510(k) SUMMARY

MAR 2 8 2008

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 #: k071489

Submitter:

Tianjin New Bay Bioresearch Co., Ltd.
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Tianjin, China
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Contact Person:

Armando Torrescano
New Product Development Director
Telephone: (760) 822-6517
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Preparation Date:

Jan 23, 2008

Device Information:

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

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

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

Regulation Number: 21 CFR§862.3650

Regulatory Name:

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

Product Code: DJG
Regulatory Class: Class II

Predicate Devices:
HomeCheck Rapid Single and Multiple (X) Abuse Drug Screen Test Cup Device are substantially equivalent to New Bay Forsure Multiple Drug Screen Test Device (Professional Use), cleared by FDA(K052882) and GC/MS for its stated intended use.

Device Description:

New Bay HomeCheck Rapid 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 1000ng/ml of Amphetamine, 1000ng/ml of Methamphetamine, 50ng of THC, 2000ng/ml of Morphine, 300ng of Benzoylecognine, 25ng/ml of Phencyclidine, 300ng/ml of Benzodiazepine, 300ng/ml of Methadone, 100ng/ml of Oxycodone, 1000ng/ml of Tricyclic Antidepressant, and 300ng/ml of Barbiturates. 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 HomeCheck Single or Multiple (X) Drug Screen Strip of Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone , Oxycodone , Tricyclic Antidepressant, and Barbiturates Test device are a Chromatographic immunoassay for qualitative determination of the presence of **Amphetamine** at a cutoff concentration of 1000ng/ml, **Methamphetamine** at a cutoff concentration of 1000ng/ml, **THC** at a cutoff concentration of 50ng/ml, **Morphine** at a cutoff concentration of 2000ng/ml, **Benzoylecgonine** at a cutoff concentration of 300ng/ml, **Phencyclidine** at a cutoff concentration of 25ng/ml, **Benzodiazepine** at cutoff concentration of 300ng/ml for Oxazepam, **Methadone** at cutoff concentration of 300ng/ml, **Oxycodone** at cutoff concentration of 100ng/ml, **Tricyclic Antidepressant** at cutoff concentration of 1000ng/ml for Nortriptyline HCl, and **Barbiturates** at cutoff concentration of 300ng/ml for Secobarbital. The assay provides a simple and rapid analytical screening procedure to detect Amphetamine, THC, Morphine, Methamphetamine,

Benzoylecognine, Phencyclidine, Benzodiazepine, Methadone, Oxycodone, Tricyclic Antidepressant, and Barbiturates 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):

Tianjin New Bay HomeCheck Multiple Rapid Drug Screen Test (K 071489) is substantially equivalent to Tianjin New Bay ForSure Multiple Drug Screen Test Device cleared by FDA(510K 052882).

Device Characteristics	**Subject Device (s) Tianjin New Bay HomeCheck Multiple (X) Drug Screen Test device .(K 071489)**	**Predicate Device(s) Tianjin New Bay ForSure Multiple (X)Drug Screen Test Device (K 052882)**
Intended Use	HomeCheck Multiple Drug Screen Immunochromatographic Qualitative test. The assay provides a simple and rapid analytical screening procedure to detect different abuse drugs in human urine for the home use.	ForSure Multiple Drug Screen Immunochromatographic Qualitative test. The assay provides a simple and rapid analytical screening procedure to detect different abuse drugs in human urine for the professional use
Analytes	Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant, and Barbiturates	Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant, and Barbiturates Propoxphene.
Cutoff	AMP: 1000 ng/ml, MET:1000 ng/ml, BEG: 300ng/ml, THC: 50ng/ml, MOR: 2000ng/ml, PCP: 25ng/ml, BZD: 300ng/ml, MAD: 300ng/ml, OXY: 100ng/ml, TCA: 1000ng/ml	AMP: 1000 ng/ml, MET:1000 ng/ml, BEG: 300ng/ml, THC: 50ng/ml, MOR: 2000ng/ml, PCP: 25ng/ml, BZD: 300ng/ml, MAD: 300ng/ml, OXY: 100ng/ml, TCA: 1000ng/ml PPX : 300 ng/ml.
Assay time	5 minutes	5 minutes
Preliminary Positive Reconfirm by GC/Mass	Yes	Yes
Matrix	Urine	Urine
Calibrator	None	None
Instrument	None, Visual read single use	None, Visual Read single use
Calibration of Reagent	None	None
Storage	Below 28 °C until expiration	Below 28 °C until expiration

Summary:

The information provided in this pre-market notification demonstrates that HomeCheck Rapid single or Multiple (X) Abuse Drug Screen Test Cup Device (Home Use) is substantially equivalent to Tianjin New Bay Forsure Multiple (X) Drug Screen Cassette Test system (Professional Use) and GC/MS or HPLC.
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 HomeCheck Rapid 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

MAR 2 8 2008

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

Re: k071489
Trade/Device Name: HomeCheck™ Multiple Drug Cup Test
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, LFH
Dated: March 14, 2008
Received: March 17, 2008

Dear Mr. Torrescano:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

INDICATIONS FOR USE STATEMENT

510(k) Number (k071489):

Device name: HomeCheck™ Multiple Drug cup test device for Amphetamine (cutoff at 1000ng/ml) , Methamphetamine (cutoff at 1000ng/ml), Benzoylecgonine (cutoff at 300ng/ml), Benzodiazepine (cutoff at 300ng/ml for Oxazepam), Marijuana (cutoff at 50ng/ml), Morphine (cutoff at 2000ng/ml), Phencyclidine (cutoff at 25ng/ml), Methadone (Cutoff at 300ng/ml), Oxycodone (Cutoff at 100ng/ml), Tricyclic Antidepressant (Cutoff at 1000ng/ml for Nortriptyline HCl), and Barbiturates (Cutoff at 300ng/ml for Secobarbital).

Indications for Use:

The assay provides a simple and rapid analytical screening procedure to detect single or multiple different abused drugs (Amphetamine, Methamphetamine, Benzoylecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant, and Barbiturates in human urine.
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. HPLC is preferred confirmatory method for Tricyclic Antidepressant.

Special Conditions for Use

This test is intended for over the counter (OTC) consumer use as the first step in a 2-step process to provide consumers with information concerning the presence or absence of the above stated drugs in a urine sample. Information regarding the confirmatory testing - the second step in the process-, along with materials for shipping the urine specimen to the laboratory is included with the test. There are no uniformly recognized levels for Benzodiazepine, Oxycodone, Tricyclic Antidepressant, and Barbiturates. The test is not intended to screen individuals who are prescribed these drugs by a physician; the test my yield positive results for individuals taking such drugs, as prescribed.

Prescription Use ____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X__ (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): K071489