K993203

DEC - 1 1999

"Summary of Safety & Effectiveness"

ACON™ One Step Pregnancy Test Strip (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG. The assay is conducted by immersing the test strip in the urine sample and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate. Positive specimens react with the specific antibody-hCG-colored conjugate and form a colored line in the Test Area of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line in the Control Area will always appear regardless of the presence or absence of hCG.

A multi-center clinical evaluation was conducted comparing the results obtained using ACON™ One Step Pregnancy Test Strip (Urine) and another commercially available urine membrane test. The study included 150 urine specimens tested with both assays. The following results were found:

	Positive Results	Negative Results
ACON™ One Step	78	72
Commercially Available Test	78	72

ACON™ One Step Pregnancy Test Strip (Urine) showed a 100% concordance with the other commercially available test.

ACON™ One Step Pregnancy Test Strip (Urine) 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 (300mUI/ml, hFSH (1000 mIU/ml), and hTSH (1000μIU/ml) to negative and positive serum and urine specimens showed no cross-reactivity.

Nora C. R. York — 9/23/99

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

Date

Premarket Notification 510(k) Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 1 1999

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

Re: K993203
Trade Name: Acon™ One Step Pregnancy Test Strip (Urine)
Regulatory Class: II
Product Code: JHI
Dated: September 23, 1999
Received: September 24, 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 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: K993203

Device Name: ACON™ One Step Pregnancy Test Strip (Urine)

"Indications For Use" - ACON™ One Step Pregnancy Test Strip (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. This test is for professional use.

(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)