OCT 2 8 2002

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 **K022589**.

Submitter:

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

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

Date:

July 30, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® MDMA One Step Ecstasy Test Strip
ACON® MDMA One Step Ecstasy Test Device

Common Name:

Immunochromatographic test for the qualitative detection of MDMA in urine.

Device Classification:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are similar to other FDA-cleared devices for the qualitative detection of MDMA in urine specimens. These tests are used to provide a preliminary analytical

result. MDMA test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Methylenedioxymetamphetamines (MDMA) test system

Intended Use:

The ACON® MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are rapid chromatographic immunoassays for the qualitative detection of MDMA in urine at a cutoff concentration of 500 ng/mL. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of MDMA in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the antibody to selectively detect elevated levels of MDMA in urine at a cutoff concentration of 500 ng/mL. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing MDMA at the concentration below the cutoff level will generate a colored-line in the test region. To serve as a procedural control, a colored-line should always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Comparison to a Predicate Device:

A comparison of the features of the ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device versus a FDA-cleared MDMA (Ecstasy) Test is shown below:

- Both tests are assays intended for the qualitative detection of MDMA 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 MDMA with a visual, qualitative end result.

- Both tests utilize the same basic immunoassay principles that rely on antigen/ antibody interactions to indicate a positive or negative result.
- Both tests have a cut-off MDMA concentration of 500 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 240 clinical urine specimens including approximately 12% of the MDMA containing specimens with MDMA concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON® MDMA One Step Ecstasy Test Strip and ACON® MDMA One Step Ecstasy Test Device with a FDA-cleared MDMA Ecstasy Test; as well as comparing against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON MDMA One Step Ecstasy Test Strip versus **FDA-cleared MDMA Test**:

Positive Agreement: 90 / 90 = 100% (96% - >99%*)
Negative Agreement: 149 / 150 = 99% (96% - >99%*)
Overall Agreement: 239/ 240 = 99% (98% - >99%*)

* Denotes 95% Confidence Intervals.

ACON MDMA One Step Ecstasy Test Device versus **FDA-cleared MDMA Test:**

Positive Agreement: 90 / 90 = 100% (96% - >99%*)
Negative Agreement: 149 / 150 = 99% (96% - >99%*)
Overall Agreement: 239/ 240 = 99% (98% - >99%*)

* Denotes 95% Confidence Intervals

ACON MDMA One Step Ecstasy Test Strips were tested with 93 MDMA positive and 147 MDMA negative urine samples in a clinical study. Nine of these positive urine samples in the +/- 25% cutoff range were derived from the concentrated MDMA clinical specimens; the rest were true clinical specimens. All positive samples used in this study were confirmed by GC/MS. Negative clinical samples were screened by a commercial MDMA rapid test kit. Approximately 10% of these negative samples were confirmed by GC/MS. The following results were tabulated.

		Negative	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff
ACON MDMA Strip	Positive	0	3	6	82
	Negative	147	2	0	0

ACON MDMA One Step Ecstasy Test Devices were also tested with 93 MDMA positive and 147 MDMA negative urine samples in a clinical study. Nine of these positive urine samples in the +/- 25% cutoff range were derived from the concentrated MDMA clinical specimens; the rest were true clinical specimens. All positive samples used in this study were confirmed by GC/MS. Negative clinical samples were screened by a commercial MDMA rapid test kit. Approximately 10% of these negative samples were confirmed by GC/MS. The following results were tabulated.

		Negative	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff
ACON MDMA Device	Positive	0	3	6	82
	Negative	147	2	0	0

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON MDMA One Step Ecstasy Test Strip, ACON MDMA One Step Ecstasy Test Device and a FDA-cleared Ecstasy Test, which is being marketed in the United States. It is also demonstrated that these tests are safe and effective in qualitatively detecting MDMA at a concentration of 500 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care sites.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 8 2002

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

Re: k022589
Trade/Device Name: ACON® MDMA One Step Ecstasy Test Strip
ACON® MDMA One Step Ecstasy Test Device
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine test system
Regulatory Class: Class II
Product Code: LAF
Dated: August 1, 2002
Received: August 5, 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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Enclosure

10. INDICATIONS FOR USE

510(k) Number: K022589

Device Name: ACON® MDMA One Step Ecstasy Test Strip

ACON® MDMA One Step Ecstasy Test Device

Indications for Use:

The ACON MDMA One Step Ecstasy Test Strip and ACON MDMA One Step Ecstasy Test Device are rapid chromatographic immunoassays for the qualitative detection of Methylenedioxymethamphetamine (MDMA) in human urine at a designated cutoff concentration of 500 ng/mL. They are intended for healthcare professionals including professionals at 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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022589