K040327

APR 1 9 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 February, 2004

III. Trade Name: Accu-Stat™ Home Drug Test for Marijuana (THC)
Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC)

IV. Common Name: At home rapid screening test for Marijuana (THC) in urine.
At home rapid screening test for Marijuana & Cocaine (THC, COC) 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) is substantially equivalent to the First Check® Home Drug Test for THC (Marijuana) and the Phamatech At Home™ Drug Test for Marijuana. The Accu-Stat™ Home Drug Test for Marijuana and Cocaine (THC, COC) is substantially equivalent to the First Check® Home Drug Test for Marijuana and Cocaine 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 Tests for Marijuana (THC) and for Marijuana & Cocaine (THC, COC) are substantially equivalent to the above listed products and are preliminary, rapid screening tests for the detection Marijuana (THC) and Cocaine (COC) and their metabolites in urine. These products are intended to be the first step in a two-step process to provide over-the-counter (OTC) consumers, including but not limited to concerned parents, with information regarding the presence of THC or COC and their metabolites in a urine sample. Information regarding the second step, confirmation testing, is provided.

VIII. Discussion of Technological Characteristics: The Accu-Stat™ Home Drug Test for Marijuana (THC) and the Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC), like other commercially available drug screening tests, qualitatively measures the presence or absence of THC and COC 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 Cocaine, if present in the urine specimen below 300 ng/ml, 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 or cocaine 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 50 ng/ml because it will saturate all the binding sites of anti-marijuana antibodies. The same holds true for cocaine if the level is above 300 ng/ml. It will saturate all the binding sites of anti-cocaine 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 multi-drug display. The consumer studies using the Accu-Stat™ Home Drug Test for Marijuana (THC) and the Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC) 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 and COC.

IX. Safety and Effectiveness: Because the Accu-Stat™ Home Drug Test for Marijuana (THC) and the Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC) are identical to the ACON Laboratories One Step Marijuana Test Device and the Multi-Drug Multi-Line Device that is legally marketed under K003557 and K020313 respectively for professional use, and because no special skills, training, education, or licensing is required to transfer a few drops of a urine sample into the test card well, 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 or THC & COC and its/their metabolite(s). Because the labeling of the Accu-Stat™

Home Drug Test for Marijuana (THC) and the Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC) is substantially equivalent to a variety of rapid screening tests currently in commercial distribution, including the First Check® Home Drug Test and the Phamatech At Home™ Drug Test, 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

APR 1 9 2004

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

Re: k040327
Trade/Device Name: Accu- Stat™ Home Drug Test for Marijuana (THC)
Accu-Stat™ Home Drug Test for Marijuana and Cocaine (THC,COC)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: MVO, LDJ, DIO
Dated: February 6, 2004
Received: February 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

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-1

Indications for Use

510(k) Number (if known): K040327

Device Name: Accu-Stat™ Home Drug Test for Marijuana (THC)

Indications For Use:

The Accu-Stat™ Home Drug Test for Marijuana (THC) is a screening test for the rapid detection of THC and its metabolites in human urine at a cut-off level of 50 ng/ml. The test is 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 THC or its 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 _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 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) K040327

Section A-2

Indications for Use

510(k) Number (if known): K040327

Device Name: Accu-Stat™ Home Drug Test for Marijuana and Cocaine (THC, COC)

Indications For Use:

The Accu-Stat™ Home Drug Test for Marijuana and Cocaine (THC, COC) is a screening test for the rapid detection of THC and/or COC and its metabolites in human urine at a cut-off level of 50 ng/ml for THC and 300 ng/ml for COC. The test is 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 either THC, COC (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 _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 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

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