

MAY 07 2013

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: k122064

Submitter:

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Preparation Date:

04,19 2013

Device Information:

Trade or Proprietary Name:
ForSure™ One Step Buprenorphine Drug Cup Test Device.

Common/Usual Name:

Lateral flow immunochromatographic assay for detection of Buprenorphine in human urine

Device Classification Name:

Immunoassay of Buprenorphine

Regulatory Name:

Buprenorphine Test System

Regulation Section: 21 CFR § 862.3650

Regulatory Class: Class II

Product Code: DJG

Panel: Toxicology (91)

Predicate Devices:

ForSure™ One Step Buprenorphine Drug Cup Test Device is substantially equivalent to predicate device (ForSure™ One Step Buprenorphine Test Strip Device) cleared by FDA (K042990) for its stated intended use.

Device Description:

ForSure™ One Step Buprenorphine Drug Cup Test Device is a convenient specimen collection cup with a built-in strip holder which is able to hold the QuikStrip of Buprenorphine within the container. The membrane of the test strip is coated with goat anti-mouse antibody and Buprenorphine-Bovine serum albumin conjugate. The sample pad contains a colloidal gold-labeled mouse monoclonal anti-Buprenorphine antibody. As the test sample flows through the absorbent device, the Colloidal Gold

labeled antibody-conjugate binds to the free drug in the specimen forming an antibody-conjugate in the test reaction zone and will not produce a magenta color band when the drug is above the detection level of 10 ng/ml of Buprenorphine. 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 test line and control area. A positive specimen produces only one color band in the control area. There is no meaning attributed to color or its intensity for either line. The test is easy and fast allowing the user to visually read the screen for abuse of drugs without the need for any other instrumentation to determine results. The tester will obtain a result in five minutes. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. This test is the first step in determining whether there are drugs in the urine. If the Buprenorphine result shows 1 line (preliminary positive) you should send the sample for laboratory testing.

ForSure™ One Step Buprenorphine Drug Cup Screen Test is for diagnostic and treatment purposes, consult with a healthcare or substance abuse professional.

Intended Use:

The ForSure One Step Buprenorphine Drug Cup Test Device is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at cutoff level of 10 ng/mL. The test is intended for prescription and over-the-counter use.

The Buprenorphine assay will yield preliminary positive results when buprenorphine is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for buprenorphine in urine. The ForSure One Step Buprenorphine Drug Cup Test Device shows the drug was or was not present at the cutoff level. The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Comparison to Predicate Device(s):

Tianjin New Bay ForSure™ One Step Buprenorphine Drug Cup Test is substantially equivalent to Tianjin New Bay ForSure™ One Step Buprenorphine Strip Test cleared by the FDA (K042990).

Device Characteristics	Subject Device (s) Tianjin New Bay ForSure™ One Step Buprenorphine Drug Cup Test device.	Predicate Device(s) Tianjin New Bay ForSure™ One Step Buprenorphine Strip Test (K 042990)	
Intended Use	ForSure™ Buprenorphine One Step Immunochromatographic Drug Cup Qualitative test. The assay provides a simple and rapid analytical screening procedure to detect Buprenorphine and its metabolite drugs in human urine .	ForSure™ One Step Buprenorphine Immunochromatographic Qualitative Strip test. The assay provides a simple and rapid analytical screening procedure to detect Buprenorphine in human urine	same
Analytes	Buprenorphine	Buprenorphine	same
Chemistry formulation and Antibody Used in	Antibody and chemistry formulation used for drug on the test strip are	Using monoclonal /polyclonal antibody for the colloidal gold	
the device	100% identical to the strips approved by FDA (k042990)	conjugate, Drug-BSA conjugate for the test line of the membrane	same
Cutoff	Buprenorphine: 10 ng/ml,	Buprenorphine: 10ng/ml,	same
Assay time	5 minutes	5 minutes	same
Preliminary Positive Reconfirm by GC/Mass	Yes	Yes	same
Matrix	Urine	Urine	same
Calibrator	None	None	same
Instrument	None, Visual read single use	None, Visual Read single use	same
Calibration of Reagent	None	None	same
Storage	Below 28°C until expiration	Below 28°C until expiration	same

**Performance
Comparison**

Subject Device:

Sensitivity: ≥ 10 ng /ml of Buprenorphine in urines show positive result

Total Precision: The results demonstrate that there is no appreciable within and inter lot variation when testing both positive and negative spiked samples across three (3) different lots of test device at different day. The test result of both within lot and inter lot reproducibility are similar to Predicate device.

Cutoff determination: The cutoff is 10 ng/ml of Bup. 50% below the cutoff level of Buprenorphine are negative. The result set at cutoff and 25 % above cutoff level of Buprenorphine are positive and similar to the predicate device.

Accuracy: A comparison study of positive and negative specimens with GC/MS was performed, the test results was correlated very well with GC/MS. It is similar to the predicate device

Predicate:

Sensitivity: ≥ 10 ng /ml of Buprenorphine in urines show positive result

Total Precision: The results demonstrate that there is no appreciable within and inter lot variation when testing both positive and negative spiked samples across three (3) different lots of test device at different day

Cutoff determination: The cut off is 10 ng/ml of BUP.50% below the cutoff level of Buprenorphine are negative. The result set at cutoff and 25% above cutoff level of Buprenorphine are positive.

Accuracy: A comparison study of positive and negative specimens with GC/MS was performed, the test results was correlated very well with GC/MS.

Same

Same

Same

Same

Summary:

The information provided in this pre-market notification demonstrates that ForSure™ One Step Buprenorphine Drug Cup Test Device is substantially equivalent to Tianjin New Bay ForSure™ One Step Buprenorphine Strip Test Device (K 042990) 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 Buprenorphine Drug Cup Test Device is safe and effective for its stated intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2013

Tianjin New Bay Bioresearch Co., Ltd.
C/O Roger De Bock
S.D. Biotek, LLC
4455 Murphy Canyon Road
SAN DIEGO CA 92123

Re: K122064

Trade/Device Name: ForSure™ One Step Buprenorphine Drug Cup Test Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: II
Product Code: DJG
Dated: February 05, 2013
Received: April 02, 2013

Dear Mr. De Bock:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122064

Device Name: ForSure One Step Buprenorphine Drug Cup Test Device

Indications for Use:

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The buprenorphine assay will yield preliminary positive results when buprenorphine is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for buprenorphine in urine. The ForSure One Step Buprenorphine Drug Cup Test Device shows the drug was or was not present at the cutoff level. The assay provides only a preliminary analytical test result.

A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.05.01 07:20:42 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122064