

MAY 31 1996

510(k) SUMMARY

K961712

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

**Contact Person:** Maureen Garner

**Date Prepared:** May 1, 1996

**Name of Device:** At-home Pregnancy Test

**Classification Name:** Human chorionic gonadotropin (HCG) test system

**Predicate Device:** CLEARBLUE EASY™ One-Step Pregnancy Test

**Description of the Device:** The TBD Pregnancy Test is a Class II *in vitro* diagnostic medical device product that functions by way of an immunochemical chromatographic-chromogenic method in detecting the presence of hCG in the urine as an aid in the early diagnosis of pregnancy. It consists of a plastic stick, housing an absorbent material that collects and delivers urine to reagents on a chromatographic strip contained within the device. The test is performed by dipping the device into a container of urine for 20 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 in the urine sample (pregnant) is indicated by the appearance of two pink lines in the result window. If there is no hCG (not-pregnant) in the urine, one pink line will appear.

The TBD Pregnancy Test is substantially equivalent to CLEARBLUE™ Easy One-Step Pregnancy Test manufactured by Whitehall Laboratories, Inc.

**Intended Use of the Device:** The TBD 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 early pregnancy.

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

**Technological Characteristics:** The TBD Pregnancy Test has similar technological characteristics as the predicate device although it differs from the predicate device in the type of direct label used to visualize the immunoreaction that indicates the presence of hCG. The TBD test uses colloidal gold which upon agglutination optically produces a pink color. The CLEARBLUE Easy™ device uses blue latex beads which upon agglutination produces a blue color. This difference has no technological significance other than to yield a pink-to-purple result line in the subject device and to yield a blue result line in the predicate device. The TBD test also differs in that it utilizes a third complexing reaction to enhance and produce the easy-to-read test result. These minor technological differences raise no new issues regarding safety or effectiveness.

The performance studies conducted included the evaluation of the laboratory accuracy of the TBD test and the ability of lay consumers to perform the test and interpret the result. Two laboratory studies were conducted to determine the performance of the TBD test in comparison to the predicate device, CLEARBLUE Easy™ test. A third laboratory study was performed to evaluate and confirm the sensitivity of the TBD test. In two separate studies, the ability of consumers to perform and interpret the TBD Pregnancy Test was evaluated.