MAY 1 9 2004

510 (K) SUMMARY

Date of Summary: 8-18-03

Product Name:

First Sign Drug of Abuse Assays

Sponsor:

WHPM
9440 Telstar Ave.
Unit 1
El Monte, CA 91731

Correspondent:

Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Devices:

Product: Acon Rapid Drug Screens
Manufactured by: Acon Laboratories

PRODUCT DESCRIPTION:

A lateral flow immunoassay for the detection of drugs of abuse.

INTENDED USE:

First Sign™ Drugs of Abuse Screening Test are one-step lateral flow immunoassays intended for the detection of drug analytes in urine. First Sign™ Drug of Abuse Screening Test are intended for use in the qualitative detection of drugs of abuse at the following Substance Abuse Mental Health Services Administration (SAMHSA) recommended levels:

Compound	Abbreviation	Level
Amphetamine (d-amphetamine sulfate)	AMP	1000 ng/ml
Methamphetamine ((+)methamphetamine HC1)	METH	1000 ng/ml
Opiates 2000 (morphine-3-P-D glucuronide)	OPI	2000 ng/ml
Opiates 300 (morphine-3-P-D glucuronide)	OPI	300 ng/ml
Cocaine (Benzoylecgonine)	COC	300 ng/ml
Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid)	THC	50 ng/ml
Phencyclidine (phencyclidine HC1)	PCP	25 ng/ml

First Sign™ Drugs of Abuse Screening Test provide only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the

preferred confirmatory method. Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

PERFORMANCE CHARACTERISTICS:

First Sign™ drugs of abuse screening test detects drugs in human urine at the levels indicated.

First Sign™ is substantial equivalent to Acon Rapid One Step Immunoassay Tests manufactured Acon Laboratories.

Product performance was compared Acon Rapid Assays manufactured by Acon Laboratories rapid tests manufactured by Acon Rapid Assays. 60 Positive and 60 negative samples were tested against each drug. All results were confirmed by GC/MS.

The First Sign™ Drugs of Abuse Screening Test was compared to a FDA substantially equivalent approved device. First Sign™ demonstrated performance of >97% for all drugs when performance was compared to a legally marketed device and GC/MS.

Reproducibility was evaluated using control urines containing drug concentrations above and below the stated cut-off. Negative controls were also tested. The results confirmed the reproducibility of the First Sign™ Drugs of Abuse Screening Test.

CONCLUSION:

First Sign™ Drug of Abuse Screening Test is substantially equivalent to Acon Laboratories drug of Abuse Screening Test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 19 2004

W.H.P.M., Inc.
Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k032575
Trade/Device Name: First Sign Drug of Abuse Screening Test
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DJC, DJG, DIO, DKE, LCM
Dated: February 23, 2004
Received: February 24, 2004

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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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

510(k) Number: K032515

Device Name: First Sign Drug of Abuse Screening Test

Indication for Use:

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For professional use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over The Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K032515