K080455

QuantRx
BIOMEDICAL CORPORATION

DEC 31 2008

510(k) Summary

Manufacturer: QuantRx Biomedical Corporation
5920 NE 112th Ave
Portland, OR 97220

Contact Person: Ms. Natalie J. Kennel
Consultant
NJK & Associates, Inc.
13721 Via Tres Vista
San Diego, CA 92129
Phone: (858) 705-0350
Fax: (858) 764-9739
email: NKennel@njkconsulting.com

Date Prepared: Dec. 23, 2008

DEVICE INFORMATION

Trade/Proprietary Name:
RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 device
Common Name: Methamphetamine assay 21 CFR 862.3610
Class II
Product Code: LAF

Intended Use:
The RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 Device is a lateral flow competitive immunoassay intended for the qualitative detection of Methamphetamine in human urine at a cut-off concentration of 1000 ng/mL. The assay is intended for use in professional laboratories by healthcare professionals. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method. Tests for methamphetamine cannot distinguish between abused drugs and certain prescribed medications. Certain foods or medications may interfere with tests for methamphetamine and cause false positive results.

Product Description:
The RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 Device is an immunoassay based on the principle of competitive binding. Methamphetamine which may be present in the urine specimen competes against its respective drug conjugate for binding sites on the specific antibody. The assay is a colored-latex particle, monoclonal antibody-based rapid test for the qualitative detection of Methamphetamine at a cut-off of 1000 ng/mL. The test utilizes the QuantRx patented, one step positive read, competitive immunoassay technology.
In the absence of the drug in the urine or if the amount of drug is below cut-off level, the visible test line zone (T) will show a clean negative (no signal on the test band). Drug positive specimens show a blue line in the visible test line zone (T). As an internal procedural control, a red control line appears in the control region (C) to verify that sufficient volume of sample was added and proper flow was obtained. The control line should always appear regardless of the presence of the drug if the assay has been performed properly.

Predicate Device:
ACON mAMP One Step Methamphetamine Test Strip & Test Device
510(k) Number K011672

Comparison to Predicate Device
Both the RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 device and the ACON mAMP One Step Methamphetamine Test Device, cleared under K011672 have the indications for use and same cut-off of 1000 ng/mL. Both assays are lateral flow competitive immunoassays which provide a visual qualitative end point. Both assays are intended as a screening method that provides a preliminary test result.

The RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 device differs from the ACON mAMP One Step Methamphetamine Test Device in that the RapidSense™ device is a positive read test and the ACON device is a negative read test.

Summary of Safety and Effectiveness Data:

Accuracy:
The RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 Device was compared to the reference method of Gas chromatography/mass spectrometry (GC/MS) on 84 specimens previously collected from subjects presenting for drug testing by an external laboratory. Methamphetamine was quantified by GC/MS with a cut-off of 1000 ng/mL as well as compared to the predicate device.

The results of the study were as follows:

RapidSense ™ Drugs of Abuse Methamphetamine (MET) 1000 Device compared to GC/MS.

Positive Agreement: 33/44 = 75.0% (60.6 to 85.4%*)

Negative Agreement: 40/40 =100% (91.2 to 100.0%*)
Total Agreement: 73/84 = 86.9% (78.1 to 92.5%*)
* 95% Confidence intervals

The results of the predicate device to GCMS showed similar performance.

Conclusion:

These studies demonstrate the substantial equivalence of the RapidSense™ Drugs of Abuse Methamphetamine (1000) device to the ACON mAMP One Step Methamphetamine Test Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Quantrx Biomedical Corporation
c/o Natalie J Kennel
NJK & Associates
13721 Via Tres Vista
San Diego, CA 92129

DEC 31 2008

Re: k080455

Trade/Device Name: Rapidsense drugs of abuse methamphetamine (met) 1000 device, model 900-0050
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Codes: LAF
Dated: December 23, 2008
Received: December 24, 2008

Dear Ms. Kennel:

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): K080455

Device Name: RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 Device

Indication For Use:

The RapidSense™ Drugs of Abuse Methamphetamine (MET) 1000 Device is a lateral flow competitive immunoassay intended for the qualitative detection of methamphetamine in human urine at a cut-off concentration of 1000 ng/mL. The assay is intended for use in professional laboratories by healthcare professionals. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method. Tests for methamphetamine cannot distinguish between abused drugs and certain prescribed medications. Certain foods or medications may interfere with tests for methamphetamine and cause false positive results.

Prescription Use __X__ And/Or Over the Counter Use

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

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

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

510(k) K080455