JUL 2 7 2000

K994398

Alfa Scientific Designs, Inc.

11494 Sorrento Valley Road, Suite M
San Diego, CA 92121

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 M San Diego, CA 92121 Telephone: (858) 350-9798 Fax: (858) 350-9709 Email: asdi@worldnet.att.net
Device Name	**Trade Name:** *Instant-View™ Cocaine (Benzoylecgonine) Urine Cassette Test* **Common Name:** Cocaine Test **Classification Name:** 21 CFR 862.3250, Class II
Predicate Device	The *Instant-View™ Cocaine (Benzoylecgonine) Urine Cassette Test* is substantially equivalent to other legally marketed devices for the similar intended use. The device used for comparison study is *QuikStrip One Step Cocaine Test*, manufactured by *Syntron Bioresearch, Inc.* with 510(K) #: K971926, Date of Approval: 07/14/97.
Device Description	This test is a one-step lateral flow chromatographic immunoassay.
Intended Use	The *Instant-View™ Cocaine (Benzoylecgonine) Urine Cassette Test* is a qualitative immunoassay device intended to detect Benzoylecgonine in human urine at a cutoff level of 300 ng/ml. It is intended for health care professional use only.
Summary of the Similarities to the Predicate Device	• Intended Use: Both devices are intended to detect Benzoylecgonine in human urine at a cutoff level of 300 ng/ml. • Interpretation of results: The appearance of only one - C line, indicates a positive result, and that the Benzoylecgonine level is at a cutoff level of 300 ng/ml or higher. And, the appearance of two

lines – both C line and T line indicates a negative result, and that the Benzoylecgonine level is below 300 ng/ml.

- Technological Characteristics:
  Both devices are one step, qualitative, competitive binding immunoassay test, utilizing the basic immunochemical sandwich assay principle of recognition and formation of the specific Benzoylecgonine/Antibody/Benzoylecgonine complexes.

Discussion and Conclusion

- The correlation of results from the *Instant-View™ Cocaine (Benzoylecgonine) Urine Cassette Test*, and the legally marketed test device compared, is higher than 92.9 %. The results from the three POL sites agreed 93.3 %.

- The Accuracy Evaluation results from the Clinical Laboratory and the three Physician's Offices Laboratory conducted by persons with diverse educational backgrounds and working experience agreed 97.8 % with the results expected.

- Based on the results of the Performance Characteristics and Comparison Studies, it may be concluded that the *Instant-View™ Cocaine (Benzoylecgonine) Urine Cassette Test* is suitable for use by health care professionals with diverse educational backgrounds and work experiences, and it is substantially equivalent to the existing legally marketed device.

Additional Information:

A: Package Insert of the Predicate Device.

B: Records of Raw Data from the In-House Sensitivity Study

C: Raw Data for Precision Study from the three different POL sites.

D: Raw Data for Accuracy Study from the three POL sites and the Reference Laboratory.

E: Tabulated Results (Ascending Concentration) of the Accuracy Study form the three POL sites and the Reference Laboratory with the GC/MS Data the Toxicology Laboratory.

Source of Clinical Samples: Unilab Corporation
Toxicology Laboratory
18408 Oxnard Street
Tarzana, CA 91356
Tel: (818) 996-7300
Fax: (818) 345-6967
Contact Person: Ali Mikhchi

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 27 2000

Ms. Rhoda Filipina
QA Manager
Alfa Scientific Designs, Inc.
11494 Sorrento Valley Road
Suite M
San Diego, California 92121

Re: K994398
Trade Name: Instant-View Cocaine (Benzoylecgonine) Urine Cassette Test
Regulatory Class: II
Product Code: DIO
Dated: June 30, 2000
Received: July 6, 2000

Dear Ms. Filipina:

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 (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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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): K994398

Device Name: Instant-View Cocaine (Benzoylecgonine) Urine Cassette Test

Indications For Use:

Instant-View Cocaine (Benzoylecgonine) Urine Cassette Test is a qualitative one step lateral flow, competitive binding immunoassay device intended to be used to detect benzoylecgonine, a metabolite of cocaine in human urine at a cutoff level of 300 ng/ml. It is intended for health care professional use only.

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

(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)

Veronica C. Chiu for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994398