K003881

MAY 2 9 2001

510(K) Summary

In accordance with the Safe Medical Devices Act of 1990, a 510(K) summary is provided as outlined in 21 CFR 807.92.

Submitter	**Name:** Alfa Scientific Designs, Inc. **Address:** 11494 Sorrento Valley Road, Suite F&M San Diego, CA 92121 Telephone: (858) 350-9798 Fax: (858) 350-9709 Email: asdi@worldnet.att.net
Device Name	**Trade Name:** *Instant-View™ Benzodiazepine (BZD) Urine Cassette Test* **Common Name:** Benzodiazepine Test **Classification Name:** 21 CFR 862.3170, Class II
Predicate Device	The *Instant-View™ Benzodiazepine(BZD) Urine Test (Cassette)* is substantially equivalent to other legally marketed devices for the similar intended use. The device used for comparison study is *QuikStrip OneStep Benzodiazepine (BZD Test*, manufactured by *Syntron Bioresearch, Inc.* with 510(K) #: K973269, Date of Approval: 02/25/98.
Device Description	This test is a one-step lateral flow chromatographic immunoassay.
Intended Use	The *Instant-View™ Benzodiazepine (BZD) Urine Cassette Test* is a qualitative immunoassay device intended for use in drug rehabilitation clinics, physician offices and reference labs. It provides qualitative screening results for benzodiazepine in human urine at a cutoff level of 300 ng/ml.
Summary of the Similarities to the Predicate Device	• Intended Use: Both devices are intended for professional use to detect benzodiazepine in human urine at a cutoff level of 300 ng/ml.

- Interpretation of results:
  The appearance of only a C line, indicates a positive result, and the benzodiazepine level in the urine sample tested is at or higher than 300ng/ml. And, the appearance of two lines – both C line and T line indicates a negative result, and the benzodiazepine level is below 300 ng/ml.

- Technological Characteristics:
  Both devices are one step, qualitative, competitive binding immunoassay test.

Accuracy studies

The accuracy of the device was evaluated with 100 human urine specimens with GC/MS data at three POL sites and one reference laboratory by personals with diverse educational backgrounds and work experiences. The correlations between all the results are 98%.

Discussion and Conclusion

- The results of the accuracy studies indicate that the correlation between the Instant-View™ *Benzodiazepine (BZD)* Urine Test (Cassette) and the GC/MS is 98 %. Therefore the Instant-View™ *Benzodiazepine (BZD)* Urine Test (Cassette) is substantially equivalent to the existing legally marketed product.

- The accuracy evaluation results from clinical lab and the three physician's offices conducted by personnel with diverse educational backgrounds and working experience agreed 99%, indicating that the Instant-View™ *Benzodiazepine (BZD)* Urine Test (Cassette) is suitable for use by health care professionals with diverse educational backgrounds and work experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 2 9 2001

Naishu Wang, MD, Ph.D.
President
Alfa Scientific Designs, Inc.
11494 Sorrento Valley Road
Suite M
San Diego, CA 92121

Re: 510(k) Number: K003881
Trade/Device Name: Instant-View™ Benzodiazepine (BZD) Urine Cassette Test
Regulation Number: 862.3170
Regulatory Class: II
Product Code: JXM
Dated: November 24, 2000
Received: December 15, 2000

Dear Dr. Wang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) NUMBER (IF KNOWN): K003881

DEVICE NAME: **Instant-View™ Benzodiazepine (BZD) Urine Cassette Test**

INDICATIONS FOR USE:

It is for health care professional, in-vitro diagnostic use only.

This test is a qualitative one step lateral flow immunoassay intended for use in drug rehabilitation clinics, physician offices and reference labs. It provides qualitative screening results for Benzodiazepine (BZD) in human urine at a cutoff concentration of 300ng/ml.

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC MS) is the preferred confirmation method.

Fred Lacy
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003881

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)