K061617

510K Submission for
Forsure One Step Dip & Read Drug Screen Test
Tianjin New Bay Bioresearch Co., Ltd.

NOV 2 2 2006

SECTION II
510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: Designed K #: k061617

Submitter:
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Contact Person:

Rodrigo Berlie
New Product Development Director
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Preparation Date:

May 18, 2006

Device Information:

Device Classification Name:
Immunoassay of Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, Phencyclidine, Benzodiazepine, Barbiturates, Marijuana. Methadone , Oxycodone , Tricyclic Antidepressants and Propoxyphene.

Common/Usual Name:
Immunoassay Test System for Detection of Single and Multiple Dip & Read Abuse Drug Screen Test Device in Human Urine.

Proprietary Name:
Forsure One Step Dip & Read Drug Screen Test for Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone, Tricyclic Antidepressants, Barbiturates and Propoxyphene.

510K Submission for

Forsure One Step Dip & Read Drug Screen Test

Tianjin New Bay Bioresearch Co., Ltd.

Regulation Number:

21CFR862.3100, Amphetamine Test System
21CFR862.3150, Barbiturate Test System
21CFR862.3170, Benzodiazepine Test System
21CFR862.3250, Cocaine and Cocaine Metabolite Test System
21CFR862.3610, Methamphetamine Test System
21CFR862.3620, Methadone Test System
21CFR862.3650, Opiates and Test System (includes Oxycodone)
21CFR862.3700, Propoxyphene Test System
21CFR862.3870, Cannabinoids Test System
21CFR862.3910, Tricyclic Antidepressant
Unclassified, Phencyclidine

Regulatory Name:
Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone , Tricyclic Antidepressant, Barbiturates and Propoxyphene test system.

Product Code: DKZ, DIS, JXM, DIO, DJC, DJR, DJG, JXN, LDJ, LFG, LCM

Regulatory Class: Class II

Predicate Devices:

Forsure One Step Dip & Read Drug Screen Test Device is substantially equivalent to UCP Bioscience Rapid Drug Screening Test Strips cleared by FDA (K050540), or TNB Forsure One Step Drug Screen Test Cup Device cleared by FDA (K052882) and GC/MS for its stated intended use.

Device Description:

Forsure One Step Dip & Read Drug Screen Test consists of a or multiple chromatographic absorbent strip in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. As the test sample flows through the absorbent strip, the Colloidal Gold labeled antibody- conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the Test reaction zone and will not produce a magenta color band when the drug is above the detection level of 1000 ng/ml of Amphetamine,1000 ng/ml of Methamphetamine, 50 ng of THC, 2000ng/ml of Morphine,300 ng of Benzoylecognine , 25 ng/ml of Phencyclidine, 300 ng/ml of Benzodiazepine, 300 ng/ml of Methadone , 100 ng/ml of Oxycodone , 1000 ng/ml of Tricyclic Antidepressant, 300 ng/ml of Barbiturates and 300 ng/ml of Propoxyphene. Unbound colloidal gold-labeled antibody conjugate binds to the reagent in the negative control zone, producing a magenta color band, demonstrating that the reagents and device are functioning correctly. A **NEGATIVE** specimen produces two distinct color bands in both the specific drug test region and control area. A **PRELIMINARY POSITIVE** specimen produces only one color band in the control area and

no color band on the specific drug test region. There is no meaning attributed to color or its intensity for either line. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Intended Use:

Forsure One Step Dip & Read Drug Screen Test of Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone, Tricyclic Antidepressant, Barbiturates and Propoxyphene Test device are a Chromatographic immunoassay for qualitative determination of the presence of **Amphetamine** at a cutoff concentration of 1000 ng/ml, **Methamphetamine** at a cutoff concentration of 1000 ng/ml, **THC** at a cutoff concentration of 50 ng/ml, **Morphine** at a cutoff concentration of 2000 ng/ml, **Benzoylecgonine** at a cutoff concentration of 300 ng/ml , **Phencyclidine** at a cutoff concentration of 25 ng/ml, **Benzodiazepine** at cutoff concentration of 300 ng/ml, **Methadone** at cutoff concentration of 300 ng/ml, **Oxycodone** at cutoff concentration of 100 ng/ml, **Tricyclic Antidepressant** at cutoff concentration of 1000 ng/ml, **Barbiturates** at cutoff concentration of 300 ng/ml, and **Propoxyphene** at cutoff concentration of 300 ng/ml. The assay provides a simple and rapid analytical screening procedure to detect Amphetamine, THC, Morphine, Methamphetamine, Benzoylecognine, Phencyclidine, Benzodiazepine, Methadone, Oxycodone, Tricyclic Antidepressant, Barbiturates and Propoxyphene in human urine. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Comparison to Predicate Device(s):

Forsure One Step Dip & Read Drug Screen Test is substantially equivalent to UCP Rapid Drug Screening Test strips system cleared by FDA, e.g., the Assay (K050540) or TNB Forsure One Step Drug Screen Test Cup Device urine test (K 052882) and GC/MS for its stated intended use.

