JUL 3 1 2001

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: **K011672**

Submitter:

ACON Laboratories, Inc.
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San Diego, California 92121

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Date:

July 12, 2001

Contact Person:

Edward Tung, Ph.D.
Director of Regulatory Affairs

Product Names:

ACON mAMP One Step Methamphetamine Test Strip

ACON mAMP One Step Methamphetamine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of methamphetamine in urine.

Device Classification:

ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are similar to other FDA-cleared devices for the qualitative detection of methamphetamine in urine specimens. These tests are used for providing only a preliminary analytical result (21 CFR 862.3610). Methamphetamine test systems have been classified as Class II devices with moderate complexity. These methamphetamine tests bear Product Code LAF.

Classification Name:

Methamphetamine test system

Intended Use:

The ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of methamphetamine in human urine at a cut-off concentration of 1,000 ng/mL. They are intended for professional and point-of-care use.

Description:

The ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are competitive binding, lateral-flow immunochromatographic assays for the qualitative detection of methamphetamine in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes a mouse monoclonal antibody to selectively detect elevated levels of methamphetamine in urine specimens at a cut-off concentration of 1,000 ng/mL. These tests can be performed and interpreted without the use of an instrument.

A drug-positive urine specimen will not generate a colored line in the test region, while a negative urine specimen will generate a colored line in the test region. To serve as procedural control, a colored line will always appear at the control region indicating that a proper volume of specimen has been applied and membrane wicking has occurred. Therefore, when performing these ACON mAMP tests, one colored line indicates a positive result and two colored lines indicate a negative result; and the test is considered to be invalid when there is no colored line in the control region.

Predicate Device:

LifeSign Status DS™ MET One-Step Methamphetamine Test

510(k) Number: K961249

Distributor:
LifeSign, LLC
71 Veronica Avenue
Somerset, New Jersey 08873

Comparison to a Predicate Device:

A comparison of the features of ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device to LifeSign Status DS™ MET One-Step Methamphetamine Test is listed below.

- Both tests are assays intended for the qualitative detection of methamphetamine and its derivatives 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 methamphetamine with a visual, qualitative end result.
- Both tests utilize the same basic immunochemistry principles that rely on antigen/antibody interactions to indicate a positive or negative result.
- Both tests have a methamphetamine cut-off concentration of 1,000 ng/mL for the detection of methamphetamine in urine specimens.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 urine specimens. This evaluation compared the study results obtained with ACON mAMP One Step Methamphetamine Test Strip, ACON mAMP One Step Methamphetamine Test Device, and LifeSign Status DS™ MET One-Step Methamphetamine Test to the customary Gas Chromatography/Mass Spectrometry analysis results. The data from this study yielded the following results:

ACON mAMP One Step Methamphetamine Test Strip compared to **LifeSign Status DS™ MET One-Step Methamphetamine Test**:

Positive Agreement: 145 / 148 = 98% (94% - 100%*)
Negative Agreement: 152 / 152 = 100% (98% - 100%*)
Overall Agreement: 297 / 300 = 99% (97% - 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Device compared to **LifeSign Status DS™ MET One-Step Methamphetamine Test:**

Positive Agreement: 147 / 148 = 99% (96% - 100%*)
Negative Agreement: 152 / 152 = 100% (98% - 100%*)
Overall Agreement: 299 / 300 = 100% (98% - 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Strip compared to **GC/MS analysis data**

Positive agreement with GC/MS: 135 / 136 = 99% (96% - 100%*)
Negative agreement with GC/MS: 154 / 164 = 94% (89% - 97%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 100%*)

Positive Predictive Value (+): 135 / 145 = 93% (88% - 97%*)
Negative Predictive Value (-): 153 / 154 = 99% (96% – 100%*)

* 95% confidence intervals

ACON mAMP One Step Methamphetamine Test Device compared to **GC/MS analysis data:**

Positive agreement with GC/MS: 135 / 136 = 99% (96% - 100%*)
Negative agreement with GC/MS: 152 / 164 = 93% (86% - 96%*)
Total agreement with GC/MS: 287 / 300 = 96% (93% - 98%*)

Positive Predictive Value (+): 135 / 147 = 92% (86% - 96%*)
Negative Predictive Value (-): 152 / 153 = 99% (96% - 100%*)

* 95% confidence intervals

Conclusion:

These study results have demonstrated ACON mAMP One Step Methamphetamine Test Strip and Test Device are substantially equivalent to LifeSign Status DS™ MET One-Step Methamphetamine Test. It has also been demonstrated that these tests are safe and effective in detecting urine methamphetamine at a concentration of 1,000 ng/mL. They are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 3 1 2001

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

Re: 510(k) Number: K011672
Trade/Device Name: ACON mAMP One Step Methamphetamine Test Strip and
ACON mAMP One Step Methamphetamine Test Device
Regulation Number: 862.3610
Regulatory Class: II
Product Code: LAF
Dated: May 18, 2001
Received: May 30 , 2001

Dear Dr. Tung:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K011672

Device Name: ACON mAMP One Step Methamphetamine Test Strip

ACON mAMP One Step Methamphetamine Test Device

Indications for Use: ACON mAMP One Step Methamphetamine Test Strip and ACON mAMP One Step Methamphetamine Test Device are rapid chromatographic immunoassays for the qualitative detection of methamphetamine in human urine at a cut-off concentration of 1,000 ng/mL. It is intended for professional and point of care use.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K011672

(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)