K993483

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"Summary of Safety & Effectiveness"

ACON™ One Step Home Pregnancy Test Strip is intended for non-professional use for the identification of hCG (human chorionic gonadotropin) in urine to aid in the determination of pregnancy. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG. The assay is conducted by dipping the absorbent wick of the test in urine and observing for the formation of colored lines. The specimen migrates via capillary action along the wick and membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate and form a colored line on the Test portion of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line at the Control zone will always appear regardless of the presence or absence of hCG.

The ACON™ One Step Home Pregnancy Test Strip detects hCG concentrations of 25 mIU/ml and greater. The test has been standardized to the World Health Organization Third International Standard. The addition of hLH (300 mIU/ml), hFSH (1000 mIU/ml), and hTSH (1000μIU/ml) to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) urine showed no cross-reactivity.

Clinical trials using ACON™ One Step Home Pregnancy Test Strip were conducted which included 73 female participants. The results of the study showed that the majority of the participants found ACON™ One Step Home Pregnancy Test Strip very easy to use, and that they had no trouble understanding the labeling, reading the instructions, or interpreting the results.

The overall results of the clinical trial confirm that ACON™ One Step Home Pregnancy Test Strip is a suitable test for over-the-counter pregnancy testing.

Nora C.R. York — 10/12/99

Nora C.R. York
ACON Laboratories, Inc.
11175 Flintkote, Avenue, Suite F
San Diego, CA 92121 UDA

K993483
Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 0 2000

Ms. Nora C.R. York
Regulatory Affairs Manager
Acon Laboratories, Inc.
11175 Flintkote Avenue
Suite F
San Diego, California 92121

Re: K993483
Trade Name: ACON™ One Step Home Pregnancy Test Strip
Regulatory Class: II
Product Code: LCX
Dated: December 2, 1999
Received: December 6, 1999

Dear Ms. York:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 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

Indications For Use

510(k)Number: K993483/S1

Device Name: ACON™ One Step Home Pregnancy Test Strip

"Indications For Use" - ACON™ One Step Home Pregnancy Test Strip is intended for non-professional use for the qualitative identification of human chorionic gonadotropin (hCG) in urine to aid in the determination of pregnancy.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993483

(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)