K100057

510(k) Summary

JUL - 6 2010

Safety and effectiveness as required by 21 CFR 807.92

Manufacturer and Submitter

Name: Alfa Scientific Designs, Inc.

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Contact Person: Naishu Wang, MD, Ph.D.
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Device Name

Trade Name:

INSTANT-VIEW® Drug of Abuse Urine *(Cassette/Cup)* Test
Drug of Abuse Urine *(Cassette/Cup)* Test

Common Name:

Immunoassay, Drug of Abuse Screen Urine Test

Classification:

Opiate Test System, Morphine Test System

Product Code:

DJG, NGI

Date of Summary Preparation

06/30/2010

Predicate Devices

INSTANT-VIEW® Multi-Drugs Urine Test (510(k) Number: K063545)
INSTANT-VIEW® Oxycodone Urine Test (510(k) Number: K063545)
INSTANT-VIEW® Morphine (300) Urine Test (510(k) Number: K060527)
Made by Alfa Scientific Designs, Inc.

Device Description	A one-step lateral flow chromatographic immunoassay. The device consists of any combination between one (1) to three (3) individual test strip(s) for the drug(s) being tested. Each test strip in the device consists of 1) a colored conjugate pad containing colloidal gold coupled with the anti-drug antibodies and 2) nitrocellulose membrane containing a test line (T line) coated with the conjugated drug antigen and a control line (C line). The C line serves as an internal quality control of the system and appears as a colored band during test regardless of the presence of the drug.
Intended Use	The proposed drug of abuse device is intended for use in an OTC setting as an IVD screening test for any single one, or combination of, the following three substances in urine: **Analyte** — **Cutoff** Morphine — 300 ng/ml Oxycodone — 100 ng/ml Oxycodone — 300 ng/ml This test provides only a preliminary result. The results provided by this device indicate whether the drug or drug metabolite may be present. A positive result from the device is considered to be a presumptive result and should never be interpreted as final without laboratory confirmation.
Similarity to the Predicate Devices	• Both are one-step lateral-flow chromatographic immunoassays. • Both are intended to provide qualitative detection of drug 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
Performance Characteristics	The proposed drug of abuse device uses the same technology and formulations for the detection of the drugs as individual test devices. The performance characteristics, such as accuracy, reproducibility, sensitivity and specificity of the multi-drug of abuse test are the same as the individual tests, which have been 510(k) cleared for professional use previously.
Stability	The shelf life stability of the test devices was done for each of the test devices, three lots for each test in each format. The shelf life of the proposed tests is two years (24 months)
Formats of the Device	The proposed multi- drug of abuse device has two formats, cassette and urine cup.
Conclusion	The proposed test is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Alfa Scientific Designs, Inc.
C/O Naishu Wang
13200 Gregg St.
Poway, CA 92064

JUL 06 2010

Re: k100051
Trade/Device Name: Instant-View Drug of Abuse Urine (Cassette/Cup) Test
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, NGI
Dated: June 16, 2010
Received: June 17, 2010

Dear Ms. 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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, 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): K100051

Device Name:

INSTANT-VIEW® Drug of Abuse Urine *(Cassette/Cup)* Test

Drug of Abuse Urine *(Cassette/Cup)* Test

Indications for Use:

The Drug of Abuse Urine (Cassette/Cup) Test is a rapid qualitative immunoassay for the detection of potential abuse of one or more drugs: Morphine/Opiates, and Oxycodone (see list below). The device is intended for in vitro diagnostic home use.

Abbreviation	Test	Calibrator	Cutoff
MOR/OPI300	Morphine/Opiates	Morphine	300 ng/mL
OXY100	Oxycodone	Oxycodone	100 ng/mL
OXY300	Oxycodone	Oxycodone	300 ng/mL

This assay provides only preliminary results. A more specific alternate 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) 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 indicated.

Prescription Use ___ AND/OR Over-The-Counter Use X
(Per 21 CFR 807 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) K100051

Page 1 of 1