U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(szs)
FOLDER:	K083716 - 291 pages
COMPANY:	CHURCH & DWIGHT CO., INC. (CHURDWIG)
PRODUCT:	KIT, TEST, PREGNANCY, HCG, OVER THE COUNTER (LCX)
SUMMARY:	Product: FIRST RESPONSE EARLY RESULT PREGNANCY TEST (OTC)
DATE REQUESTED:	Sep 26, 2011
DATE PRINTED:	Sep 26, 2011

Note: Printed

K083716

510(k) Summary

JUN - 8 2009

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

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

Device Name: FIRST RESPONSE® Early Result Pregnancy Test

Indication For Use:

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.

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

510(k) K083716

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 6/30/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K083716/A8

To: Division Director: CH/DCTD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

✓ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

✓ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: Chris May

Date: 7/13/09

DMC 9/8

K083716 / A7

Memo

FDA CDRH DMC

JUN 30 2009

Received

To: Memo to File

From: Vicki Moyer, Scientific Reviewer, CDRH/OIVD/DCTD

Vicki Moyer 6/23/09

Date: June 23, 2009

Re: k083716 Church and Dwight First Response pregnancy test Decision Making

(b)(4)

[redacted]

K SF

(b)(4)

[redacted]

Moyer, Vicki

From: Harper, Courtney C
Sent: Tuesday, June 09, 2009 9:42 AM
To: 'Stephen.Kolakowsky@churchdwight.com'
Cc: Moyer, Vicki
Subject: Re: FIRST RESPONSE Early Result Pregnancy Test

Mr. Kolakowsky

We would be happy to have a call. Although it would be more productive to do so in the context of a proposal, we are willing to have a preliminary call with you as well. Unfortunately I am on travel and will not be available Thursday.

Vicki- please log this request in as a new pre-Ide and work with Mr. Kolakowsky to schedule a preliminary call at a mutually available time.

Thank you,

Courtney

From: Kolakowsky, Stephen <Stephen.Kolakowsky@churchdwight.com>
To: Harper, Courtney C
Sent: Tue Jun 09 09:16:14 2009
Subject: FIRST RESPONSE Early Result Pregnancy Test

Dr. HARPER .....

We are following up on your offer to have a conference call to discuss with you what would be needed in a 510(k) submission to support the (b)(4) for the FIRST RESPONSE Early Result Pregnancy Test. We propose a call at 10:30 AM, this Thursday morning, June 11, 2009. We do not have anything specific to propose at this time and are seeking this discussion to obtain your thoughts on the subject. If this time is not convenient, please provide times and dates that are more convenient with your schedule. If convenient, we can conduct the conversation under Pre-IDE I080286.

..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

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Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 11:26 AM
To: St. Pierre, Don J.; Gutierrez, Alberto; Benson, Carol; Moyer, Vicki; Danishefsky, Avis ; Beaston, Patricia; Phillips, Tracy
Subject: Church and Dwight update

Church and Dwight have accepted our labeling requests. They plan to come back in to get some of the claims we did not get them (b)(4) [redacted] Therefore a panel meeting will not be necessary.

Tracy - Don't do anything to cancel the meeting until we actually sign out the 510(k) (hopefully Monday). Just in case anything changes in the meantime.

Thanks all,

Courtney

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 1:17 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test

Thank you very much for this prompt response. We will let you know if we have any questions as we prepare our final documentation.

Regards,

Courtney

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
2098 Gaither Rd.
Rockville, MD 20850
Ph 240-276-0694
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From: Kolakowsky, Stephen [mailto:Stephen.Kolakowsky@churchdwight.com]
Sent: Friday, June 05, 2009 1:11 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Dr. Harper .....

Attached per the request contained in your earlier eMail below are revised versions of our Intended Use Statement and our 510(k) Summary incorporating the language suggested in your attached "Labeling and Intended Use Modifications" document.

This will also serve to confirm our agreement to the "Labeling and Intended Use Modifications" as discussed earlier today.

It is our understanding that the above now clears the way for clearance of the 510(k) and avoidance of the need for a Panel meeting.

Stephen C. Kolakowsky

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 8:41 AM
To: Moyer, Vicki; Danishefsky, Avis
Cc: Benson, Carol
Subject: RE: k083716 - First Response Early Pregnancy Test

They will likely put it on the insert based on what we asked them. Let's see first if they agree to put it at all...

