DEC 21 1999 K992232

II. 510(k) SUMMARY

Submitted By: Carter-Wallace
Carter Products Division
P.O. Box 1001, Half Acre Road
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(609) 655-6000

Contact Person: Maureen Garner

Date Prepared: July 1, 1999

Proprietary Name: First Response® 1-Step Pregnancy

Common Name: At-Home Pregnancy Test

Classification Name: Human chorionic gonadotropin (hCG) test system

Predicate Device: First Response® 1-Step Pregnancy Test

Description of the Device: The First Response®1-Step Pregnancy Test is a Class II *in vitro* diagnostic medical device product that functions by way of a double antibody immunochromatographic assay in detecting the presence of hCG in the urine as an aid in the early diagnosis of pregnancy. It consists of a plastic stick, which contains an absorbent tip that protrudes from the end of the device and collects and delivers urine to reagents on a chromatographic strip contained within the device. The test is performed by placing the absorbent tip of the device in the urine stream for 5 seconds or by immersing the absorbent tip into a container of urine for 5 seconds. The absorbent section of the strip allows the urine sample to move chromatographically along the reagent strip reconstituting the diffusible reagents placed strategically along the strip and delivering them to the appropriate capture zones for visualization of the test results. The detection of hCG (pregnant) in the urine sample is indicated by the appearance of two pink lines in the test window. If there is no hCG (not-pregnant) in the urine, one pink line will appear.

Intended Use of the Device: The First Response® 1-Step Pregnancy Test is a simple-to-use at-home pregnancy test marketed over-the-counter (OTC) to lay consumers. The test device product is intended for the detection of human chorionic gonadotropin (hCG) in urine as an aid in the detection of pregnancy. The directions for use for the First Response® 1-Step Pregnancy Test state that the test can be used as early as three days before the expected menses.

II. ***510(k) SUMMARY*** (cont'd)

III.

Technological Characteristics: The First Response® 1-Step Pregnancy Test utilizes a plastic stick with an absorbent tip which protrudes from the end of the device and collects and delivers the urine to reagents on the chromatographic strip contained within the device. The test product detects hCG, the hormone produced during pregnancy, by utilizing a double antibody immunochromatographic assay and uses a direct label to visualize the immunoreaction indicating the presence of hCG. The test uses colloidal gold, which upon agglutination produces a pink/purple color and also utilizes a third complexing reaction (between biotin and streptavidin) to produce an easy-to-read test result.

The performance studies conducted included the evaluation of consumer accuracy in reading low levels of hCG using the First Response® 1-Step Pregnancy Test and the ability of lay consumers to perform the test and interpret the result. A quantitative market research study was performed to evaluate consumers' ability to understand the package insert, which indicates that the test can be used before the expected period. A laboratory study was performed to evaluate and confirm the clinical sensitivity of the First Response® 1-Step Pregnancy Test using samples collected prior to missed menses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Ms. Maureen N. Garner
Manager, Regulatory Affairs
Carter-Wallace, Inc.
Half Acre Road
P.O. Box 1001
Cranbury, New Jersey 08512-0181

Re: K992232
Trade Name: First Response® 1-Step Pregnancy Test
Regulatory Class: II
Product Code: LCX
Dated: October 4, 1999
Received: October 5, 1999

Dear Ms. Garner:

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

VI. INDICATIONS FOR USE STATEMENT

510(k) Number: K992232

Device Name: First Response® 1-Step Pregnancy Test

Indications For Use: The First Response® 1-Step Pregnancy Test is an at-home pregnancy test marketed over-the-counter (OTC) to lay consumers. The First Response® 1-Step Pregnancy Test detects the presence of hCG in the urine as an aid in the early diagnosis of pregnancy. The test, which can be used anytime of the day, can detect hCG as early as three days before the expected period.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Veronica J Calvert for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992232/A4

Prescription Use_____ OR Over-The-Counter Use ✓ *(Per 21 CFR 801.109)*