510(K) SUMMARY

Submitted by:	Church & Dwight Co., Inc./ArmKel, LLC 469 North Harrison Street Princeton, NJ 08543
Contact Person:	Stephen C. Kolakowsky Director, Regulatory Affairs (609) 279-7748
Date Prepared:	April 2004
Proprietary Name:	FIRST RESPONSE® One-Step Digital Pregnancy Test
Common Name:	At-home Pregnancy Test (OTC)
Classification Name:	Human chorionic gonadotropin (hCG) test system [21 CFR §862.1155; LCX] Kit, Test, Pregnancy, hCG, Over-the-Counter
Predicate Device:	FIRST RESPONSE® One-Step Pregnancy Test — 510(k) #K992232 and CLEAR BLUE® Easy Digital Pregnancy Test (Unipath Ltd., UK) — 510(k) #K030659

Description of Device: The FIRST RESPONSE® One-Step Digital Pregnancy Test is a human chorionic gonadotropin (hCG) test system. It is a device intended for use by the lay user in the early detection of pregnancy by the detection of hCG, a placental hormone in urine. The FIRST RESPONSE® One-Step Digital Pregnancy Test labeling provides for the use of the test as early as three (3) days before the expected period. [Refer to K992232.] 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, which is integral with the digital component that reads and displays the result of the immunochemical reaction on the Display Screen of the device housing, as opposed to an analog display of the predicate device. The immunochemical reagents that are striped onto a chromatographic strip are unchanged from the predicate FIRST RESPONSE® One-Step Pregnancy Test.

Following the instructions for use provided with the device, the test is performed by placing the Absorbent Tip into the urine stream (alternatively a cup of urine may be used) for 5 seconds, then allowing the test to continue for 3 minutes. During this time, a blinking clock icon appears on the Display Screen of the device housing to indicate that the test is working. After the elapse of 3 minutes, a digital display of the result appears on the Display Screen: a "**YES+**" test result indicates that the pregnancy hormone (hCG) was detected (pregnant); a "**-NO**" test result indicates that the pregnancy hormone (hCG) was not detected (not pregnant). A " ? " (question mark) appears when a test error has occurred.

Intended Use of the Device: The FIRST RESPONSE® One-Step Digital Pregnancy Test is an *in vitro* diagnostic test device for use by the lay user for the early detection of pregnancy prior to the expected menses.

Technological Characteristics: Both the subject 510(k) device and the predicate FIRST RESPONSE® One-Step (analog) Pregnancy Test device utilize the identical immunochemical principles for the assay of hCG: an immunochromatographic assay using colloidal gold as a direct label. The subject 510(k) device differs solely in that it provides a digital display of the test result for the consumer to read in place of the colored lines of the predicate device. The digital version of the device incorporates into the stick housing an electronic component consisting of a microchip with specific circuitry and algorithms capable of determining and correctly interpreting the reaction result and displaying a simple "**YES+**" or "**-NO**" on a Display Screen. The digital device is battery powered and will display the result for at least thirty minutes after completion of the reaction. All components are integrated and unitized into the stick housing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 19 2004

Mr. Stephen C. Kolakowsky
Director, Regulatory Affairs
Armkel, LLC
Church & Dwight CO., Inc.
469 North Harrison Street
Princeton, NJ 08543-5297

Re: k040866
Trade/Device Name: FIRST RESPONSE™ One- Step Digital Pregnancy Test
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: August 26, 2004
Received: August 27, 2004

Dear Mr. Kolakowski:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K040866

Device Name: FIRST RESPONSE® One-Step Digital Pregnancy Test

Indications for Use: The FIRST RESPONSE® One-Step Digital Pregnancy Test is an *in vitro* diagnostic test device that incorporates a digital read out of the test result for the early detection of pregnancy (hCG in urine) by the lay user prior to the expected menses

Prescription Use _____ OR Over-the-Counter Use ___X___
(Per 21 CFR §801.109)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040866