

MAR 20 2002

K014101

### 510(k) Summary

**Submitter's Name/Address:**

American Bio Medica Corporation  
122 Smith Road  
Kinderhook, NY 12106

**Contact Person:**

Henry Wells  
VP Product Development  
Phone: 518 758 8158  
Fax: 518-758 8171

**Date of Preparation of this Summary:**

December 12, 2001

**Device Trade or Proprietary Name:**

'RapidOne-OXY' Test

**Device Common/Usual Name or  
Classification Name:**

Oxycodone test system

**Classification Number/Class**

[no classification regulation]/ClassII

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is:

**Predicate Device:** The technology utilized in 'RapidOne'-OXY Test is the same as that utilized in the RDS opiate test products.

**Test Description:**

The assay employed in the 'RapidOne-OXY' Test is based on the same principle of highly specific reaction between antigens and antibodies.

This assay is a one-step, immunoassay in which a specially labeled drug (drug conjugate) competes with drug that may be present in the sample for the limited number of binding sites on the antibody. The test device consists of a membrane strip onto which a drug conjugate has been immobilized. A colloidal gold-antibody complex is dried at one end of a membrane. In the absence of any drug in the urine sample, the colloidal gold-antibody moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the 'test' area. The formation of a visible line in the 'test' area occurs when the test is negative.

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 sites on the colloidal

gold-antibody complex. If sufficient amount of drug is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color band (line) in the 'test' area is indicative of a positive result.

A control band (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 drug in the urine, and therefore, should be present in all reactions.

**Intended use:**

'RapidOne-OXY' Test is used for the qualitative detection of oxycodone in human urine. This immunoassay 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., GC/MS.

**Performance Characteristics:**

'RapidOne-OXY' Test will detect 100 ng/ml of oxycodone in urine.

'RapidOne-OXY' Test was compared to GC/MS. Ninety (90) samples were selected for evaluation, fifty (50) of which were found to be drug-free and forty (40) tested as positive by Syva Emit II. The forty positive specimens were confirmed as positive and quantified by GC/MS. 'RapidOne-OXY' Test correctly identified all the specimens that contained no drug as negative. Specimens, ranging in concentration of 54 to 1025 ng/ml, were shown to be positive by 'RapidOne-OXY' test. Two specimens containing 40 and 43 ng/ml of oxycodone were determined as negative by 'RapidOne-OXY' test.

Reproducibility was evaluated using control urines containing methadone concentrations above and below the stated cut-off. Forty (40) replicates were run at each concentration by three different operators.

Concentration (ng/ml)	#	RDS Result	
		Pos	Neg
No drug	80	0	80
50	80	8	72
75	80	65	15
100	80	80	0
125	80	80	0

**Conclusion:**

'RapidOne-OXY' Test obtains results substantially equivalent to GC/MS.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAR 20 2002

Mr. Henry Wells  
VP Product Development  
American Bio Medica Corporation  
122 Smith Road  
Kinderhook, NY 12106

Re: k014101  
Trade/Device Name: RapidOne-OXY Test  
Regulation Number: 21 CFR 862.3650  
Regulation Name: Opiate test system  
Regulatory Class: Class II  
Product Code: DJG  
Dated: February 12, 2002  
Received: February 13, 2002

Dear Mr. Wells:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

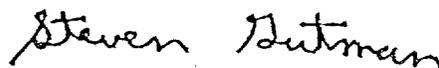
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,



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): K014101

Device Name: RapidOne-OXY' Test

**Indications For Use:**

'RapidOne-OXY' Test is a one-step, lateral flow immunoassay for the detection of oxycodone in urine.

'RapidOne-Oxy' Test is intended for the qualitative detection of oxycodone in human urine at 100 ng/ml.

'RapidOne-OXY' Test is intended for professional use. It is not intended for over the counter sales to nonprofessionals. The assay is easy to perform, but should not be used without proper supervision. This immunoassay 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.)

**'RapidOne-OXY' Test provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a more confirmed result. 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.**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K014101

Prescription Use  X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use