K083716

510(k) Summary

Submitted by:	Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Stephen C. Kolakowsky Director, Regulatory Affairs
Date Prepared:	December 12, 2008; Revised June 5, 2009
Proprietary Name:	FIRST RESPONSE® Early Result 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) #K030258 and#K992232

JUN - 8 2009

Description of Device: The FIRST RESPONSE® Early Result Pregnancy Test is a human chorionic gonadotropin (hCG) test system. It is a screening device intended for early detection of pregnancy by the lay user for the qualitative measurement of hCG in urine as early as six (6) days before the day of the missed period. The device detects the presence of hCG in the urine of a pregnant woman by way of a series of immunochemical reactions via component reagents that are striped onto a chromatographic strip contained within a plastic housing. Following the instructions for use provided with the device, the test is performed by placing the absorbent collection tip into the urine stream (alternatively a cup of urine may be used) for 5 seconds. The test result is read in the housing window after the elapse of 3 minutes. Two pink lines indicate hCG has been detected (pregnant); one pink line indicates no hCG has been detected (not pregnant).

Intended Use of the Device: The FIRST RESPONSE® Early Result Pregnancy Test is an *in vitro* diagnostic home use test device intended for the early detection of pregnancy. The test may detect the pregnancy hormone (hCG), in some cases, as early as 6 days before the missed period (5 days before the expected period).

This test is only intended for individual use at home. It is not intended for use in a healthcare setting.

Important note regarding negative results:
Some pregnant women will not be able to detect hCG in their urine 6 days before the missed 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.

Important note regarding positive results:
Because this test detects very low levels of hCG, there is a small chance that this test will give positive results even if you are not pregnant. Chances of this are greater for women nearing age 40 and older.

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

Technological Characteristics: The modified 510(k)-subject device does not represent a change in technology, only an enhancement, and thus is substantially equivalent to the predicate device. The 510(k)-subject device and the predicate device are essentially identical. They differ in that the 510(k)-subject device has been modified to use a different size gold particle and a modified streptavidin to achieve an increased analytical and clinical sensitivity, and thus, the ability to detect the presence of hCG earlier in pregnancy, *viz.*, six (6) days rather than five (5) days before the day of the missed period. The labeling claim and directions for use relative to the time of use prior to the expected period that the test may be used have been correspondingly modified. A consumer study confirmed professional testing and verified the device performance characteristics with early pregnancy urines demonstrating that the results of the test can be accurately read and interpreted by consumers as early as 6 days before the missed period. The device housing has also been modified to be more user-friendly.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Church & Dwight Co., Inc.
c/o Stephen C. Kolakowsky, Director
Regulatory Affairs
469 North Harrison Street
Princeton, NJ 08543

JUN - 8 2009

Re: k083716
Trade/Device Name: FIRST RESPONSE® Early Result Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (hcg) test system
Regulatory Class: Class II
Product Code: LCX
Dated: April 23, 2009
Received: April 24, 2009

Dear Mr. Kolakowsky:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k083716

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Prescription Use _____ And/Or Over the Counter Use __X__.
(21 CFR Part 801 Subpart D) (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 Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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