FEB 25 2005

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 K043507.

Submitter:

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

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

Date:

December 17, 2004

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® OXY II One Step Oxycodone Test Strip
ACON® OXY II One Step Oxycodone Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Oxycodone in urine.

Regulation Name:

Oxycodone test system.

Product Code:

DJG

Classification Number:

21 CFR, 862.3650

Device Classification:

The Oxycodone test systems have been classified as Class II devices with moderate complexity. The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are similar to another FDA-cleared device for the qualitative detection of Oxycodone in urine specimens. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis.

Intended Use:

The ACON OXY II One Step Oxycodone Test Strip and ACON OXY II One Step Oxycodone Test Device are rapid chromatographic immunoassays for the qualitative detection of Oxycodone in urine at a cutoff concentration of 100 ng/mL. These tests are used to provide only a preliminary analytical result. All positive test results obtained with these devices must be confirmed by another test method, preferably GC/MS analysis. They are intended for healthcare professionals including professionals at point-of-care sites.

Description:

The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Oxycodone in a urine sample. The test is based on the principle of antigen-antibody immunochemistry. It utilizes the mouse monoclonal antibody to selectively detect elevated levels of Oxycodone and its metabolite in urine at a cutoff concentration of 100 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 Oxycodone 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 OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device versus a FDA-cleared Oxycodone test with 100 ng/mL Oxycodone cutoff is shown below:

- Both tests are assays intended for the qualitative detection of Oxycodone 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 Oxycodone 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 cutoff Oxycodone concentration of 100 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including approximately 10% of the specimens containing Oxycodone concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between the ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device with a FDA-cleared Oxycodone test; as well as compared against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON OXY II One Step Oxycodone Test Strip versus a FDA-cleared OXY Test:

Positive Agreement: 135 / 140 = 96% (92% - 99%)*
Negative Agreement: 159 / 160 = 99% (97% - 99%)*
Overall Agreement: 294 / 300 = 98% (96% - 99%)*
* 95% confidence intervals

ACON OXY II One Step Oxycodone Test Device versus a FDA-cleared OXY Test:

Positive Agreement: 135 / 140 = 96% (92% - 99%)*
Negative Agreement: 159 / 160 = 99% (97% - 99%)*
Overall Agreement: 294 / 300 = 98% (96 % - 99%)*
* 95% confidence intervals

ACON OXY II One Step Oxycodone Test Strip versus data obtained with GC/MS at the cutoff concentration of 100 ng/mL:

ACON OXY II One Step Oxycodone Test Strip versus GC/MS.

	Test Result	Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative†	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OXY II Test Strip	Positive	0	0	1	2	133	99% (135/136) (96% - 99%)*
	Negative	147	6	8	0	3	98% (161/164) (95% - 99%)*

Total agreement with GC/MS: 296/300 = 98.67% (97%- 99%)*

* Denotes 95% confidence interval.

† Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

ACON OXY II One Step Oxycodone Test Device versus GC/MS.

	Test Result	Specimen Cutoff Range by GC/MS Data					% Agreement
		Negative†	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON OXY II Test Device	Positive	0	0	1	2	133	99% (135/136) (96% - 99%)*
	Negative	147	6	8	0	3	98% (161/164) (95% - 99%)*

Total agreement with GC/MS: 296/300 = 98.67% (97%- 99%)*

* Denotes 95% confidence interval.

† Negative specimens were confirmed using GC/MS analysis by pooling these samples in groups of 5.

Performance Characteristics and Other information:

The performance characteristics of the ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device were verified by analytical sensitivity study, specificity and cross reactivity study, interference studies, precision study, read time flex study, temperature flex study, specimen storage and stability study. Study results indicate that these test devices are robust and can perform satisfactorily when used according to the "Indication for Use" statement specified in their package inserts.

POL Study Summary:

Test results obtained from three POL study sites indicated that personnel at different doctor's offices with various educational background and working experience could perform the ACON® OXY II One Step Oxycodone tests properly and interpret test results correctly in most cases (97%, 262/270). The POL study results are also comparable to those obtained from a trained lab technician (97%, 87/90).

Conclusion:

These clinical studies demonstrated substantial equivalency on performance among the ACON OXY II One Step Oxycodone Test Strip, the ACON OXY II One Step Oxycodone Test Device and a FDA-cleared Oxycodone test with the same Oxycodone cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Oxycodone at a concentration of 100 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

FEB 25 2005

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

Re: k043507
Trade/Device Name: ACON OXY II One Step Oxycodone Test Strip
ACON OXY II One Step Oxycodone Test Device
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: December 17, 2004
Received: December 20, 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 (240)276-0484. 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/industry/support/index.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

11. INDICATIONS FOR USE

510(k) Number (if known): K043507

Device Name: ACON OXY II One Step Oxycodone Test Strip

ACON OXY II One Step Oxycodone Test Device

Indications for Use:

The ACON OXY II One Step Oxycodone Test Strip and the ACON OXY II One Step Oxycodone Test Device are rapid chromatographic immunoassays for the qualitative detection of Oxycodone levels in urine at a designated cutoff concentration of 100 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) are the preferred confirmatory methods.

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 (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (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

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