K041221

JUL 1 3 2004

Section D

510(k) Summary
[As required by 21 CFR 807.92]

I. Submitter:

A. Name: Accu-Stat Diagnostics, Inc.

B. Address: 11 Orchard Road, Suite # 108, Lake Forest, CA 92630

C. Phone and Fax Numbers: Phone 949-916-7560
Fax 949-916-7595

D. Contact Person: James G. Barrons

II. Date of Preparation of this Summary: 6 May 2004

III. Trade Name: Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP)

IV. Common Name: At home rapid screening test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP) in urine.

V. Classification Name: Immunoassay for the qualitative detection of drugs of abuse in urine.

VI. The Marketed Products to Which Equivalence is claimed: The Accu-Stat™Home Drug Test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP) is substantially equivalent to the Phamatech At Home™ Drug Test for Cup for Amphetamine, Methamphetamine (Ecstasy), Marijuana, Cocaine, and Opiates and other commercially available drug screening tests that qualitatively measure the presence of target drugs or metabolites by visual color one-step immunoassay technology.

VII. Statement of Intended Use Compared to Other Products: The intended use of the Accu-Stat™ Home Drug Test Cup for Marijuana, Cocaine, Amphetamine, Opiates, Methamphetamine, Ecstasy, and Phencyclidine is substantially equivalent to the above listed products and is a single unit screening test for the rapid detection of from three to seven of the listed drugs in human urine. The designated cut-off concentrations for these drugs are as follows: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Ecstasy at 500 ng/ml, Opiates at 2000

ng/ml, and Phencyclidine at 25 ng/ml. The tests are intended for over-the-counter (OTC) consumer use as the first step in a two-step process that includes confirmatory testing of preliminary positive results. Information, along with the materials for shipping a portion of the urine specimen to the laboratory is provided.

VIII. Discussion of Technological Characteristics: The Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine, like other commercially available drug screening tests, qualitatively measures the presence or absence of THC, COC, AMP, mAMP, MDMA, OPI, PCP and their metabolites in urine, using a one step, rapid chromatographic immunoassay which operates under the principle of competitive binding. Drugs, which may be present in the urine specimen, compete against the drug conjugate for binding sites on the antibody. During testing, a urine specimen migrates upward by capillary action. Marijuana, if present in the urine specimen below 50 ng/ml, and the other drugs being tested for, if below the cut-off levels stated in **Attachment 3 Table 2,** will not saturate the binding sites of the antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized marijuana, cocaine, or other listed drug conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the marijuana level is above the 50 ng/ml because it will saturate all the binding sites of anti-marijuana antibodies. The same holds true for cocaine and the other drugs if the level is above the cut-off. It will saturate all the binding sites of anti-cocaine (or other drug) antibodies and therefore the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of a drug competition. To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

Examples of predicate devices include the First Check® Home Drug Tests and the Phamatech At Home Drug Tests using a single or a multi-drug display. The consumer studies using the Accu-Stat™ Home Drug Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine Ecstasy, Opiates, and Phencyclidine demonstrates that the test exhibits excellent overall performance in the hands of lay users. The data supports the conclusion that the consumer can use the Accu-Stat™ Home Drug Tests to obtain immediate, preliminary information regarding the possible use of THC, COC, AMP, mAMP, MDMA, OPI, and PCP.

IX. Safety and Effectiveness: Because the Accu-Stat™ Home Drug Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine,

(mAMP), MDMA, Opiates (OPI), and Phencyclidine (PCP) are identical to the ACON Laboratories One Step Multi-Drug Multi-Line Screen Test Card with Integrated Cup that is legally marketed under K031759 for professional use, and because no special skills, training, education, or licensing is required to collect a urine specimen and activate the test, there is no issue regarding the safety or effectiveness of the product to perform its intended function, i.e., to screen urine for the presence or absence of THC, COC, AMP, mAMP, MDMA, OPI, or PCP and their metabolite(s). Because the labeling of the Accu-Stat™ Home Drug Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP) is substantially equivalent to a variety of rapid screening tests currently in commercial distribution, including the Phamatech At Home™ Drug Test Cup, First Check® Home Drug Test, the Advantage Diagnostics Home Drug Tests, and there have been no reports of consumer inability to follow instructions or interpret results over the many months these products have been purchased, it should be concluded that the product can be used effectively by the lay user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 1 3 2004

Mr. James G. Barrons
President
Accu-Stat Diagnostics
11 Orchard Road
Suite 108
Lake Forest, CA 92630

Re: k041221
Trade/Device Name: Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: MVO, LDJ, DIO, DKZ, LAF, DJG, LCM
Dated: May 6, 2004
Received: May 10, 2004

Dear Mr. Barrons:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section A

Indications for Use

510 (k) Number (if known): K041221

Device Name: Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP)

Indications for Use:

The Accu-Stat™ Drugs of Abuse Home Test Cup for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP), is a screening test for the rapid detection of three to seven of the above listed drugs in a variety of combinations human urine. The designated cut-off concentrations for these drugs are as follows: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Ecstasy at 500 ng/ml, Opiates at 2000 ng/ml, and Phencyclidine at 25 ng/ml. The tests are intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The Counter Use_X_____ (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) K041221