement	Overall Agreement
Nortriptyline	97.5%	>99%	98.7%
Secobarbital	97.4%	97.6%	97.5%
MDMA	92.5%	>99%	96.2%
Oxazepam	95.7%	>99%	97.5%
Methadone	93.7%	97.9%	96.2%
Oxycodone	95%	>99%	97.5%

Conclusion

Clinical studies demonstrate the substantial equivalence between the First Sign Drugs of Abuse Tests [Nortriptyline, Secobarbital, MDMA, Oxazepam, Methadone, and Oxycodone] and commercially available FDA-cleared drugs of abuse tests. The studies also demonstrated that the First Sign tests are safe and effective in detecting drugs of abuse at or above their stated cut-off concentrations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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WHPM, Inc
c/o Ms. Fran White
President
MDC Associates, LLC.
163 Cabot Street
Beverly, MA 01915

Re: k052197
Trade/Device Name: First Sign Drug of Abuse Urine Screening Test
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR, LFG, DIS, LAF, JXM, DJG
Dated: May 11, 2006
Received: May 12, 2006

Dear Ms. White:

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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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

510(k) Number (if known): K052197

Device Name: First Sign Drug of Abuse Urine Screening Test

Indications For Use: The First Sign Drug of Abuse Tests are rapid, chromatographic immunoassays for the qualitative detection of drugs-of-abuse in human urine. The tests may be run singly of in combinations of up to six drugs simultaneously. The cut-off concentrations and specific analytes tested for are listed below.

This assay provides only a preliminary test result. A more specific alternate chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment must be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

For Professional Use Only.

Test Name	Analyte Tested	Cut-off Concentration
First Sign Nortriptyline	nortriptyline	1,000ng/mL
First Sign Secobarbital	secobarbital	300ng/mL
First Sign MDMA	mdma	500ng/mL
First Sign Oxazepam	oxazepam	300ng/mL
First Sign Oxycodone	oxycodone	100ng/mL
First Sign Methadone	methadone	300ng/mL

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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