K012215

AUG - 7 2001

Summary of Safety & Effectiveness

The Quik-Check™ Home Pregnancy Test Device is intended for non-professional/Over-The-Counter use for the identification of human Chorionic Gonadotropin (hCG) 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 adding urine to the test device 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 on the "Test Region" of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line at the Control Region will always appear regardless of the presence or absence of hCG.

The Quik-Check™ Home Pregnancy test 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 (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.

Clinical trials using Quik-Check™ Home Pregnancy Test were conducted which included 117 female participants. The results of the study showed that the majority of the participants found Quik-Check™ Home Pregnancy test 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 Quik-Check™ Home Pregnancy Test is a suitable test for over-the-counter pregnancy testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

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

Re: 510(k) Number: K012215
Trade/Device Name: Quik-Check™ Home Pregnancy Test
Regulation Number: 862.1155
Regulatory Class: II
Product Code: LCX
Dated: July 10, 2001
Received: July 16, 2001

Dear Dr. Tung:
This letter replaces and corrects letter dated August 7, 2001. The device name was incorrect. It was spelled Quick-Check. It should be spelled Quik-Check.

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 to 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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

Indications For Use

510(k) Number: K012215

Device Name: Quik-Check™ Home Pregnancy Test

"Indications For Use" - Quik-Check™ Home Pregnancy is intended for non-professional/Over-The Counter use for the qualitative identification of hCG (human Chorionic Gonadotropin) in urine to aid in the determination of pregnancy.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012215

Prescription Use_____ or Over-The-Counter Use ✓
(per 21 CFR 801.109)