MAY 3 0 2008

K073078

510 (k) Summary

Submitters Name/Address:
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122 Smith Road
Kinderhook, NY 12106

Contact Person:
Richard Reilly
QA/RA Manager
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Date of Preparation of this Summary May 7, 2008

Device Trade or Proprietary Name: "Rapid Tox Cup"

Device Common/Usual Name or Classification Name: Multi-Drug Test System

Classification Number/Class: (No classification Regulation) / Class II

This 510 (k) summary is being submitted in accordance with requirement of 21 CFR 807.92.

The assigned 510 (k) number is:

Predicate Device:

The Technology utilized in the 'Rapid Tox Cup' is based on the same principle as that utilized in both "Rapid Tec 4,' 510(k) No. K041712, 'Rapid Tec 5" 510(k) No K023869, and 'Rapid Tox' 510 (k) No. K053359.

Test Description:
The immunoassays employed in each test strip of the 'Rapid Tox Cup' are based on the same principle of the highly specific reaction between antigens and antibodies.

Each assay consists of a membrane strip onto which up to five different drug conjugates have been immobilized. A colloidal gold-antibody complex consisting of up to five antibodies is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-multi-antibody complex moves with the urine sample by capillary action to contact the immobilized drug conjugate. Antibody-antigen reactions occur forming a visible line in all "test" areas. The formation of a visible line in the test areas occur when the test is negative for the adjacent labeled drug.

When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody binding sites on the colloidal gold-labeled antibody complex, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a colored line in any of the test areas is indicative of a presumptive positive result.

A control line, comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug in the urine, and therefore, should be present in all reactions.

A negative urine will produce up to six colored lines, and a positive sample will produce a colored line in the control area and no colored line(s) in the test area corresponding to the individual analyte(s) that are present in the sample.

INTENDED USE

'Rapid Tox Cup'-is a one-step, lateral flow immunoassay contained in a polypropylene cup for the simultaneous detection of abused drugs in urine. 'Rapid Tox Cup'- is intended for professional use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

The barbiturate BAR, benzodiazepine BZO and tricyclic antidepressant TCA will yield preliminary positive results when BAR, BZO, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, or tricyclic antidepressant in urine. Certain foods or medicines may interfere with tests for Barbiturates, Benzodiazepines, and Tricyclic Antidepressants and may cause positive results.

Performance Characteristics:

Amphetamine	500 ng/mL
Amphetamine	1000 ng/mL
Methamphetamine	500 ng/mL
Methamphetamine	1000 ng/mL
3,4-methylenedioxymethamphetamine (MDMA)	500 ng/mL
3,4-methylenedioxymethamphetamine (MDMA)	1000 ng/mL
Buprenorphine	12.5 ng/mL
Benzodiazepines (Oxazepam)	300 ng/mL
Barbiturates (Butalbital)	300 ng/mL
Oxycodone	100 ng/mL
Methadone	300 ng/mL
Phencyclidine	25 ng/mL
Propoxyphene	300 ng/mL
Opiates	300 ng/mL
Opiates	2000 ng/mL
Cocaine, (Benzoylecgonine	300 ng/mL
Cocaine, (Benzoylecgonine)	150 ng/mL
Tricyclic Antidepressants, (Nortriptyline)	1000 ng/mL
THC/ Cannabinoids (11 norΔ9-THC-9-carboxylic	50 ng/mL

Reproducibility was evaluated using commercially available control urines containing concentrations above and below the stated cut-off. Negative controls were also used. All concentrations were verified by GC/MS. Each sample was tested 4 times, twice daily, for 5 days. The results demonstrate the reproducibility of the 'Rapid Tox Cup' performance.

Conclusion:

'Rapid Tox Cup' is performs equivalent to 'Rapid Tec,' and 'Rapid Tox' products previously cleared under listed 510k numbers above. The device in (Cup) form houses the identical strips used in these predicate cleared devices which are cassettes or test cards. Testing of the identical strips housed in the Rapid Tox Cup device performed as expected and showed no difference relative to results from the Rapid Tec or Rapid Tox products.

