FEB 0 5 2003

8. 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K023946.

Submitter:

ACON Laboratories, Inc.
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Date: November 22, 2002

Contact Person: Edward Tung, Ph.D.

Product Names:

ACON One Step Multi-Drug Multi-Line Screen Test Card

ACON One Step Multi-Drug Multi-Line Screen Test Device

Common Name:

Immunochromatographic test for the simultaneously qualitative detection of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants in urine.

Device Classification:

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are similar to other FDA-cleared devices for the qualitative and simultaneous detection of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants in urine specimens. These tests are used to provide a preliminary analytical result only. Benzodiazepines, Tricyclic Antidepressants, Barbiturates, MDMA, Methadone and Opiates test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Barbiturate, Benzodiazepine, Methadone, MDMA, Opiate and Tricyclic Antidepressant test system

Intended Use:

The ACON® One Step Multi-Drug Multi-Line Screen Test Card and Test Device are rapid chromatographic immunoassays for the qualitative and simultaneous detection of two to six drugs in a variety of combinations in human urine samples. The designated cutoff concentrations for these drugs are as follows: Barbiturates at 300 ng/mL, Benzodiazepines at 300 ng/mL, Methadone at 300 ng/mL, Methylenedioxymethamphetamine (Ecstasy) at 500 ng/mL, Opiates at 300 ng/mL and Tricyclic antidepressant at 1,000 ng/mL. They are intended for healthcare professionals including professionals at point of care sites.

Description:

The ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous detection of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants in urine samples. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse antibodies to selectively detect elevated levels of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants in urine at Cutoff concentrations of 300 ng/mL (BZO), 1,000 ng/mL (TCA), 300 ng/mL (BAR), 500 ng/mL (MDMA), 300 ng/mL (MTD) and 300 ng/mL (MOP). These tests can be performed without the use of an instrument.

A positive urine specimen will not generate a colored-line for the specific drug tested in the designated test region. A negative urine specimen or a urine specimen containing of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants at the concentrations below the designated cutoff levels will generate a colored-line in the designated test region for the drug. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Predicate Devices:

ACON™ Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants Single Drug Test strips were used as the predicate devices for the ACON® One Step Multi-Drug Multi-Line Screen Test Card and Test Device to compare their performance with clinical urine specimens.

The 510(k) Numbers for these predicate devices are:

ACON BAR One Step Barbiturates Test Strip	**K012824**
ACON BZO One Step Benzodiazepines Test Strip	**K012300**
ACON MTD One Step Methadone Test Strip	**K012595**
ACON MDMA One Step MDMA Test Strip	**K022589**
ACON MOP One Step Opiates Test Strip	**K011353**
ACON TCA One Step Tricyclic Antidepressant Test Strip	**K021526**

Comparison to a Predicate Device:

A comparison of the features of the ACON™ One Step Multi-Drug Multi-Line Screen Test Card and Test Device versus the ACON™ Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants Single Tests is shown below:

- Both tests are assays intended for the qualitative detection of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants in urine samples.

- Both tests are intended as a screening method that provides a preliminary analytical test result.

- Both tests are immunochromatographic, lateral flow assays for the rapid detection of Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants with a visual, qualitative end result, while ACON Multi-Drug Multi-Line Test detects 2 to 6 of the above drugs simultaneously.

- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.

- Both tests have the same Cutoff for each drug test.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using clinical urine specimens. This evaluation compared the test results between the ACON One Step Multi-Drug Multi-Line Screen Test Card and the Test Device versus previously FDA-cleared Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants Single tests; as well as against data obtained from the customary GC/MS analysis. Over 1,000 clinical specimens were employed including approximately 10% of the samples with drug concentrations in the –25% to +25% Cutoff range. The comparisons of data obtained from this study yielded the following results:

Clinical study results of ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device are compared to GC/MS analysis data:

The GC/MS Cutoff levels for each of the six drugs tested are as follows:

Barbiturates (BAR) at	300 ng/mL
Benzodiazepines (BZO) at	300 ng/mL
Methadone (MTD) at	300 ng/mL
MDMA (Ecstasy) at	500 ng/mL
Opiates (MOP) at	300 ng/mL
Tricyclic Antidepressants (TCA) at	1,000 ng/mL

Samples with drug concentration above the Cutoff level were considered presumptive positive and concentrations below the Cutoff are considered negative.