From: Moyer, Vicki
Sent: Friday, June 05, 2009 8:15 AM
To: Harper, Courtney C; Danishefsky, Avis
Cc: Benson, Carol
Subject: RE: k083716 - First Response Early Pregnancy Test

I thought of this on the way in this morning...
Do we want the black box warning on the box packaging? Or prominently at the start of the test instructions? I don't think we specified this.
Most of the information does appear throughout the labeling, however some does not (such as intended for home use....)

Vicki

From: Harper, Courtney C
Sent: Thursday, June 04, 2009 5:00 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test

Mr. Kolakowsky –

Thank you very much for responding so quickly to our request. It is very helpful as we try to resolve this issue. We have carefully considered your proposed modifications and believe that some of them are acceptable. However, there are a few of your suggestions that do not address our concerns. We have tracked our modified requests for the labeling changes based on your proposed modifications.

If you agree to modify your labeling, indications for use form, and 510(k) summary in accordance with our requests, please let us know and we will let the panel members know that the panel is not necessary. If, however, you do not agree with our requests, we will be happy to obtain our panel experts' input on this new type of device.

Thank you again for your prompt response,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices

Moyer, Vicki

From: Harper, Courtney C
Sent: Thursday, June 04, 2009 5:00 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test
Attachments: Labeling and Intended use modifications k083716 6 4 09.doc

Mr. Kolakowsky –

Thank you very much for responding so quickly to our request. It is very helpful as we try to resolve this issue. We have carefully considered your proposed modifications and believe that some of them are acceptable. However, there are a few of your suggestions that do not address our concerns. We have tracked our modified requests for the labeling changes based on your proposed modifications.

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Thank you again for your prompt response,

Courtney C. Harper, Ph.D.
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courtney.harper@fda.hhs.gov

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From: Kolakowsky, Stephen [mailto:Stephen.Kolakowsky@churchdwight.com]
Sent: Thursday, June 04, 2009 3:10 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Dr. HARPER .....

First Response Early Pregnancy Test (k083716)

OIVD reply
6/4/09

Change to Intended use with black boxed information:

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~~5~~ days before the ~~expected~~ missed period.

Comment [c1]: This recommendation is for the labeling. We request that for the indications for Use form for the submission that you also insert to read"... 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:
~~Many~~ Some pregnant women will not be able to detect hCG in their urine 6~~5~~ days before the expected period. If you test negative before your ~~expected~~ 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~~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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute (This full statement may be on the side if it fits better. An asterisk should not be used.):
"Early results. In ~~half~~ one study, in 68% of the samples tested, pregnancy could be detected up to 6~~5~~ days ~~prior to~~before the day of the ~~expected~~ missed period."

- Remove (b)(4) [redacted] ~~because this is not the accuracy at 5 days before the missed period.~~ There is not sufficient data for us to conclude that your test is (b)(4) [redacted] in the hands of the intended users ~~(both pregnant and not pregnant)~~ (both pregnant and not pregnant). This may be because of the (b)(4) [redacted] limit for your device which affects this performance metric.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":

We recommend you aAdd ~~a recommendation that women should use first morning urine.~~the following statement (or similar): "Your first morning urine contains the highest concentration of pregnancy hormone. However, you may test at any time of the day."

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by ~~5~~6 days before the ~~expected~~ missed period. In this study, all samples from pregnant women tested positive by 3~~2~~ days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because some women sometimes have difficulty predicting the exact ~~date~~date of their next ~~it is sometimes difficult to exactly predict the day of the expected~~ period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

Moyer, Vicki

From: Kolakowsky, Stephen [Stephen.Kolakowsky@churchdwight.com]
Sent: Thursday, June 04, 2009 3:10 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High
Attachments: Labeling and Intended use modifications k083716.doc; 10Lblg.doc

Dr. HARPER .....

Thank you for your input on our proposed labeling. We are able to agree to the majority of the revisions that you recommend and have incorporated our comments and other revisions to the proposed labeling for your consideration. See the attached file "10Lblg.doc". (Your original file is attached.) If you would like to discuss our comments, I can arrange a conference call this afternoon or tomorrow morning.

