DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 25 2006

American BIO Medica Corp.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k053359
Trade/Device Name: RapidTox™
Regulation Number: 21 CFR§ 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, DIO, DJC, DJR, DJG, JXN, LDJ, LFG, LCM
Dated: May 9, 2006
Received: May 11, 2006

Dear Ms. White:

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) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, 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 (if known): K053359

Device Name: RapidTox™

Indications For Use:

The RapidTox™ is a one-step, lateral flow immunoassay for the simultaneous detection of up to ten abused drug analytes in urine (each analyte is represented by a line in the test window of the cassette).

Rapid Tox is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Compound	Test Abbreviation	Level (ng/ml)
Amphetamine (d-amphetamine sulfate)	AMP	1000
Barbiturates (secobarbital)	BAR	300
Benzodiazepine (oxazepam)	BZO	300
Cocaine (benzoylecgonine)	COC	300
MDMA ((+/-)3,4-methylenedioxy-methamphetamine) (Ecstasy)	MDMA	1000
Methadone	MTD	300
Methamphetamine ((+/-)methamphetamine HCl)	MET	1000
Opiates (morphine-3-b-D-glucuronide)	OPI	300 2000
Oxycodone	OXY	100
Phencyclidine (phencyclidine HCl)	PCP	25*
Propoxyphene/Norpropoxyphene	PPX	300
THC/Cannabinoids (11-nor-Δ9-THC-9-carboxylic-acid)	THC	50*
Tricyclic Antidepressants (nortriptyline)	TCA	1000

Rapid Tox provides only a preliminary analytic test result. More specific alternative chemical methods must be used to obtain a 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 results are used.

The Test is recommended for professional use. It is not intended for over-the-counter sales to nonprofessionals.

Prescription Use √ AND/OR Over-The-Counter Use _____
(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) K053359