K023101

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

DEC 16 2002

Device name: Amedica Drug Screen Methamphetamine Test

Design and Materials: Membrane based one-step, lateral flow, competitive immunoassay use colloidal gold for visual detection. The test cutoff is1000 ng/ml.

Intended Use: The Amedica Drug Screen Methamphetamine Test is a immunochromatographic assay for the rapid detection of methamphetamine in human urine at a cutoff concentration of 1000 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 Methamphetamine 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 methamphetamine concentration in the urine is below 1000 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 methamphetamine conjugates immobilized on the strip and a colored line will appear in the test line region. The test result is negative. If the methamphetamine level is above 1000 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 methamphetamine 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 cartridge should be discarded. 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 > 94% agreement with GC/MS results. In addition, clinical site study was performed at two certified laboratories and demonstrated that Amedica Biotech Drug Screen Methamphetamine 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 methamphetamine test demonstrated that Amedica Biotech Drug Screen Methamphetamine 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 Methamphetamine Test
Rapid Diagnostics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

DEC 16 2002

Re: k023101
Trade/Device Name: Amedica Drug Screen Methamphetamine Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF
Dated: November 12, 2002
Received: November 19, 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 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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023101

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

Indications For Use:

The Amedica Drug Screen Methamphetamine Test is an in vitro diagnostic test for the rapid detection of methamphetamine in human urine at a cutoff of 1000 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 [illegible]
510(k) Number K023101

(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)