

510(k) SUMMARY

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JUL 10 1996

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Date Prepared: June 5, 1996

Name of Device: Brand Name 1-Step Pregnancy Test

Classification Name: Human chorionic gonadotropin (hCG) test system

Predicate Device: One-Step CLEARBLUE Easy™ Pregnancy Test

Description of the Device: The Brand Name 1-Step 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 pad that collects and delivers urine to reagents on a chromatographic strip contained within the device. The test is performed by placing the absorbent pad of the device in the urine stream for 5 seconds or by dipping the device 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 in the urine sample (pregnant) 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.

The Brand Name 1-Step Pregnancy test is substantially equivalent to the One Step CLEARBLUE™ Easy Pregnancy test distributed by Whitehall Laboratories, Inc.

Intended Use of the Device: The Brand Name 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 early pregnancy.