DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 17 2004

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

Re: k040464
Trade/Device Name: Amedica Drug Screen THC/COC, OP1300, PPX, OXY, BAR/BZO Test
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ, DIO, DJG, JXN, DIS, JXM
Dated: February 12, 2004
Received: February 23, 2004

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,

Jean M. Cooper MS, D.V.M.

Jean M. Cooper, MS, 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

Final

Indications for Use

510(k) Number (if known): k040464

Device Name: Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test

Indications For Use:

The Amedica Drug Screen THC/COC, OPI300, PPX, OXY, BAR/BZO Test is an in vitro diagnostic test for the rapid detection of THC, benzoylecgonine, morphine, propoxyphene, oxycodone, secobarbital and oxazepam in human urine at the following cut-off concentration

THC	11-nor-Δ^9-THC-9-COOH	50 ng/ml
COC	benzoylecgonine	300 ng/ml
OPI	morphine	300 ng/ml
PPY	propoxyphene	300 ng/ml
OXY	oxycodone	100 ng/ml
BAR	secobarbital	300 ng/ml
BZO	oxazepam	300 ng/ml

This test kit is used to obtain a visual, qualitative result and is intended for use in laboratories and workplaces by trained users. It is not intended for over the counter sale. For in vitro diagnostic use

Minimum training for operators is defined as those individuals who have received instructions for drugs of abuse testing from a physician or medical review officer. Operators may be lay users with no prior experience in running laboratory tests, but who are expected to perform at least 5 tests per week. Training should cover a variety of topics such as the value of confirmation testing, how to obtain confirmation testing, false positive results, false negative results, and quality control procedures. We recommend that operators take a written and practical exam before performing any testing and that employers keep documentation of the training.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

Prescription Use ___v___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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

510(k) K040464