NOV 6 2002

K022955

Summary of Safety and Effectiveness
(As required by 21CFR 807.92(c))

Device name: Amedica Drug Screen THC Test

Design and Materials: Membrane based one-step, lateral flow, competitive immunoassay use colloidal gold for visual detection. The test cutoff is 50 ng/ml.

Intended Use: The Amedica Drug Screen THC Test is a immunochromatographic assay for the rapid detection of THC in human urine at a cutoff concentration of 50 ng/ml. This assay has not been evaluated at point-of-care locations and is intended for use by healthcare professionals. This assay provides only a preliminary result. A more specific alternative chemical method is needed to obtain a confirmed result.

Test Principle and Description: The Amedica Drug Screen THC Test is based on the principle of highly specific competitive immunochemical reactions between antigens and antibodies for the analysis of specific substances in urine. During testing, a urine specimen moves along membrane on the strip by capillary action. When THC concentration in the urine is below 50 ng/ml, it is not enough to saturate all of the binding sites of the antibody-coated colored particles in the test strip. The unsaturated antibody-coated particles will then be captured by THC conjugates immobilized on the strip and a colored line will appear in the test region. The test result is negative. If the THC level is above 50 ng/ml, it is sufficient to occupy all of the binding sites on the antibody-coated particles. The saturated antibody-coated particles will not be captured by THC conjugate coated on the strip. The colored line will not form in the test region. The test result is positive. The device also provides a built-in control with a different antigen/antibody reaction at the control region. This control line should always appear whether or not the drugs or metabolites are present. If the control line does not appear the test result is invalid. This means that negative urine will produce two colored bands, and positive urine will produce only one band at control region.

Performance: The product performance was evaluated by correlation study using blind-labeled clinical specimens that have been measured by GC/MS. This study produced > 96% agreement with GC/MS results. In addition, clinical site study was performed at two certified laboratories and demonstrated that Amedica Biotech Drug Screen THC Test can be use by professionals to obtain a visual, qualitative detection of drugs of abuse. The results of these study and comparison with Rapid Diagnostics THC test demonstrated that Amedica Biotech Drug Screen THC Test is substantially equivalent to the predicate kit.

Manufacturer:

Amedica Biotech, Inc.
28301 Industrial Blvd. Suite K
Hayward, CA 94545
Phone: (510) 785-5980
Fax: (510) 785-5973

Predicate kit:

Rapid THC Test
Rapid Diagnostics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 6 2002

Mr. Jeff Chen
President
Amedica Biotech, Inc.
28301 Industrial Blvd., Suite K
Hayward, CA 94545

Re: k022955
Trade/Device Name: Amedica Drug Screen THC Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: August 30, 2002
Received: September 5, 2002

Dear Mr. Chen:

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

510(k) Number (if known): _____

Device Name: **Amedica Drug Screen THC Test**

Indications For Use:

The Amedica Drug Screen THC Test is an in vitro diagnostic test for the rapid detection of THC in human urine at a cutoff of 50 ng/ml. This test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale.

This assay provides only a preliminary result. A more specific alternative chemical method is needed to obtain a confirmed result.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Device
510(k) Number K022955

(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)