



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

**AUG 19 2008**

Re: K080872  
Trade/Device Name: Amedicheck Drug Screen Test, THC/COC/OPI/AMP/MET/PCP/  
BAR/BZO/MDMA/OXY/MTD/PPX/TCA  
Regulation Number: 21 CFR 862.3870  
Regulation Name: Cannabinoid Test System.  
Regulatory Class: Class II  
Product Code: LDJ, DIO, OJG, DKZ, LAF, LCM, DJC, DIS, JXM, DJR, MLR, JXN  
Dated: July 18, 2008  
Received: July 21, 2008

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).

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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 (240) 276-0490. 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 (240) 276-3150 or at its Internet address at <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Jean M. Cooper, M.S., 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

## Indications for Use

510(k) Number: K080872

Device Name: AmediCheck Drug Screen Test

THC/COC/OPI/AMP/MET/PCP/BAR/BZO/MDMA/OXY/MTD/PPX/TCA

### Indications For Use:

The AmediCheck Drug Screen Test THC/COC/OPI/AMP/MET/PCP/BAR/BZO/MDMA/OXY/MTD/PPX/TCA is an in vitro diagnostic test for the rapid detection of THC, benzoylecgonine, morphine, amphetamine, methamphetamine, phencyclidine, barbiturates, benzodiazepines, MDMA, oxycodone, methadone, propoxyphene and tricyclic antidepressants in human urine at the following cutoff concentration:

THC	11-nor- $\Delta^9$ -Tetrahydrocannabinol-9-carboxylic	50 ng/ml
COC	Benzoylecgonine	300 ng/ml
OPI	Morphine	2000 ng/ml
OPI	Morphine	300 ng/ml
AMP	Amphetamine	1000 ng/ml
MET	Methamphetamine	1000 ng/ml
PCP	Phencyclidine	25 ng/ml
MDMA	3,4 methylenedioxyamphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BZO	Oxazepam	300 ng/ml
MTD	Methadone	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
PPX	Propoxyphene	300 ng/ml
OXY	Oxycodone	300 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 must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) 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 used.

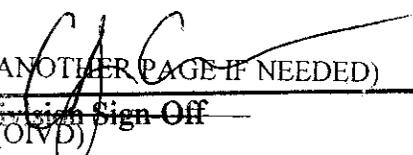
Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(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