FEB 0 7 2002

K013778

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is:

1. Date of summary: November 8, 2001

2. Submitted by: aLATEX Scientific Inc.
6355 Westheimer Rd.
Suite 105
Houston TX 77057

3. Device Name: Peace of Mind Home Drug Test

4. Device Classification: Class II, Panel 91 Toxicology

5. Device description: The Peace of Mind Home Drug Test is an immunochromatographic based one step *in vitro* test for use at home.

6. Intended Use: The Peace of Mind Home Drug Test is designed for the qualitative determination of five drugs of abuse and their metabolites in human urine at the following cut off concentrations:

THC	50ng/mL
PCP	25ng/mL
Opiates	2000ng/mL
Cocaine	300ng/mL
Methamphetamine	1000ng/mL

The test is the first part of a two-step process to provide consumers with information regarding the presence or absence of any of these drugs in a urine sample. Confirmation, using GC/MS, of any possible drug result is recommended as the second step.

7. Substantial Equivalence: The Peace of Mind Home Drug Test is substantially equivalent to several other professional and over the counter immunoassay Drugs of Abuse Tests, such as Phamatec QuickScreen™ At Home Test and the Drug Stop Test. These home drug tests are the first of a two-step process to detect the presence or absence of drugs of abuse in human urine and require consumers to confirm possible positive results with GC/MS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 7 2002

aLATEX Scientific Inc.
c/o Ms. Janis Freestone
Director, Regulatory Affairs
Advantage Diagnostics Corporation, Ltd.
1201 Douglas Avenue
Redwood City, CA 94063

Re: k013778
Trade/Device Name: Peace of Mind Home Drug Test
Regulation Number: 21 CFR 862.3870; 21 CFR 862.3250; 21CFR 862.3610; 21 CFR 862.3640
Regulation Name: Cannabinoid test system; Cocaine and cocaine metabolite test system; Methamphetamine test system; Morphine test system
Regulatory Class: Class II; Class II; Class II; Class II; Class II
Product Code: MVO; LDJ; DIO; DJC; DPK; LCM
Dated: November 12, 2001
Received: November 13, 2001

Dear Ms. Freestone:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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/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

510k Number: K013778

Device Name:
Peace of Mind Home Drug Test

Indications for Use:

The Peace of Mind Home Drug Test is a qualitative, one step, immunochromatographic competitive assay used to screen human urine for the presence of THC, PCP, Opiates, Cocaine and Methamphetamine at the following cut off concentrations:

THC	50ng/mL
PCP	25ng/mL
Opiates	2000ng/mL
Cocaine	300ng/mL
Methamphetamine	1000ng/mL

The test is the first part of a two-step process to provide consumers with information regarding the presence or absence, of any of the five drugs. Confirmation, using GC/MS, of a possible drug result is recommended as the second step.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013778

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ (Per 21 CFR 801.109) OR Over the counter use_X_