ACON One Step Multi-Drug Multi-Line Screen Test Card vs. GC/MS Analysis

ACON Test Card	Positive Agreement	Negative Agreement	Overall Agreement
BAR	127/133 = 95% (90% - 98%)*	160/160 = >99% (98% - 99%)*	287 / 293 = 98% (96% - 99%)*
BZO	128/131=98% (93% - 99%)*	160/160=>99% (98% - 99%)*	288/291= 99% (97% - 99%)*
MTD	120/129 = 93% (87% - 97%)*	177/177 = >99% (98% - 99%)*	297 / 306 = 97% (97% - 99%)
MDMA	86/87 = 99% (94% - 99%)*	155/155 = >99% (98% - 99%)*	241/242 = 99% (98% - 99%)*
MOP	122/122 = >99% (97% - 99%)*	157/160 = 98% (95% - 99%)*	279/282 = 99% (97% - 99%)*
TCA	34/34 = >99% (90% - 99%)*	181/192 = 94% (90% - 97%)*	215/226 = 95% (91% - 98%)*

* 95% Confidence Interval

ACON One Step Multi-Drug Multi-Line Screen Test Device vs. GC/MS Analysis

ACON Test Device	Positive Agreement	Negative Agreement	Overall Agreement
BAR	124/133 = 93% (88% - 97%)*	160/160 = >99% (98% - 99%)*	284 / 293 = 97% (94% - 97%)*
BZO	127/131=98% (92% - 99%)	160/160=>99% (98% - 99%)	287/291= 99% (97% - 99%)*
MTD	120/129 = 93% (87% - 97%)*	177/177 = >99% (98% - 99%)*	297 / 306 = 97% (97% - 99%)
MDMA	87/87 = >99% (96% - 99%)*	154/155 = 99% (96% - 99%)*	241/242 = 99% (98% - 99%)*
MOP	122/122 = >99% (97% - 99%)*	158/160 = 99% (97% - 99%)*	280/282 = 99% (95% - 99%)*
TCA	34/34 = >99% (90% - 99%)*	181/192 = 94% (90% - 97%)*	215/226 = 95% (91% - 98%)*

* 95% Confidence Interval

Conclusion:

Clinical study results demonstrate the substantial equivalency between the ACON One Step Multi-Drug Multi-Line Screen Test Card and Test Device and the Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants single tests, which have already been cleared by FDA and marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Barbiturates, Benzodiazepines, Methadone, MDMA, Opiates and Tricyclic Antidepressants at the following Cutoff concentrations: Barbiturates 300 ng/mL, Benzodiazepines 300 ng/mL, Methadone 300 ng/mL, MDMA 500 ng/mL, Opiates 300 ng/mL and Tricyclic Antidepressants 1,000 ng/mL. The physician's office laboratory POL study demonstrated that these tests are also suitable for use by professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 5 2003

Edward Tung, Ph.D.
Director of Regulatory Affair
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

Re: k023946
Trade/Device Name: ACON® One Step Multi-Drug Multi-Line Screen Test Card
ACON® One Step Multi-Drug Multi-Line Screen Test Device
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: DJC; DJG; DIS; JXM; DJR; LFG
Dated: November 25, 2002
Received: November 27, 2002

Dear Dr. Tung:

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). 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/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

10. INDICATIONS FOR USE

510(k) Number: K023946

Device Name: ACON® One Step Multi-Drug Multi-Line Screen Test Card

ACON® One Step Multi-Drug Multi-Line Screen Test Device

Indications for Use:

The ACON® One Step Multi-Drug Multi-Line Screen Test Card and Test Device are rapid chromatographic immunoassays for the qualitative and simultaneous detection of two to six drugs in a variety of combinations in human urine. The designated Cutoff concentrations for these drugs are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Conc.
Barbiturates	**BAR**	**Secobarbital**	**300 ng/mL**
Benzodiazepines	**BZO**	**Oxazepam**	**300 ng/mL**
Methadone	**MTD**	**Methadone**	**300 ng/mL**
MDMA (Ecstasy)	**MDMA**	**MDMA**	**500 ng/mL**
Opiates	**MOP or OPI**	**Morphine**	**300 ng/mL**
Tricyclic Antidepressants	**TCA**	**Nortriptyline**	**1,000 ng/mL**

These tests are intended for healthcare professionals including professionals at the point of care sites.

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-The-Counter Use_____

(Per 21 CFR 801.109)

Sean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K023946