NOV 1 4 2003

III. 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the regulation of SMDA 1990 and 21 CFR 807.92"

"The assigned 510(k) number is K032661 "

Device Names:

ACON Quik-Check II Home Pregnancy Test Device

Common Name:

Pregnancy Test Kit, Over-the-Counter

Classification Name:

Gonadotropin

Name of the Predicate Device

ACON Home Pregnancy Test Device (K012215)

Medical Specialty:

Clinical Chemistry

Device Description:

The test utilizes a combination of mouse monoclonal and goat polyclonal antibody in conjunction with a Strepavidin-Biotin ligand-binding system to qualitatively detect elevated levels of hCG in urine sample. The assay is conducted by using a dropper to transfer three drops of urine from a urine sample that has been collected in a cup, or clean, dry container and observing for the formation of colored lines. The specimen migrates via capillary action along the components of the test device to react with the colored conjugate. During migration, hCG molecules in the positive urine sample react with the hCG-specific antibodies, which were conjugated with colored particles, and form a colored line on the "Test Region" of the membrane.

A colored line forms in the test (T) region indicates a **positive** result; while absence of this colored line indicates a **negative** result. To serve as a procedural control, a colored line at the control (C) region will always appear, indicating adequate sample volume and proper wicking, regardless of the presence of hCG. Absence of this control line in the C region indicates that the test result is "**invalid**".

The ACON Quik-Check II Home Pregnancy Test Device qualitatively detects hCG in urine with a designated cutoff hCG concentration of 25 mIU/ml. This test has been standardized to the World Health Organization Third International Standard. The addition of hLH (300 mIU/ml), hFSH (1,000 mIU/ml), and hTSH (1,000 μIU/ml) to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) urine showed no cross-reactivity.

Intended Use:

The ACON Quik-Check II Home Pregnancy Test Device is for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is intended for non-professional, over-the-counter use.

Clinical Studies:

Clinical studies were conducted to compare the results of ACON Quik-Check II Home Pregnancy Test Device to the current ACON QUIK-CHECK Home Pregnancy Test Device (K012215). The consumer field study included 113 female participants and demonstrated an accuracy of over 99% correlation between the two hCG tests. The retrospective focus group study on reproducibility and precision included 35 female participants and demonstrated an accuracy of over 99% correlation between the two hCG tests. The results also showed that the vast majority of the participants found ACON Quik-Check II Home Pregnancy Test Device very easy to use, and that they had no trouble understanding the labeling, reading the instructions, or interpreting the results.

Additional Laboratory Studies to Establish Substantial Equivalence:

Additional laboratory study results on performance include specificity, interference substances, urinary pH, urinary specific gravity, and does hook effect. These results indicate that the ACON Quik-Check II Home Pregnancy Test Device is robust and will give accurate results under many adverse conditions. The should be suited for OTC use.

The overall performance data indicate that ACON Quik-Check II Home Pregnancy Test Device is safe, effective and substantially equivalent to ACON QUIK-CHECK Home Pregnancy Test Device (K012215) currently on the U. S. OTC market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 4 2003

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

Re: k032661
Trade/Device Name: ACON Quik-Check II Home Pregnancy Test Device
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: August 27, 2003
Received: August 28, 2003

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

V. Indications For Use

510(k) Number: K032661

Device Name: ACON Quik-Check II Home Pregnancy Test Device

"Indications for Use": The ACON Quik-Check II Home Pregnancy Test Device is intended for non-professional, over-the counter use for the qualitative identification the elevated level of human Chorionic Gonadotropin (hCG) in urine to aid in the determination of pregnancy.

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) 03 2661

(Please do not write below this point)

Concurrence of CDRH, Office of the *In vitro* Diagnostic Device Evaluation and Safety

Prescription Use_____ or Over-The-Counter Use ✓

(per 21 CFR 801.109)