DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 20 1998

John B. Dubeck, Esq.
American Bio Medica Corporation
C/O Keller and Heckman LLP
1001 G Street, NW, Suite 500W
Washington, D.C. 20001

Re: K980872
"Rapid Drug Screen" 8-Panel Drug Test
Regulatory Class: II
Product Code: DIO, DKZ, JXM, DJG, LCM, LAF, LDJ, DIS
Dated: March 6, 1998
Received: March 6, 1998

Dear Mr. Dubeck:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K980872

DEVICE NAME: "Rapid Drug Screen" 8 Panel test

INDICATIONS FOR USE:

"Rapid Drug Screen" 8-Panel test is a one-step, lateral flow immunoassay for the simultaneous detection of eight abused substances in urine (each assay occupies a separate channel). "Rapid Drug Screen" 8-Panel test is intended for use in the qualitative detection of the following 8 drugs of abuse in human urine at the following levels:

d-Amphetamine	750 ng/ml
Barbiturates	300 ng/ml
Benzodiazepines	300 ng/ml
Benzoyl ecognine	225 ng/ml
Cannabinoids	
(11-nor-9-carboxy-delta-9-THC)	50 ng/ml
Methamphetamine	1000 ng/ml
Opiates (codeine)	225 ng/ml
(morphine-3-glucuronide)	225 ng/ml
Phencyclidine (PCP)	19 ng/ml

"Rapid Drug Screen" 8-Panel test is intended for use by professional laboratories and physicians offices in a clinical setting. The assays are easy to perform, but should not be used without proper supervision. This immunoassay is a simplified qualitative screening method that provides only a preliminary analytical test result for use in determining the need for additional or confirmatory testing (i.e., gas chromatography/mass spectrometry (GC/MS)).

"Rapid Drug Screen" 8-Panel test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a more confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980872