PREMARKET NOTIFICATION
510(k) SUMMARY

This 510(k) information required in 21 C.F.R.§ 807.87 for a 510(k) premarket notification is itemized below:

Date Prepared: June 15, 2004

Applicant: American Bio Medica Corporation
122 Smith Road
Kinderhook, NY 12106

Contact: Fran White, MDC Associates
163 Cabot Street, Beverly, MA
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1. **Device Trade Name:** Rapid Reader™

2. **Common Name:** Densitometer/scanner

3. **Classification Name:** Densitometer/scanner (Integrating, Reflectance, TLC, Radiochromatogram) for clinical use

4. **Device Description:** The Rapid Reader utilizes a digital camera, pictures are analyzed using software algorithm developed to read any of American Bio Medica Corporation's (ABMC's) drugs of abuse screening immunoassays. These immunoassays include the Rapid Drug Screen®, Rapid One®, or Rapid TEC® drug of abuse test for the simultaneous detection of up to 10 drugs of abuse in human urine. All of these tests have been previously FDA cleared as Class II devices.

5. **Intended Use:** The Rapid Reader System is designed to read , capture, document and archive ABMC's Rapid Drug Screen®, Rapid One®, and Rapid TEC® screening immunoassays ("ABMC test"). The Rapid Reader is used to obtain qualitative results (equivalent to manual read test results) and is intended for professional and point of care use only. It is not intended for over the counter sale to non-professionals. This Reader, combined with ABMC tests is a simplified qualitative 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).

After performing an ABMC test (according to instructions for use for each ABMC test) the test is inserted into the device holder of the Rapid Reader. The Rapid Reader reads the test device, and the results are displayed as a "POSITIVE", "NEGATIVE", or "INVALID" generating a result for each individual drug test on the ABMC test device being used.

6. **Substantial Equivalence:** The Rapid Reader test system is substantially equivalent to **BioSite Inc.'s Triage® Meter**.

Product Attribute	Triage Meter (K973547)	Rapid Reader	Substantially Equivalent
Intended Use	Determines qualitative positive or negative result from drug of abuse immunoassays screens	Determines qualitative positive or negative result from drug of abuse immunoassay screens	✓
Measurement Method	Reads the results generated by the test device (Triage Test)	Reads the results generated by the test device (Rapid Drug Screen, Rapid One, or Rapid TEC)	✓
Output	Outputs "Positive" or "Negative" qualitative test result and provides a print out of test result comparable to a manual read test result.	Outputs "Positive" or "Negative" qualitative test result and provides a print out of test results comparable to a manual read test result. .	✓

7. **Summary of Comparison Data:** The Rapid Reader interpretation of results was compared to manual interpretation (human eye interpretation) of ABMC's Rapid One devices. Certified negative and positive controls for each of the 14 drugs of abuse were tested using ABMC's Rapid One assay. Testing was conducted by three untrained professionals. The results were read in accordance with defined procedures then test devices were read using two ABMC Rapid Readers. Results generated by the reader were compared to manual test results.

   - The Rapid Reader and manual interpretation correctly identified 100% of drug free specimens as negative.
   - The Rapid Reader and manual interpretation correctly identified 100% of specimens containing drug at a concentration above the cutoff level for each of the 14 drugs of abuse as positive.

8. **Conclusion:** The design control process led to a determination that the Rapid Reader is substantially equivalent to the previously cleared predicate device. The evaluation has led to the assurance that the performance of the Rapid Reader in correctly interpreting the ABMC test result is equivalent to the performance of reading the test manually.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 12 2005

American Bio Media Corp.
c/o Ms. Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k041696
Trade/Device Name: Rapid Reader™
Regulation Number: 21 CFR 862.3150
Regulation Name: Barbiturate test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DPK, DJG, LCM, JXN, LFG, KHO
Dated: June 16, 2005
Received: June 17, 2005

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,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Supplement – Request for Additional Information
K041696
Rapid Reader™
American BioMedica, Corp.

STATEMENT OF INDICATIONS FOR USE:

510(k) Number: K041696

Device Name: Rapid Reader™

Indications For Use:

The Rapid Reader System is a reader designed to capture, document and archive ABMC Drug of abuse test results using Rapid Drug Screen®, Rapid One®, and Rapid TEC® screening immunoassays ("ABMC tests"). The Rapid Reader is used to obtain qualitative results and is intended for professional use only. This Reader, combined with ABMC tests is a simplified qualitative screening method that provides a preliminary indication of drugs in urine. Results should be confirmed using appropriate confirmation methods. i.e., gas-chromatography/mass spectrometry (GC/MS).

After having performed the ABMC tests (according to instructions for use of each ABMC tests) the ABMC test is inserted into the device holder of the Rapid Reader. The Rapid Reader scans the device, and the results are displayed.

The performance characteristics of the device have not been determined for use at point of care. This statement of intended use will be included in the operation manual.

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041696

Prescription Use ✓ **AND/OR** **Over The Counter Use**_____
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)