 NOV 2 2 2002

510 (k) SUMMARY (21 CFR PART 807.92)

Product

Rapid Methadone Test Strip and Rapid Methadone Test Card

Name of Manufacturer

Rapid Diagnostics, Division of ICN BIOmedicals Inc.
1429 Rollins Road, Burlingame, CA 94010, U.S.A.

Principle

The RapidMTD test is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding anti-methadone antibody between methadone-protein conjugate and free drug which may be present in the urine specimen being tested.

When methadone is present in the urine specimen, it competes with methadone-protein conjugate for the limited amount of antibody-colloidal conjugate. When the amount of methadone is equal or more than the cut-off, it will prevent the binding of methadone-protein conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line composed of Goat anti-Mouse IgG antibody is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

Intended Use

The RapidMethadone Tests are immunochromatography based one step *in vitro* test. It is designed for qualitative determination of methadone in human urine specimen above the cutoff level of 300 ng/ml.

Performance

The studies performed are listed below:

Rapid Methadone Test Strip
- Sensitivity
- Accuracy (comparison study of clinical urine specimens)
- Stability – Specimen

Stability – Product
Precision
Reproducibility
Specificity
Interference

Rapid Methadone Test Card
Accuracy (comparison study of clinical urine specimens)
Precision
Comparison between Rapid Methadone Test Strip and Test Card

Both urine control specimen and clinical urine specimen were tested to evaluate the safety and effectiveness of Rapid Methadone Test Strip and Rapid Methadone Test Card.

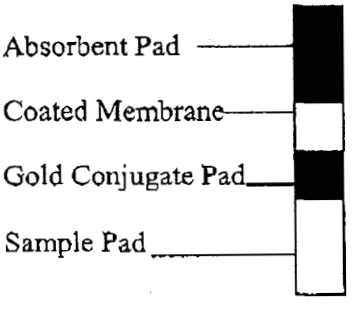
The results of performance characteristics demonstrate Rapid Methadone Test Strip and Rapid Methadone Test Card to be substantially equivalent to the Applied Biotech ***SureStep*** ™**Drug Screen Test Methadone,** which received 510 (k) approval.

PRODCUT DESCRIPTION

Rapid Methadone Test Strip is a dipstick device for detecting the presence or absence of the tested drug. The test strip is also used for the composition of Rapid Methadone Test Card. These test devices are manufactured with the same formulation and procedure except the test card consists a plastic housing containing one methadone test strip. There is no any functional design that may affect the test strip's performance in the test card.

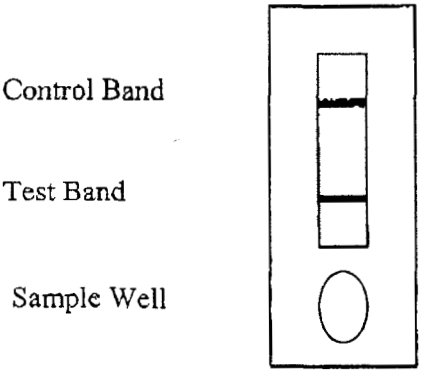
A. Test Strip

Test strips that containing absorbent pad, coated membrane, gold conjugate pad, and sample pad with adhesive sticker in each strip, are used to assemble Rapid Methadone Test Strip as shown below:



B. Test Card Format

The above test strip that contains an absorbent pad, coated membrane, gold conjugate pad, and sample pad with adhesive sticker in each strip, is used to assemble the Test Card Device as shown below.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 22 2002

Mr. Charles Yu
Director of Technical Operation
Official FDA Correspondent
ICN Biomedicals, Inc.
Rapid Diagnostics
1429 Rollins Road
Burlingame, CA 94010

Re: k023252
Trade/Device Name: Rapid Methadone Test Card
Regulation Number: 21 CFR 862.3620
Regulation Name: Methadone test system
Regulatory Class: Class II
Product Code: DJR
Dated: September 23, 2002
Received: September 30, 2002

Dear Mr. Yu:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (K) number (if known): K023252

Device Name: Rapid Methadone Test Strip

Indications for Use:

Rapid Methadone Test Strip is an imunochromatorgraphy based one step *in vitro* test. It is designed for qualitative determination of Methadone and its metabolites in human urine specimens. The presence of Methadone in human urine above a cutoff level of 300ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

This test provides only a preliminary analytical test result. A more specific chemical method, such as GC/MS, must be used in order to obtain a confirmed analytical result.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over the Counter Use: ____
(Per 21 CFR 801.109)

INDICATIONS FOR USE STATEMENT

510 (K) number (if known): K023252

Device Name: Rapid Methadone Test Card

Indications for Use:

Rapid Methadone Test Card is an imunochromatorgraphy based one step *in vitro* test. It is designed for qualitative determination of Methadone and its metabolites in human urine specimens. The presence of Methadone in human urine above a cutoff level of 300ng/ml can be detected.

The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons.

This test provides only a preliminary analytical test result. A more specific chemical method, such as GC/MS, must be used in order to obtain a confirmed analytical result.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Alan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023252

Prescription Use: ✓ OR Over the Counter Use: _____
(Per 21 CFR 801.109)