Sep 23, 2005
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: K052882

Submitter:
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Contact Person:

Rodrigo Berlie
New Product Development Director
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Preparation Date:

Sep. 28, 2005

Device Information:

Device Classification Name:
Immunoassay Of Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, Phencyclidine. Benzodiazepine, Barbiturates, Marijuana. Methadone , Oxycodon , Tricyclic antidepresant and Propoxyphene.

Common/Usual Name:
Immunoassay Test System for Detection of Single or Multiple(X) Abuse Drug Screen Test Cup Device in Human Urine.

Proprietary Name:
Forsure Rapid One Step Multiple(X) Abuse Drug Screen Test Cup Device for Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone , Tricyclic Antidepressant, Barbiturates and Propoxyphene.

Regulation Number: 21 CFR§862.3650

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

Product Code: DJG
Regulatory Class: Class II

Predicate Devices:

Rapid One Step Single and Multiple (X) Abuse Drug Screen Test Cup Device is substantially equivalent to Monitect Multiple Drug Screen Test of Branan Medical Corporation, cleared by FDA(K004034), or Alfa Scientific Design Instant-View Propoxyphene (PPX) urine test cleared by FDA (K022915)and GC/MS for its stated intended use.

Device Description:

New Bay Forsure Rapid One Step Single and Multiple(X) Abuse Drug Screen Test Cup Device 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 **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:

The Forsure One Step Single or Multiple (X) Drug Screen Strip 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 Chromatogrphy/mass spectrometry (GC/MS) is the preferred confirmatory method.

Comparison to Predicate Device(s):

Forsure Multiple Rapid One Step Drug Screen Test is substantially equivalent to Branan's Monitect Drug Screen Cassette Test system cleared by FDA, e.g., the Brana's Monitect Assay (004034)and GC/MS for its stated intended use.

Device Characteristics	Subject Device	Predicate Devicce(s) Monitect Drug Screen Cassette Assay (K004034) and GC/MS	Predicate Device(S) Instant-View Propoxyphens Urine test(K022915) and GC/MS
Intended Use	Forsure Multiple Drug Screen one step Immunochromatographic Qualitative test . The assay provides a simple and rapid analytical screening procedure to detect different abuse drug in human urine	Monitect Multiple Drug Screen immunochromatographic assay for qualitative determination of the presence of different drug in human urine.	Instant View Drug Screen Immunochromatographic Assay for qualitative Determination of the presence of Propoxyphene 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 , Tricyclic Antidepressant, and Barbiturates .	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, 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, TCA: 1000 ng/ml,	PPX : 300 ng/ml

Device Characteristics	Subject Device	Predicate Devicce(s) Monitect Drug Screen Cassette Assay (K004034) and GC/MS	Predicate Device(S) Instant-View Propoxyphens Urine test(K022915) and GC/MS
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	15°C – 30 °C until expiration date

Summary:

The information provided in this pre-market notification demonstrates that Forsure Rapid One Step single or Multiple (X) Abuse Drug Screen Test Cup Device is substantially equivalent to Branan's Monitect Multiple Drug Screen Cassette Test system or Alfa Scientific design Instant-View Propoxyphene Urine Test 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 Rapid One Step Single or Multiple(X) Abuse Drug Screen Test Cup Device 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

FEB 15 2006

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

Re: k052882
Trade/Device Name: Forsure Rapid One Step Single or Multiple(X) Abuse Drug Screen Test Cup Device for Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Cannabinoid, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant, Barbiturates, Propoxyphene.
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM, JXN, LFH
Dated: February 6, 2006
Received: February 7, 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 STATEMENT

510(k) Number (if known):

Device name: Forsure Rapid One Step Single or Multiple(X) Abuse Drug Screen Test Cup Device for Amphetamine , Methamphetamine , Benzoylecgonine , Benzodiazepine , cannabinoid , Morphine , Phencyclidine, Methadone , Oxycodone , Tricyclic Antidepressant), Barbiturates and Propoxyphene.

Indications for Use:

Forsure Rapid One Step Single or Multiple(X) Abuse Drug Screen Test Cup Device for Detection of Amphetamine , Methamphetamine, Benzoylecgonine , Benzodiazepine, Cannabinoid , Morphine, Phencyclidine, Methadone , Oxycodone , Tricyclic Antidepressant , Barbiturates , Propoxyphene and their metabolites in human urine at the following cutoff concentrations :

Test	Analytes or metabolites to be determined	Cut-off (ng/ml)
Amphetamine	D-Amphetamine	1000
Methamphetamine	(+) Methamphetamine	1000
Cocaine	Benzoylecgonine	300
Cannabinoid	(-)11-nor-9-carboxy-delta 9 THC	50
Opiate	Morphine	2000
Benzodiazepine	Oxazepam	300
Phencyclidine	Phencyclidine	25
Methadone	(+/-) Methadone Hydrochloride	300
Oxycodone	Oxycodone Hydrochloide	100
Tricyclic Antidepressant	Nortriptyline Hydrochloride	1000
Barbiturates	Secobarbital	300
Propoxyphene	(+) Propoxyphene	300

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /Mass spectrometry (GC/MS) is the preferred confirmatory method. The testing and results are intended to be used by medical professional and clinical setting.

Prescription Use ___X_____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety
510(k): K052882