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Harper, Courtney C [mailto:Courtney.Harper@fda.hhs.gov]
Sent: Thursday, June 04, 2009 9:26 AM
To: Kolakowsky, Stephen
Cc: Benson, Carol; Moyer, Vicki
Subject: k083716 - First Response Early Pregnancy Test
Importance: High

Dear Mr. Kolakowsky -
Per your conversation with Don St.Pierre regarding the planned public panel meeting for your First Response device (k083716), the review team has worked hard to determine whether there are potential solutions to our review questions that would allow clearance in lieu of a panel meeting. We very much appreciate that you have quickly responded to our recent requests for additional analyses of data.

(b)(4)

[redacted]

Please let us know if you agree to these changes and submit modified labeling, indications for use form, and 510(k) summary that reflect these changes. Because of the scheduled panel meeting, we need this

information very quickly (i.e., if the meeting is to be canceled, it must be done this week). Therefore, please send us your response to this proposal by COB today or early Friday, June 5. We apologize for the quick turn-around that is necessary.

In the meantime, please let us know if you have any questions on this and we will be happy to address them.
Thank you,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
2098 Gaither Rd.
Rockville, MD 20850
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<<Labeling and Intended use modifications k083716.doc>>

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First Response Early Pregnancy Test (k083716)

Church + Dwight Changes 6/4/09

Change to Intended use with black boxed information:

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,~~ *in many cases* as early as ~~5~~6 days before the ~~expected~~ missed 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:
~~Many~~ Some pregnant women will not be able to detect hCG in their urine ~~5~~6 days before the ~~expected~~missed period. If you test negative before your ~~expected~~ 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 if you are a woman age 40 or older:
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~~ and you are a womean nearing age 40 and older.

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

Other Changes to the Box:

- ~~Remove "Early results 6 days sooner". Substitute:~~
- ~~"Early results. In half the samples tested, pregnancy could be detected up to 5 days prior to the day of the expected period."~~
  We propose the following: "Early Results 6 days before your missed period.*"
  And we also propose to place the asterisked information (as follows) on the side panel in bold typeface:
  "* 68 % of users have a correct result when used at this time."

- ~~Remove~~ (b)(4) ~~because this is not the accuracy at 5 days before the missed period.~~
  We propose to keep the (b)(4) statement but will modify the statement by adding, "from the day of the missed period" in clear, large typeface

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Comment [CaDCI1]: We will revise our intended use statement in the 510 (k) as noted.

Comment [CaDCI2]: We have removed "some" since this is not correct. Our data indicates that 68% of women will get the correct answer when using this test. Thus we have used the word "many."

Comment [CaDCI3]: We have removed "5 days before the expected period" and replaced it with "6 days before the missed period" which is what consumers understand. Ever since this early detection segment of products have been on the market (for the fast decade), all marketed products have used the reference to the missed period. If we were to change it at this point there would be consumer confusion as to how and when this test could be used. More importantly, this is the way consumers understand how these products are used. The missed period is the first clinical sign of pregnancy and is the first sign that most woman look for when considering if they are pregnant or not. This is the language they use.

Comment [CaDCI4]: This is an OTC device and is only sold to retailers and is not marketed directly to healthcare professionals.

Comment [CaDCI5]: "Some" is the more correct characterization of the test results.

Comment [CaDCI6]: Please see comment 3 above.

(b)(4)

Comment [CaDCI8]: We agree to remove this but you should be aware that the NAD preferred that manufactures place the clinical accuracy results on the outer packaging so that consumers would be aware of test limitations regarding early testing.

Changes to the package insert information:

Under "instructions and use":

Add a recommendation that women should use first morning urine.

Comment [CaDCI9]: Our data is based on using urine from any time of the day. We do not believe there is a scientific basis for this. Please explain.

Changes to "Q and A" section:

How does the test work?

[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?

[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women ~~may test positive even if they are not pregnant. For example, a study of women~~ aged 41-55 may test positive when using this test. A study showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

Comment [CaDCI10]: See comment 8 above.

What does it mean if the result is negative (not pregnant)

[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?

