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8. SUMMARY OF 510(k) SAFETY AND EFFECTIVENESS

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 K041685.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

June 18, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® multi-CLIN™ Drug Screen Test Device

Common Name:

Immunochromatographic test for the simultaneously qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants in human urine.

Device Classification:

The ACON multi-CLIN™ Drug Screen Test Device is similar to other FDA-cleared devices for the qualitative and simultaneous detection of drugs in urine specimens. These drug tests are used only to provide a preliminary analytical result. The test systems have been classified as Class II devices with moderate complexity. Product codes DKZ, DIS, JXM, DIO, LDJ, LAF, DJG, LCM, JXN and LFG have been assigned for the test system.

Classification Name:

Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxy-methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants test systems

Intended Use:

The ACON multi-CLIN™ Drug Screen Test Device is a rapid chromatographic immunoassays for the qualitative and simultaneous detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants in human urine at cut-off concentrations:

1,000 ng/mL Amphetamine
300 ng/mL Barbiturates
300 ng/mL Benzodiazepines
300 ng/mL Cocaine
50 ng/mL Marijuana
500 ng/mL Methylenedioxymethamphetamine
300 ng/mL Opiates
100 ng/mL Oxycodone
25 ng/mL Phencyclidine
300 ng/mL Propoxyphene
1,000 ng/mL Tricyclic Antidepressants

They are intended for healthcare professional use only including professionals at the point of care sites.

Description:

The ACON multi-CLIN™ Drug Screen Test Device is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxy-methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants in human urine.

The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibodies to selectively detect elevated levels of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants in human urine. These tests can be performed without the use of an instrument.

A drug-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 the drug concentration below the cut-off level will generate a colored-line in the designated test region for the drug. To serve as a procedural control, there must be no line next to the

Positive Control Region (POS) and a clear line will always appear in the Negative Control region (NEG), indicating that sufficient volume of specimen applied and proper membrane wicking occurred. If NO line appears in the Negative Control region (NEG) and/or a line appears in the Positive Control Region (POS) during testing, the test becomes INVALID. A true positive control is incorporated in each test strip employed.

Predicate Devices

ACON Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants Single Drug Test Strips were used as the predicate devices for the ACON multi-CLIN™ Drug Screen Test Device to compare their performance with clinical urine specimens.

510(k) Numbers for these predicate devices are:

ACON AMP One Step Amphetamine Test Strip:	K011673
ACON BAR One Step Barbiturates Test Strip:	K012824
ACON BZO One Step Benzodiazepine Test Strip:	K012300
ACON COC One Step Cocaine Test Strip:	K010841
ACON THC One Step Marijuana Test Strip:	K003557
ACON MDMA One Step Ecstasy Test Strip:	K022589
ACON MOP One Step Opiates Test Strip:	K013380
ACON OXY One Step Oxycodone Test Strip:	K033047
ACON PCP One Step Phencyclidine Test Strip:	K011730
ACON PPX One Step Propoxyphene Test Strip:	K040445
ACON TCA One Step Tricyclic Antidepressants Test Strip:	K021526

Comparison to a Predicate Device:

A comparison of the features of the ACON® multi-CLIN™ Drug Screen Test Device versus the ACON One Step Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants Single Tests is shown below:

- Both tests are immunoassays intended for the qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxy-methamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene 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 Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine,

Propoxyphene, and Tricyclic Antidepressants and their derivatives with a visual, qualitative end result, while the ACON® multi-CLIN™ Drug Screen Test detects 2 to 11 of the above drugs simultaneously.

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

- Both tests have the same cut-off concentration for a specific drug tested.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using clinical urine specimens. This evaluation compared the test results between the ACON multi-CLIN™ Drug Screen Test Device versus previously FDA-cleared Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants Single tests; as well as against data obtained from the customary GC/MS analysis. 1,704 clinical specimens were employed including approximately 10% of the samples with drug concentrations in the -25% to +25% cut-off range. The comparisons of data obtained from this study yielded the following results:

Clinical study results of the ACON multi-CLIN™ Drug Screen Test Device are compared to GC/MS analysis data.

