DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

DEC 19 2008

Re: k082898
Trade Name: Amedica Home Drug Test Cup
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Codes: NGL, NFT, NFY, NGG, DIS, NFV, DJR, LCM, LFG, NFW
Dated: September 29, 2008
Received: September 30, 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).

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.

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 Statement

510(k) Number (if known): k082891

Device Name: Amedica Home Drug Test Cup

Indications For Use:

The Amedica Home Drug Test Cup is an *in vitro* diagnostic test for the rapid detection of the following drugs in human urine.

Drug	Analyte	Cutoff	Device Code
Marijuana	THC	50 ng/mL	THC
Cocaine	Benzoecgonine	300 ng/mL	COC
Amphetamine	Amphetamine	1000 ng/mL	AMP
Methamphetamine	Methamphetamine	1000 ng/mL	MET
Opiates	Morphine	2000 ng/mL	OPI
Opiates300	Morphine	300 ng/ml	OPI300
Pencyclidine	Phencylidine	25 ng/mL	PCP
Barbiturates	Secobarbital	300 ng/mL	BAR
Benzodiazepines	Oxazepam	300 ng/mL	BZD
Methadone	Methadone	300 ng/mL	MTD
Oxycodone	Oxycodone	100 ng/mL	OXY
MDMA	MDMA	500 ng/mL	MDMA
Tricyclic Antidepressants	Nortriptyline	1000 ng/mL	TCA

This test is intended for over-the-counter (OTC) consumer use 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 801 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

510(k) k082891