K060527

Alfa Scientific Designs, Inc.
FDA Registered • ISO 9001/EN 46001 Certified
In-Vitro Diagnostic (IVD) Devices Manufacturer • Contract R&D • OEM

I.S. EN ISO 9001
I.S. EN 46001

510(k) Summary

JUL 25 2006

Safety and Effectiveness as Required by 21 CFR 807.92

Manufacture and Submitter	**Name:**	Alfa Scientific Designs, Inc.
	Address:	13200 Gregg Street Poway, CA 92064 Telephone: (858) 513-3888 x 308 Fax: (858) 513-8388
	Contact Person:	Naishu Wang, MD, Ph.D. E-mail: wnss@alfascientific.com
Device Name	**Trade Name:** *INSTANT-VIEW®* BUP/NBUP Urine Test (Cassette, Dip-Strip) *INSTANT-VERDICT®* BUP/NBUP Urine Test (Cassette, Dip-Strip) *INSTANT-CONFIRMATORY®* BUP/NBUP Urine Test (Cassette, Dip-Strip) **Common Name:** Immunoassay, BUP/NBUP Urine Test **Classification:** Immunoassay, Opiates **Product Code:** DJG	
Date of Summary Preparation	February 20, 2006	
Predicate Device	510K Number: K042988 OneStep Buprenorphine Test, New Bay Bioresearch, Co. Ltd.	
Device Description	A one-step lateral flow chromatographic immunoassay. The test strip in the device consists of 1) a burgundy-colored conjugate pad containing colloidal gold coupled with Rabbit anti-buprenorphine antibodies and mouse IgG, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line). The T line is coated with Buprenorphine-BSA, and the C line is coated with goat anti-mouse IgG antibodies.	
Intended Use	This device is a qualitative immunoassay intended to detect buprenorphine (BUP) and its metabolite, norbuprenorphine (NBUP) in human urine. Results are preliminary positive when the combination of the concentrations of BUP and NBUP is greater than 10 ng/ml. It is for health care professional use only.	

Similarity to the Predicate Device	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of buprenorphine abuse. • Both are in-vitro diagnostic devices. • Both have a built-in quality control feature, C line, to indicate that an adequate volume of specimen is applied and the liquid flow occurred properly
Sensitivity and Specificity	• The sensitivity of the proposed device is 96.3% and the specificity is 97.3%.
Accuracy	Ninety four (94) clinical specimens were studied. Fifty four (54) are HPLC/MS or GC/MS confirmed BUP/NBUP clinical samples and forty (40) were drug free clinical samples. The overall agreement of the proposed device to the HPLC/MS and GC/MS is 96.8%.
Reproducibility	• This study was carried out at three (3) sites outside Alfa, two Physician's Office Laboratories (POL) and one medical reference laboratory. Evaluations were performed by personnel with diverse educational backgrounds and working experiences. • The agreement of the three sites is 97.1% for BUP and 98.4% for NBUP.
Stability	To assess shelf life stability claims of the proposed test, accelerated degradation of the proposed device was studied. Three lots from each of the two formats (cassette and dip strip) were tested. Based on the results from accelerated degradation study, two years (24 months) shelf life of the proposed test was predicted.
Urine Specific Gravity and pH	The specific gravity of urine specimens, ranging from 1.002 to 1.035, and the pH of urine specimens, ranging from 3.0 to 9.0, found no influence on this test results.
Formats of the Device	The proposed device has two formats, cassette and dip-strip. The cassette is a device that assembles a dip-strip in a plastic housing. The studies demonstrate that the two formats are equivalent.
Conclusion	The results of specificity, sensitivity, reproducibility, cross reactivity, and interference studies demonstrate that the proposed test is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Naishu Wang, M.D., Ph.D.
President
Alfa Scientific Designs, Inc.
13200 Gregg Street
Poway, CA 92064

JUL 25 2006

Re: k060527
Trade/Device Name: *INSTANT-VIEW*® BUP/NBUP Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® BUP/NBUP Urine Test (Cassette, Dip-Strip)
INSTANT-CONFIRMATORY® BUP/NBUP Urine Test (Cassette, Dip-Strip)
Regulation Number: 21 CFR§ 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: July 14, 2006
Received: July 17, 2006

Dear Dr. Wang:

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): K060527

Device Name: *INSTANT-VIEW®* BUP/NBUP Urine Test (Cassette, Dip-Strip)
INSTANT-VERDICT® BUP/NBUP Urine Test (Cassette, Dip-Strip)
INSTANT-CONFIRMATORY® BUP/NBUP Urine Test (Cassette, Dip-Strip)

Indications For Use:

The proposed BUP/NBUP Urine Test is a qualitative immunoassay for the rapid detection of buprenorphine and norbuprenorphine from human urine specimens. The test provides only a preliminary result. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use X AND/OR Over-The-Counter Use
(Pert 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)

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