Device Characteristics	Subject Device	Predicate Devicce(s) UCPDrug Screening Test Strip (K050540)	Predicate Devicce(s) Forsure One Step Drug Screen Test Cup Device (K052882)
Intended Use	The assay provides a simple and rapid analytical screening procedure to qualitative determination of different abuse drug in human urine	UCP Multiple Drug Screen assay for qualitative determination of the presence of different drug in human urine.	For qualitative determination Of the presence of different drug in human urine.
Analytes	Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone, Tricyclic Antidepressant, Barbiturates and Propoxyphene	Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone , and Barbiturates	Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone, Tricyclic Antidepressant, Barbiturates and Propoxyphene
Cutoff	Amp:1000 ng/ml, Mamp:1000 ng/ml, BEG:300 ng/ml, THC:50 ng/ml, MOR:2000 ng/ml. PCP:25 ng/ml, BZD:300 ng/ml, MAD:300ng/ml, OXY:100 ng/ml, BAR: 300ng/ml, TCA:1000 ng/ml, PPX: 300 ng/ml.	Amp:1000 ng/ml, Mamp:1000 ng/ml, BEG:300 ng/ml, THC:50 ng/ml, MOR:2000 ng/ml. PCP:25 ng/ml, BZD:300 ng/ml, MAD:300ng/ml, OXY:100 ng/ml, BAR:300 ng/ml.	Amp:1000 ng/ml, Mamp:1000 ng/ml, BEG:300 ng/ml, THC:50 ng/ml, MOR:2000 ng/ml, PCP:25 ng/ml, BZD:300 ng/ml, MAD:300ng/ml, OXY:100 ng/ml, TCA:1000 ng/ml, PPX:300 ng/ml.
Test Principle	Immunochromatographic, Lateral Flow	Immunochromatographic, Lateral Flow	Immunochromatographic, Lateral Flow
Matrix	Urine	Urine	Urine
Calibrator	None	None	None
Instrument	None, Visual read single use	None, Visual Read single use	None, Visual Read single use
Calibration of Reagent	None	None	None
Storage	Below 28 °C until expiration	15°C - 30°C until expiration date	Below 28 °C until expiration

Summary:

The information provided in this pre-market notification demonstrates that Forsure One Step Dip & Read Drug Screen Test is substantially equivalent to UCP Rapid Drug Screening Test strips system, TNB One Step Drug Screen Test Cup Device and GC/MS. Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate devices. The information supplied in this pre-market notification provides reasonable assurance that the Forsure One Step Dip & Read Drug Screen Test is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Tianjin New Bay Bioresearch Co., Ltd.
c/o Rodrigo Berlie
Aventir Biotech, LLC
3108 Avenida Olmeda
Carlsbad, CA 92009

NOV 2 2 2006

Re: k061617
Trade/Device Name: Forsure One Step Dip & Read Drug Screen Test
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DJS, JXM, DIO, DJC, DJR, DJG, JXN, LDJ, LFG, LCM
Dated: September 26, 2006
Received: September 28, 2006

Dear Mr. Berlie:

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 (240) 276-0484. 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): k061617

Device Name: Forsure One Step Dip & Read Drug Screen Test

Indications for Use:

Forsure One Step Dip & Read Drug Screen Test is a prescription assay intended for professional use in central laboratories only. It provides qualitative screening results for Amphetamine (AMP), Methamphetamine (MET), Benzodiazepine (BZD), Barbiturate (BAR), Cocaine (COC), Cannabinoids (THC), Opiates (OPI), Phencyclidine (PCP), Methadone (MAD), Oxycodone (OXY), Tricyclic Antidepressant (TCA) and Propoxyphene (PPX) in human urine at the following cutoff levels:

Test	Calibrator	Cutoff
Amphetamine	D-Amphetamine	1000 ng/ml
Methamphetamine	D-Methamphetamine	1000 ng/ml
Benzodiazepine	Oxazepam	300 ng/ml
Barbiturate	Secobarbital	300 ng/ml
Cocaine	Benzoylecgonine	300 ng/ml
Cannabinoids	11-nor-Δ9-THC-9 COOH	50 ng/ml
Opiates	Morphine	2000 ng/ml
Phencyclidine	Phencyclidine	25 ng/ml
Methadone	Methadone	300 ng/ml
Oxycodone	Oxycodone	100 ng/ml
Tricyclic Antidepressant	Nortriptyline	1000 ng/ml
Propoxyphene	Propoxyphene	300 ng/ml

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

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

k061617

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