MAY 1 2 2005

March 30th, 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.

51O{k) Number: Design K # 042988

Submitter:
Tianjin New Bay Bioresearch Co., Ltd.
#3 Jian She Rd, Ba Li Tai Industry Area Jin Nan District,
Tianjin, China
Telephone: 86-22-28751515
Facsimile: 86-222-875-1516

Contact Person:

Rodrigo Berlie
Marketing Director
Telephone: (760) 602-2929
Facsimile: (760) 602-2999

Preparation Date:

March 30, 2005

Device Information:

Device Classification Name: Immunoassay, Buprenorphine
Common/Usual Name: Immunoassay Test System for detection of Buprenorphine in Human Urine
Proprietary Name: Rapid One Step Buprenorphine Test Card, For Sure Buprenorphine Rapid Test Card
Regulation Number: 21 CFR§862.3650
Regulatory Name: Buprenorphine test system
Product Code: DJG
Regulatory Class: Class II

Predicate Devices:

For Sure Buprenorphine Rapid Test Card is substantially equivalent to The CEDIA® Buprenorphine Assay cleared by FDA (K040316), and GC/MS for its stated intended use.

Device Description:

For Sure Buprenorphine Rapid Test Card consists of a chromatographic absorbent device 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 device, 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 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. 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:

For Sure Buprenorphine Rapid Test Card is an immunochromatographic enzyme immunoassay for qualitative determination of the presence of buprenorphine in human urine at cutoff concentration of 10 ng/ml. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine 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. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used.

Comparison to Predicate Device(s):

For Sure Buprenorphine Test Card is substantially equivalent to CEDIA buprenorphine test system cleared by FDA, e.g., the CEDIA Buprenorphine Assay (K040316) and GC/MS for its stated intended use.

Device Characteristics	Subject Device (For Sure Buprenorphine Test Card)	Predicate Device(s) CEDIA Buprenorphine Assay (K040316) and GC/MS
Intended Use	Buprenorphine one-step Immunochromatographic test card with 10 ng/ml cutoff. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine	The CEDA® Buprenorphine assay is homogenous enzyme immunoassay for qualitative or semi-quantitative determination of the presence of buprenorphine in human urine at cutoff concentration of 5 ng/ml.
Analyte	Buprenorphine	Buprenorphine
Cutoff	10 ng / ml	5 ng/ml

Matrix	Urine	Urine
Calibrator	None	5 levels (0,5,20,50 and 75 mg/ml
Instrument	None, Visual read single use	Expensive Auto-analyzer
Calibration of Reagent	None	Yes, multiple reagents require calibration.
Storage	Below 28 °C until expiration	2°C - 8°C until expiration date

Summary:

The information provided in this pre-market notification demonstrates that the Rapid One Step Buprenorphine Test Card is substantially equivalent to CEDIA Buprenorphine test assay system 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 Rapid One Step Buprenorphine Test Card is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 12 2005

Tianjin New Bay Bioresearch Co., Ltd.
c/o Mr. Rodrigo Berlie
Marketing Director
Aviara Biotech, LLC.
2720 Loker Ave-West
Suite U
Carlsbad, CA 92008

Re: k042988
Trade/Device Name: For Sure One Step Buprenorphine Test Card Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: April 28, 2005
Received: May 2, 2005

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting 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): K042988

Device name: For Sure One Step Buprenorphine Test Card Device

Indications for Use:

For Sure One Step Buprenorphine Test Card is an immunochromatographic immunoassay for qualitative determination of the presence of buprenorphine in human urine at cutoff concentration of 10 ng/ml. The assay provides a simple and rapid analytical screening procedure to detect buprenorphine 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. Clinical and professional judgment should be applied to any drug of abuse test results particularly when preliminary results are used.

Prescription Use ✓ 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)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety
510(k): K042988