The GC/MS cut-off levels for each of the eleven drugs tested are as follows:

Amphetamine	1,000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepines	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methylenedioxymethamphetamine	500 ng/mL
Opiates	300 ng/mL
Oxycodone	100 ng/mL
Phencyclidine	25 ng/mL
Propoxyphene	300 ng/mL
Tricyclic Antidepressants	1,000 ng/mL

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

ACON Multi-CLIN™ Drug Screen Test Device
vs.
GC/MS Analysis

ACON Test Device	Positive Agreement	Negative Agreement	Overall Agreement
AMP	134/136 = 99% (95% - 99%)*	308/314 = 98% (96% - 99%)*	442/450 = 98% (97% - 99%)*
BAR	99/101 = 98% (93% - 99%)	305/309 = 99% (97% - 99%)*	404/410 = 99% (97% - 99%)*
BZO	139/140 > 99% (96% - 99%)*	308/310 > 99% (98% - 99%)*	447/450 > 99% (98% - 99%)*
COC	119/119 > 99% (97% - 99%)**	308/325 = 95% (92% - 97%)*	427/444 = 96% (94% - 98%)*
THC	116/121 = 96% (91% - 99%)*	311/327 = 95% (92% - 97%)*	427/448 = 95% (93% - 97%)*
MDMA	88/88 > 99% (96% - 99%)**	301/305 = 99% (97% - 99%)*	389/393 = 99% (97% - 99%)*
OPI	140/140 > 99% (97% - 99%)**	300/309 = 97% (95% - 99%)*	440/449 = 98% (96% - 99%)*
OXY	140/141 = 99% (96% - 99%)*	306/309 = 99% (97% - 99%)*	446/450 = 99% (98% - 99%)*
PCP	85/86 = 99% (94% - 99%)*	300/304 = 99% (97% - 99%)*	385/390 = 99% (97% - 99%)*
PPX	145/146 > 99% (96% - 99%)*	304/304 > 99% (99% - 99%)**	449/450 > 99% (99% - 99%)*
TCA	32/32 > 99% (89% - 99%)**	316/338 = 93% (90% - 96%)*	348/370 = 94% (91% - 96%)*

* Denotes 95% confidence interval.
** Since the proportion can not go above 100%, this is really a 97.5% confidence interval.

Conclusion:

Clinical study results demonstrate the substantial equivalency between the ACON multi-CLIN™ Drug Screen Test Device and the ACON Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants single tests, which have already being cleared by FDA and marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants at the following cut-off concentrations: Amphetamine 1,000 ng/mL, Barbiturates 300 ng/mL, Benzodiazepines 300 ng/mL, Cocaine 300 ng/mL, Marijuana 50 ng/mL, Methylenedioxymethamphetamine 500 ng/mL, Opiates 300 ng/mL, Oxycodone 100 ng/mL, Phencyclidine 25 ng/mL, Propoxyphene 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 site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 3 0 2004

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

Re: k041685
Trade/Device Name: ACON multi-CLIN™ Drug Screen Test Device
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, DIS, JXM, DIO, LDJ, LAF, DJG, LCM, JXN, LFG
Dated: June 18, 2004
Received: June 22, 2004

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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, 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

Indications for Use

510(k) Number (if known): K041685

Device Name: ACON multi-CLIN™ Drug Screen Test Device

Indications For Use:

The ACON multi-CLIN™ Drug Screen Test Device is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methylenedioxymethamphetamine, Opiates, Oxycodone, Phencyclidine, Propoxyphene and Tricyclic Antidepressants in urine. The designated cut-off concentrations for these drugs are as follows: Amphetamine 1,000 ng/mL, Barbiturates 300 ng/mL, Benzodiazepines 300 ng/mL, Cocaine 300 ng/mL, Marijuana 50 ng/mL, Methylenedioxymethamphetamine 500 ng/mL, Opiates 300 ng/mL, Oxycodone 100 ng/mL, Phencyclidine 25 ng/mL, Propoxyphene 300 ng/mL and Tricyclic Antidepressants 1,000 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K041685