OCT 17 2003

K031497

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

Device name: Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test

Design and Materials: Membrane based one-step, lateral flow, competitive immunoassay use colloidal gold for visual detection of 3,4 methylenedioxymethamphetamine, secobarbital, oxazepam, methadone and nortriptyline.

Intended Use: The Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test is a immuno-chromatographic assay for the rapid detection of of 3,4 methylenedioxymethamphetamine, secobarbital, oxazepam, methadone and nortriptyline in human urine at the following cutoff concentration:

MDMA	3,4 methylenedioxymethamphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Nortriptyline	1000 ng/ml

This test kit is used to obtain a visual, qualitative result and is intended for professional use.

Test Principle and Description: The Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA 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 drugs concentrations in the urine are below cutoff, they are 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 drug-protein conjugates immobilized on the strip and colored lines will appear in the test region. The test result is negative. If the drugs levels are above cutoff, they are sufficient to occupy all of the binding sites on the antibody-coated particles. The saturated antibody-coated particles will not be captured by drug-protein conjugate coated on the strip. The colored lines 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 colored bands in test and control region, while positive urine will produce only colored bands in the control region.

Performance: The product performance was evaluated by correlation study using blind-labeled 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 a certified laboratorie and demonstrated that Amedica Biotech Drug Screen MDMA-BAR-BZO-MTD-TCA Test can be use by professionals to obtain a visual, qualitative detection of drugs of abuse. The results of these studies and comparison with predict devices demonstrated that Amedica Biotech Drug

Screen MDMA-BAR-BZO-MTD-TCA Test is substantially equivalent to the legally marketed devices.

Manufacturer:	Amedica Biotech, Inc. 28301 Industrial Blvd. Suite K Hayward, CA 94545 Phone: (510) 785-5980 Fax: (510) 785-5973
Predicate kits:	Instant-View Drug Screen MDMA, Barbiturate, Benzodiazepine, Methadone, TCA Test

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 2003

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

Re: k031497
Trade/Device Name: Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC; DIS; JXM; DJR; MLK
Dated: July 29, 2003
Received: July 31, 2003

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). 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,

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): K031497

Device Name: **Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test**

Indications For Use:

The Amedica Drug Screen MDMA-BAR-BZO-MTD-TCA Test is an in vitro diagnostic test for the rapid detection of 3,4 methylenedioxymeth-amphetamine, secobarbital, oxazepam, methadone and nortriptyline in human urine at the following cut-off concentration.

MDMA	**3,4 methylenedioxymethamphetamine**	**500 ng/ml**
BAR	**secobarbital**	**300 ng/ml**
BZO	**oxazepam**	**300 ng/ml**
MTD	**methadone**	**300 ng/ml**
TCA	**nortriptyline**	**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.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031497

(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)