K123567

510(k) SUMMARY

Submitted by:	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Joseph Ciccone, Senior Regulatory Manager, Regulatory Affairs
Date Prepared:	September 9, 2013
Proprietary Name:	FIRST RESPONSE™ Gold™ Digital Pregnancy Test
Common Name:	At-home Pregnancy Test
Classification Name:	Human chorionic gonadotropin (hCG) test system [21 CFR §862.1155] 75 LCX; Class II
Predicate Device:	FIRST RESPONSE™ Early Result Pregnancy Test 510(k) #K083716

SEP 10 2013

Description of Device:
The FIRST RESPONSE™ Gold™ Digital Pregnancy Test is a test system for the detection of human chorionic gonadotropin (hCG) hormone. Specifically, it is a screening device intended for the early detection of pregnancy by the lay user through the qualitative detection of hCG in urine as early as six (6) days before the day of the missed period. The detection of hCG in the urine of a pregnant woman is accomplished by a series of immunochemical reactions via component reagents that are deposited onto a chromatographic strip contained within a plastic housing. A digital component integral with the chromatographic strip reads and displays the result of the immunochemical reaction on an LCD (Liquid Crystal Display) screen of the device in place of the colored lines of the predicate device. Following the instructions for use provided with the device, the test is performed by placing the absorbent collection tip of the device into the urine stream for 5 seconds (or alternatively by fully immersing the collection tip for 5 seconds in a urine sample that was collected in a cup). A clock symbol will begin to blink in about 30 seconds after the urine is applied to indicate to the consumer that the test is working. The test result is read on the LCD screen of the device within 3 minutes. A "YES+" test result indicates that the pregnancy hormone (hCG) was detected (pregnant) and a "NO-" test result indicates that no hCG was detected (not pregnant).

Intended Use of the Device: The FIRST RESPONSE™ Gold™ Digital Pregnancy Test is a single-use *in vitro* diagnostic test device intended for the early detection of pregnancy by the lay user. The test detects human chorionic gonadotropin (hCG) hormone in urine. The device is indicated for use as early as five (5) days before the day of expected period, i.e., as early as six (6) days before the day of the missed period.

Technological Characteristics: The 510(k)-subject FIRST RESPONSE™ Gold™ Digital Pregnancy Test device and its analog predictate counterpart utilize identical immunochemical principles for the determination of hCG. They differ in that the reagent system of the 510(k)-subject device has been enhanced to include an additional monoclonal antibody capable of detecting hCG beta core fragment (hCG βcf). hCG βcf is produced in early pregnancy (1) and its detection is intended to improve the clinical performance of the device. Detection of hCG βcf also prevents or reduces the potential for a false negative test result because hCG βcf is the major form of immunoreactive

urinary hCG commonly found in later pregnancy (2, 3). In addition, the subject 510(k) device differs from the predicate device in that it provides a digital display of test result for the consumer to read in place of the colored lines of the predicate device. The digital version of the predicate device incorporates into the device housing electronic and optical components along with a microprocessor and an optimized algorithm capale of determining and correctly interpreting the assay result and displaying a simple "YES+" or "NO-" on the LCD screen. The digital device which is battery powered will display the result for at least thirty minutes after completion of the reaction. All components are integrated and unitized into the device housing.

A number of laboratory and consumer use studies were undertaken to demonstrate that the 510K-subject device is substantially equivalent to the predicate device for the detection of pregnancy as early as 6 days before the day of missed period. These studies are as follows:

- A laboratory study to demonstrate the accuracy of the 510(k)-subject device compared to the accuracy of the predicate device using urine samples quantified for hCG levels from pregnant and non-pregnant women. The study showed no discrepancies in accuracy.
- A laboratory study to determine the analytical sensitivity and cut-off of the 510(k)-subject device using hCG standards of known concentration. The data demonstrate that the analytical sensitivity is 10 mIU/mL with a 50/50 cutoff of 6 mIU/mL for both midstream and dip method.
- A consumer study to demonstrate the ability of lay users to obtain similar results around the established sensitivity and cutoff as laboratory professionals. The data demonstrate no difference in device performance between lay users and laboratory professionals.
- A laboratory study to assess intra and inter lot precision of the 510(k)-subject device using hCG standards of known concentration. The data demonstrate no intra nor inter lot-to-lot variability.
- Laboratory studies to demonstrate that potential interfering substances and homologous hormones do not affect the performance of the 510(k)-subject device. The data demonstrate no effect on the performance of the device.
- A laboratory study to demonstrate that no high dose hook effect is observed when the 510(k)-subject is challenged with very high levels of intact hCG. The data demonstrate no effect on the performance of the device.
- A laboratory study to confirm high levels of hCG βcf. The results of this study show no detrimental effect on the performance of the device.
- An early pregnancy detection study using urine samples from conceptive cycles to demonstrate that the 510(k)-subject device can detect hCG days before the missed period. The data demonstrate that the device can detect hCG 6 days before the missed period.
- A laboratory study to determine the performance of the 510(k)-subject device with urine samples quantified for hCG from pre-, peri-, and post-menopausal women. The data demonstrate that the potential for false positive results in the sub-populations is zero.

- A consumer self-use study to determine the ability of the consumers to perform the test and interpret the results correctly. The data demonstrate that consumers can perform the test and interpret the result correctly.

The results of the above listed studies demonstrate that the 510(k)-subject device is substantially equivalent to the currently marketed First Response™ Early Result Pregnancy Test. The device is safe and effective for the intended use.

References:

1. McChesney R, Wilcox AJ, O'Connor JF, Weinberg CR, Baird DD, Schlatterer JP, et al. Intact hCG, free hCG beta subunit and hCG beta core fragment: longitudinal patterns in urine during early pregnancy. Hum Reprod 2005:20:928-35.

2. Gronowski A, Cervinski M, Stenman UH, Woodworth A, Ashby L, Scott MG. False-negative results in point-of-care qualitative human chorionic gonadotropin (hCG) devices due to excess hCGβ core fragment. Clin Chem 2009; 55:7; 1389-1394.

3. Kato Y, Braunstein GD. Beta-core fragment is a major form of immunoreactive urinary chorionic gonadotropin in human pregnancy. J Clin Endocrinol Metab 1988;66:1197-201.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 10, 2013

Church & Dwight Co., Inc.
C/O Joseph Ciccone
469 North Harrison Street
PRINCETON NJ 08543

Re: K123567
Trade/Device Name: FIRST RESPONSE™ Gold™ Digital Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: II
Product Code: LCX
Dated: September 3, 2013
Received: September 4, 2013

Dear Mr. Ciccone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123567

Device Name: FIRST RESPONSE™ Gold Digital Pregnancy Test

Indications for Use:

The FIRST RESPONSE™ Gold Digital Pregnancy Test is an over-the-counter chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. The device is intended for use as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your missed period, but think you may still be pregnant, you should re-test again a few days after your missed period.

All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k123567