



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center – WO66-0609  
Silver Spring, MD 20993-0002

Amedica Biotech Inc.  
c/o Mr. Jeff Chen  
28301 Industrial Blvd Suite K  
Hayward, CA 94545  
USA

APR 14 2010

Re: k100108  
Trade/Device Name: Amedica Drug Test Cup  
Regulation Number: 21 CFR 862.3650  
Regulatory Class II  
Product Code: NGL, DIS, DJR, LCM, LFG, NFT, NFV, NFW, NFY, NGG  
Dated: March 25, 2010  
Received: March 26, 2010

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal line extending to the right.

Courtney C. Harper, Ph.D.  
Director  
Division of Chemistry and Toxicology  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number: k100108

Device Name: Amedica Drug Screen Test  
THC/COC/OPI/AMP/MET/PCP/MDMA/BAR/BZO/MTD/TCA/OXY

### Indications for Use:

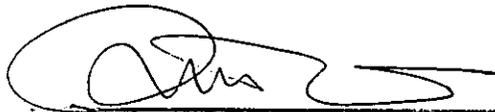
The Amedica Drug Screen Test  
THC/COC/OPI/AMP/MET/PCP/MDMA/BAR/BZO/MTD/TCA/OXY is an in vitro  
diagnostic test for the rapid detection of the following drugs in human urine

THC 11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic 50 ng/ml  
COC Benzoyllecgonine 300 ng/ml  
OPI Morphine 300 ng/ml  
OPI Morphine 2000 ng/ml  
AMP Amphetamine 1000 ng/ml  
MET Methamphetamine 1000 ng/ml  
PCP Phencyclidine 25 ng/ml  
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  
OXY Oxycodone 300 ng/ml

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) k100108

This test is intended for use by over-the-counter (OTC) consumers as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Tests for prescription drugs will yield preliminary positive results when prescription drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug cutoffs for barbiturates, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Prescription Use \_\_\_\_\_ AND/OR Over-The-Counter Use  X

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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