APR 2 1 2006

5. 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 K060466.

Submitter:

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

Tel.: 858-535-2030
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Date:

February 21, 2006

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® BUP One Step Buprenorphine Test Strip
ACON® BUP One Step Buprenorphine Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Buprenorphine in urine.

Regulation Name:

Buprenorphine test system.

Product Code:

DJG

Classification Number:

21 CFR, 862.3650

Device Classification:

The Buprenorphine test systems have been classified as Class II devices with moderate complexity. 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 LC/MS analysis.

Intended Use:

The ACON BUP One Step Buprenorphine Test Strip and ACON BUP One Step Buprenorphine Test Device are rapid chromatographic immunoassays for the qualitative detection of Buprenorphine in urine at a cutoff concentration of 10 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 LC/MS analysis. They are intended for use by healthcare professionals including professionals at point-of-care sites to assist in the determination of drug compliance.

Description:

The ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Buprenorphine 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 Buprenorphine in urine at a cutoff concentration of 10 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 Buprenorphine 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.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 226 clinical urine specimens including approximately 10% of the specimens containing Buprenorphine concentration fell between –25% cutoff to +25% cutoff range. This evaluation compared the test results between ACON BUP One Step Buprenorphine Test Strip and ACON BUP One Step Buprenorphine Test Device with a FDA-cleared Buprenorphine test; as well as compared against data obtained from the customary

Liquid Chromatography/Mass Spectrometry analysis. These comparisons of data yielded the following results:

ACON BUP One Step Buprenorphine Test Strip versus a FDA-cleared BUP Test:

Positive Agreement: 54 / 64 = 84% (73% - 92%)*
Negative Agreement: 161 / 162 = 99% (97% - 99%)*
Overall Agreement: 215 / 226 = 95% (91% - 98%)*
* 95% confidence intervals

ACON BUP One Step Buprenorphine Test Device versus a FDA-cleared BUP Test:

Positive Agreement: 54 / 64 = 84% (73% - 92%)*
Negative Agreement: 161 / 162 = 99% (97% - 99%)*
Overall Agreement: 215 / 226 = 95% (91% - 98%)*
* 95% confidence intervals

ACON BUP One Step Buprenorphine Test Strip versus data obtained with LC/MS at the cutoff concentration of 10 ng/mL:

ACON BUP One Step Buprenorphine Test Strip versus LC/MS.

		Specimen Cutoff Range by LC/MS Data					% Agreement
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON BUP Test Strip	Positive	0	0	0	5	50	98% (55/56) (90% - 99%)*
	Negative	150	15	5	1	0	>99% (170/170) (98% - 100%)**

Total agreement with LC/MS: 225/226 = 99.6% (98% - 99%)*
* Denotes 95% confidence interval.
** Since the proportion cannot go above 100%, this is really a 97.5% confidence interval.

ACON BUP One Step Buprenorphine Test Device versus LC/MS.

		Specimen Cutoff Range by LC/MS Data					% Agreement
		Negative	< -25% Cutoff	-25% to Cutoff	Cutoff to +25%	> +25% Cutoff	
ACON BUP Test Device	Positive	0	0	0	5	50	98% (55/56) (90% - 99%)*
	Negative	150	15	5	1	0	>99% (170/170) (98% - 100%)**

Total agreement with LC/MS: 225/226 = 99.6% (98% - 99%)*
* Denotes 95% confidence interval.
** Since the proportion cannot go above 100%, this is really a 97.5% confidence interval.

Performance Characteristics and Other information:

The performance characteristics of the ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine 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.

Conclusion:

These clinical studies demonstrated substantial equivalency on performance between the ACON BUP One Step Buprenorphine Test Strip, the ACON BUP One Step Buprenorphine Test Device and a FDA-cleared Buprenorphine test with the same Buprenorphine cutoff concentration. It is also demonstrated that these tests are safe and effective in qualitatively detecting Buprenorphine at a concentration of 10 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

APR 2 1 2006

Re: k060466
Trade/Device Name: ACON BUP One Step Buprenorphine Test Strip
ACON BUP One Step Buprenorphine Test Device
Regulation Number: 21 CFR§862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG
Dated: February 21, 2006
Received: February 22, 2006

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,

Alberto Gutierrez, Ph.D.
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): K060466

Device Name: ACON BUP One Step Buprenorphine Test Strip

ACON BUP One Step Buprenorphine Test Device

Indications for Use:

The ACON BUP One Step Buprenorphine Test Strip and the ACON BUP One Step Buprenorphine Test Device are rapid chromatographic immunoassays for the qualitative detection of Buprenorphine in human urine at a designated cutoff concentration of 10 ng/mL. They are intended for use by healthcare professionals including professionals at point-of-care sites to assist in the determination of drug compliance.

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. Liquid chromatography/mass spectrometry (LC/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 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
K060466