Similarities and Differences between the predicate devices and the Rapid Tox Cup:

	Rapid Tox Cup	**Rapid Tox**	**Rapid Tec**
Device Housing	Cup Format	Cassette Format	Card Format
Sampling Method	Fill Cup	Dip or Pipette	Dip or Pipette
Device Test Strips	Identical Strips	Identical Strips	Identical Strips
Results Reading	Identical	Identical	Identical
Time to Results	3-5 minutes	3-5 minutes	5-7 minutes
Confirmation	Sample can be sent in the cup itself or in a separate container.	Sample sent out in separate container.	Sample sent out in separate container.
Quality Control	Control Line Observation for valid test	Control Line Observation for valid test	Control Line Observation for valid test
Drug Testing Quantity	Can test for greater than 10 drugs if desired	Can test up to 10 drugs	Can test up to 5 drugs
Storage	Identical	Identical	Identical
Shelf Life	2 years	2 years	2 years
Rapid Reader compatible	No	Yes	Yes
Calibration Required	No	No	No
User interaction once sampled	None	None	None
Stability Test Result	8 hours	8 hours	1 hour
Minimum Sample Volume	5 mL	100 µl	100 µl
Cross Reactivity	Over 500 drugs tested, same results	Over 500 drugs tested, same results	Over 500 drugs tested, same results
Drug ID being tested	Drug abbreviation adjacent to test line	Drug abbreviation adjacent to test line	Drug abbreviation adjacent to test line

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

American Bio Medica Corp.
c/o Rich Reilly
603 Heron Dr.
Logan Township, NJ 08085

MAY 30 2008

Re: k073078/S001
Trade Name: Rapid Tox Cup
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Test System
Regulatory Class: Class II
Product Codes: LAG, DJG, DIO, DKE, LCM, DKZ, JXM, DJR, LFI, JXN
Dated: May 13, 2008
Received: May 14, 2008

Dear Mr. Reilly:

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

Indication for Use

510(k) Number (if known): k073078

Device Name: Rapid Tox Cup

Indications For Use

Rapid Tox Cup™ is a one-step, lateral flow immunoassay contained in a polypropylene cup for the simultaneous detection of abused drugs in urine. 'Rapid Tox Cup'- is intended for use in the qualitative detection of the following 14 drugs of abuse in human urine at the following levels:

Amphetamine	1000 ng/mL
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Methamphetamine	1000 ng/mL
Methamphetamine	500 ng/mL
3,4-methylenedioxymethamphetamine (MDMA)	1000 ng/mL
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Barbiturates (Butalbital)	300 ng/mL
Oxycodone	100 ng/mL
Methadone	300 ng/mL
Phencyclidine	25 ng/mL
Propoxyphene	300 ng/mL
Opiates	300 ng/mL
Opiates	2000 ng/mL
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Cocaine (Benzoylecgonine)	150 ng/mL
Tricyclic Antidepressants (Nortriptyiline)	1000 ng/mL
THC/ Cannabinoids (11 nor△9-THC-9-carboxylic acid)	50 ng/mL

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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'Rapid Tox Cup' is intended for professional use. It is not intended for over-the-counter sale to non-professionals. This assay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas-chromatography/mass spectrometry (GC/MS).

The barbiturate BAR, benzodiazepine BZO and tricyclic antidepressant TCA will yield preliminary positive results when BAR, BZO, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, or tricyclic antidepressant in urine. Certain foods or medicines may interfere with tests for Barbiturates, Benzodiazepines, and Tricyclic Antidepressants and may cause positive results.

There is no calibration necessary and therefore no calibrator needed for this device.

'Rapid Tox Cup' provides only a preliminary analytical result. A more specific alternate method must be used in order to obtain a more confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are used.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

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