JUL 17 2002

8. SUMMARY OF 510(k)

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 K021516.

Submitter:

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

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

Date:

May 8, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® TCA One Step Tricyclic Antidepressant Test Strip

ACON® TCA One Step Tricyclic Antidepressant Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Tricyclic Antidepressant in urine

Device Classification:

The ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are similar to other FDA-cleared devices for the qualitative detection of Tricyclic Antidepressant in urine specimens. These tests are used to provide a preliminary analytical result. Tricyclic Antidepressant test systems have been classified as Class II devices with moderate complexity. The product code for these devices is LFG and the regulation number is 862.3910.

Classification Name:

Tricyclic Antidepressant test system

Intended Use:

The ACON® TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are rapid chromatographic immunoassays for the qualitative detection of Tricyclic Antidepressant in urine at a cut-off concentration of 1,000 ng/mL in reference to Nortriptyline. They are intended for healthcare professionals and professionals at point-of-care sites.

Description:

The ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Tricyclic Antidepressant in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Tricyclic Antidepressant in urine at a cut-off concentration of 1000 ng/mL for Nortriptyline. 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 Tricyclic Antidepressant at the concentration below the cut-off level will generate a colored-line in the test region. 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 Device:

Status DS™ TCA One step Tricyclic Antidepressants Test

510(k) Number: K980249

Comparison to a Predicate Device:

A comparison of the features of the ACON TCA One Step Tricyclic Antidepressant Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device versus the Status™ One step Antidepressants Test is shown below:

- Both tests are assays intended for the qualitative detection of Tricyclic Antidepressant 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 Tricyclic Antidepressant 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 for Nortriptyline concentration of 1,000 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 226 clinical urine specimens including over 10% of the samples with Antidepressants concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® TCA One Step Tricyclic Antidepressants Test Strip and Test Device with Status DS™ One Step Tricyclic Antidepressants Test; as well as against data obtained from the customary HPLC analysis. The comparisons of data obtained from this study yielded the following results:

ACON TCA One Step Tricyclic Antidepressant Test Strip versus the Status DS™ One Step Tricyclic Antidepressants Test:

Positive Agreement: 55 / 58 = 95% (86% - 99%*)
Negative Agreement: 164 / 164 = 100% (98% - 99%*)
Overall Agreement: 219 / 222 = 99% (96% - 99 %*)
* 95% Confidence Intervals

ACON TCA One Step Tricyclic Antidepressant Test Device versus the Status DS™ One Step Tricyclic Antidepressant Test:

Positive Agreement: 55 / 58 = 95% (86% - 99%*)
Negative Agreement: 164 / 164 = 100% (98% - 99%*)
Overall Agreement: 219 / 222 = 99% (96% - 99 %*)
* 95% Confidence Intervals

ACON TCA One Step Tricyclic Antidepressant Test Strip versus HPLC at the cutoff of 1,000 ng/ml:

Acon TCA test strip	**HPLC**					
	Drug – free urine	**<-25% cutoff**	**-25% cutoff to cutoff**	**Cutoff to +25% cutoff**	**>+25% cutoff**	**% agreement**
Negative	150	17	0	0	0	89% (84% - 93%)*
Positive	0	12	8	15	20	>99% (90% - 99%)*

* 95% Confidence Intervals

ACON TCA One-Step Tricyclic Antidepressant Test Device versus HPLC at the cutoff of 1,000 ng/ml:

Acon TCA test Device	HPLC					
	Drug – free urine	<-25% cutoff	-25% cutoff to cutoff	Cutoff to +25% cutoff	>+25% cutoff	% agreement
Negative	150	17	0	0	0	89% (84% - 93%)*
Positive	0	12	8	15	20	>99% (90% 99%)*

- 95% Confidence Intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON TCA One Step Tricyclic Antidepressant Test Strip, ACON TCA One Step Tricyclic Antidepressant Test Device and the Status DS™ One Step Tricyclic Antidepressant Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Tricyclic Antidepressant at a concentration of 1,000 ng/mL. The POL study demonstrated that these tests are suitable for healthcare professionals including professionals at point-of-care site.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 17 2002

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

Re: k021526
Trade/Device Name: ACON® TCA One Step Tricyclic Antidepressants Test Strip
ACON® TCA One Step Tricyclic Antidepressants Test Device
Regulation Number: 21 CFR 862.3910
Regulation Name: Tricyclic antidepressant drugs test system
Regulatory Class: Class II
Product Code: LFG
Dated: May 8, 2002
Received: May 10, 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

K021526

10. INDICATIONS FOR USE

510(k) Number: K021526

Device Name: ACON® TCA One Step Tricyclic Antidepressants Test Strip

ACON® TCA One Step Tricyclic Antidepressants Test Device

Indications for Use:

The ACON TCA One Step Tricyclic Antidepressants Test Strip and ACON TCA One Step Tricyclic Antidepressant Test Device are rapid chromatographic immunoassays for the qualitative detection of Tricyclic Antidepressants in human urine at a cut-off concentration of 1,000 ng/mL in reference to Nortriptyline. They are intended for Healthcare professionals including professionals at the point-of-care sites.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021526

(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)