SEP 1 7 2001

8. 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 **K012300**

Submitter:

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

Tel.: 858-535-2030
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Date:

July 16, 2001

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® BZO One Step Benzodiazepines Test Strip

ACON® BZO One Step Benzodiazepines Test Device

Common Name:

Immunochromatographic test for the qualitative detection of Benzodiazepines in urine

Device Classification:

The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are similar to other FDA-cleared devices for the qualitative detection of Benzodiazepines in urine specimens. These tests are used to provide a preliminary analytical result. (21 CFR 862.3170) Benzodiazepines test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Benzodiazepines test system

Intended Use:

The ACON® BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzodiazepines in urine at a cut-off concentration of 300 ng/mL set relative to Oxazepam. They are intended for healthcare professionals including professionals at point of care sites.

Description:

The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are competitive binding, lateral flow immunochromatographic assays for the qualitative screening of Benzodiazepines 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 Benzodiazepines in urine at a cut-off concentration of 300 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 Benzodiazepines 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:

LifeSign Status DS™ BZO One-Step Benzodiazepines Test

510(k) Number: K991079

Comparison to a Predicate Device:

A comparison of the features of the ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device versus the LifeSign Status DS™ BZO One-Step Benzodiazepines Test is shown below:

- Both tests are assays intended for the qualitative detection of Benzodiazepines 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 Benzodiazepines 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 Benzodiazepines concentration of 300 ng/mL.

Safety and Effectiveness Data:

Accuracy

A clinical evaluation was conducted using 300 clinical urine specimens including 10% of the samples with benzodiazepine concentrations at –25% cut-off to +25% cut-off range. This evaluation compared the test results between ACON® BZO One Step Benzodiazepines Test Strip and Test Device with LifeSign Status DS™ BZO One-Step Benzodiazepines Test; as well as against data obtained from the customary Gas Chromatography/Mass Spectrometry analysis. The comparisons of data obtained from this study yielded the following results:

ACON BZO One Step Benzodiazepines Test Strip versus the LifeSign Status DS™ BZO One- Step Benzodiazepines Test:

Positive Agreement: 131 / 145 = 90% (84% - 95%*)
Negative Agreement: 149 / 153 = 97% (93% - 99%*)
Overall Agreement: 280 / 298 = 94% (91% - 96%*)
* 95% Confidence Intervals

ACON BZO One Step Benzodiazepines Test Device versus the LifeSign Status DS™ BZO One-Step Benzodiazepines Test:

Positive Agreement: 130 / 144 = 90% (84% - 94%*)
Negative Agreement: 149 / 154 = 97% (92% - 99%*)
Overall Agreement: 279 / 298 = 94% (90% -96%*)
* 95% Confidence Intervals

ACON BZO One Step Benzodiazepines Test Strip versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 131 / 135 = 97% (92% - 99%*)
Negative agreement with GC/MS: 157 / 165 = 95% (91% - 98%*)
Total agreement with GC/MS: 288 / 300 = 96% (93% - 98%*)
* 95% confidence intervals

ACON BZO One-Step Benzodiazepines Test Device versus GC/MS at the cutoff of 300 ng/ml:

Positive agreement with GC/MS: 130 / 135 = 96% (92% - 98%*)
Negative agreement with GC/MS: 159 / 165 = 96% (92% - 99%*)
Total agreement with GC/MS: 289 / 300 = 96% (94% - 98%*)
* 95% confidence intervals

Conclusion:

These clinical studies demonstrate the substantial equivalency between the ACON BZO One Step Benzodiazepines Test Strip, ACON BZO One Step Benzodiazepines Test Device and the LifeSign Status DS™ BZO One-Step Benzodiazepines Test, which has already being marketed in the United States. It is also demonstrated that these tests are safe and effective in detecting Benzodiazepines at a concentration of 300 ng/mL. The POL study demonstrated that these tests are suitable for professional and point-of-care use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 7 2001

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

Re: k012300
Trade/Device Name: ACON BZO One Step Benzodiazepines Test Strip
ACON BZO One Step Benzodiazepines Test Device
Regulation Number: 21 CFR 862.3170
Regulation Name: Benzodiazepine test system
Regulatory Class: Class II
Product Code: JXM
Dated: July 16, 2001
Received: July 20, 2001

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: K012300

Device Name: ACON® BZO One Step Benzodiazepines Test Strip

ACON® BZO One Step Benzodiazepines Test Device

Indications for Use: The ACON BZO One Step Benzodiazepines Test Strip and ACON BZO One Step Benzodiazepines Test Device are rapid chromatographic immunoassays for the qualitative detection of Benzodiazepines in human urine at a cut-off concentration of 300 ng/mL set relative to oxazepam, a major metabolite of benzodiazepines. 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)

Kesia Alexander for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K012300