K973310

II. 510(k) Summary

Submitted by:

Carter-Wallace
Carter Products Division
P.O. Box 1001, Half Acre Road
Cranbury, New Jersey 08512-0181
(609) 655-6000

Contact Person: Theresa Sines

Date Submitted: September 2, 1997

Proprietary Name: TBD* One-Step Ovulation Predictor Test
*May be marketed under brand names yet to be determined, including ANSWER®, ANSWER QUICK & SIMPLE®, FIRST RESPONSE®, or others.

Common Name: At-Home Ovulation Predictor Test

Classification Name: Luteinizing hormone test system

Predicate Device: FIRST RESPONSE® Ovulation Predictor Test

Description of the Device: The TBD One-Step Ovulation Predictor Test is a simple to use, plastic stick, *in vitro* device. The top of the stick is clear to allow the user to visualize the migration of the test reagents. The stick contains a chromatographic test strip which has all the necessary reagents to perform the test. An absorbent tip collects and delivers the urine sample to the reagents on the chromatographic strip. The test is performed by placing the absorbent tip into the urine stream for 5 seconds. Alternatively, the test may be performed by immersing the absorbent tip into a container of urine for 5 seconds. The urine sample from the absorbent tip migrates by capillary action along the chromatographic strip, reconstituting the reagents placed strategically along the strip. Visualization of the test results occurs when the appropriate reagents react producing one or two pink-purple lines which appear in a window in the hull of the test stick. The luteinizing hormone (LH) surge is indicated if the test line is similar to or darker than the reference line. If there is no test line or the test line is lighter than the reference line, then there has been no LH surge.

The TBD One-Step Ovulation Predictor Test is substantially equivalent to the FIRST RESPONSE® Ovulation Predictor test marketed by Carter Products, Division of Carter-Wallace, Inc.

Intended Use of the Device: The *TBD One-Step* Ovulation Predictor Test is an at-home *in vitro* diagnostic use test to be marketed over-the-counter (OTC) to lay consumers. The test device product is intended for the detection of human luteinizing hormone (hLH) in urine as an aid in the prediction of ovulation.

II. 510(k) Summary (cont'd)

Technological Characteristics: The TBD One-Step Ovulation Predictor Test incorporates the same technological characteristics as the predicate device. It differs from the predicate device by utilizing a plastic stick with an "exposed wick" (the absorbent tip) to collect and deliver the urine sample to the reagents on the chromatographic strip. The First Response® Ovulation Predictor Test utilizes a plastic stick device which *encloses* the absorbent pad and exposes a Urine Collection area on the under side of the stick. This difference raises no new issue regarding safety or effectiveness of the product.

Another difference of the TBD One-Step Ovulation Predictor Test is the exposure time of the absorbent tip to the urine sample which is 5 seconds. The First Response Ovulation Predictor Test exposure time is 10 seconds. The support data in this submission validate the 5 second urination time. No new issues regarding safety or effectiveness are raised.

In a direct laboratory comparison, the TBD One-Step Ovulation Predictor Test was found to have equivalent performance to that of the predicate device, and in consumer use studies, the TBD One-Step test was at least as accurate as the predicate device with regard to consumers' accuracy in performing the test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 27 1997

Stephen C. Kolakowsky
Director, Regulatory Affairs
Carter-Wallace, Inc.
Half Acre Road
P.O. Box 1001
Cranbury, New Jersey 08512-0181

Re: K973310
TBD One-Step Ovulation Predictor Test
Regulatory Class: I
Product Code: CEP
Dated: September 2, 1997
Received: September 3, 1997

Dear Mr. Kolakowsky:

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 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/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 (if known):

Device Name: TBD One-Step Ovulation Predictor Test

Indications For Use: The TBD One-Step Ovulation Predictor Test is an at-home ovulation predictor test marketed over-the-counter (OTC) to lay consumers. The TBD One-Step Ovulation Predictor Test detects the presence of human luteinizing hormone (hLH) in the urine as an aid in the prediction of ovulation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973310