[The current text should be replaced with the following:

"One study showed positive results for 68% of the samples by 56 days before the ~~expected~~ missed period. In this study, all samples from pregnant women tested positive by ~~2~~3 days before the ~~expected~~ missed period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because ~~it is~~ some women sometimes have difficulty ~~to exactly~~ predicting the exact start ~~day~~ of their ~~expected~~ next period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

Comment [CaDCI11]: See comments above.

No changes to other sections in the Q and A.

Moyer, Vicki

From: Danishefsky, Avis
Sent: Thursday, June 04, 2009 4:45 PM
To: Harper, Courtney C; Moyer, Vicki
Subject: Labeling and Intended use modifications k083716 6 4 09.doc
Attachments: Labeling and Intended use modifications k083716 6 4 09.doc

minor suggestions

First Response Early Pregnancy Test (k083716)

Change to Intended use with black boxed information:

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~~5~~ days before the ~~expected~~ missed period.

Comment [c1]: This recommendation is for the labeling. We request that for the Indications for Use form for the submission that you also insert to read"... 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:
~~Many~~ Some pregnant women will not be able to detect hCG in their urine 6~~5~~ days before the expected period. If you test negative before your ~~expected~~ 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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute (This full statement may be on the side if it fits better. An asterisk should not be used.):
"Early results. In ~~half~~ one study, in 68% of the samples tested, pregnancy could be detected up to 6~~5~~ days ~~prior to~~before the day of the ~~expected~~ missed period."

- Remove (b)(4) [redacted] ~~because this is not the accuracy at 5 days before the missed period.~~ There is not sufficient data for us to conclude that your test is (b)(4) [redacted] in the hands of the intended users (both pregnant and not pregnant). This may be because of the (b)(4) [redacted] for your device which affects this performance metric.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":

We recommend you a~~A~~dd ~~a recommendation that women should use first morning urine.~~the following statement (or similar): "Your first morning urine contains the highest concentration of pregnancy hormone. However, you may test at any time of the day."

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced *with the following:*
"One study showed positive results for 68% of the samples by ~~5~~6 days before the ~~expected~~ missed period. In this study, all samples from pregnant women tested positive by 3~~2~~ days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because some women sometimes have difficulty predicting the exact date~~start~~ of their next ~~it is sometimes difficult to exactly predict the day of the expected~~ period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

Moyer, Vicki

From: Harper, Courtney C
Sent: Wednesday, June 03, 2009 5:49 PM
To: Moyer, Vicki; Danishefsky, Avis
Cc: Benson, Carol; Beaston, Patricia
Subject: Labeling and Intended use proposal k083716 (06 02 09)).doc

Attachments: *Labeling and Intended use proposal k083716 (06 02 09)).doc*

Vicki and Avis -

I wanted to mark up the label, but I see that without a word copy that will be impossible. I edited this to be more definitive and less tentative. We need to add the ages of the perimenopausal subjects. Please take a look and see what you think:

Labeling and Intended use prop...

Courtney

First Response Early Pregnancy Test (k083716)

Courtney's email

Change to Intended use with black boxed information:

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 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:
Many pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected 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 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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute:
"Early results. In half the samples tested, pregnancy could be detected up to 5 days prior to the day of the expected period."
- Remove (b)(4) because this is not the accuracy at 5 days before the missed period.
- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":
Add a recommendation that women should use first morning urine.

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged ?-? showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

Comment [c1]: Need to add ages

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by 5 days before the expected period. In this study, all samples from pregnant women tested positive by 2 days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because it is sometimes difficult to exactly predict the day of the expected period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

Moyer, Vicki

From: Danishefsky, Avis
Sent: Wednesday, June 03, 2009 6:02 PM
To: Harper, Courtney C; Ramamurthy, Lakshman; Benson, Carol; Moyer, Vicki; Beaston, Patricia
Subject: Labeling and Intended use proposal k083716 (06 02 09)) (2).doc
Attachments: Labeling and Intended use proposal k083716 (06 02 09)) (2).doc

I added in the ages 41-55.

First Response Early Pregnancy Test (k083716)

Avis -
add ages
41-55

Change to Intended use with black boxed information:

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 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:
Many pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected 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 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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute:
"Early results. In half the samples tested, pregnancy could be detected up to 5 days prior to the day of the expected period."

- Remove (b)(4) [redacted] because this is not the accuracy at 5 days before the missed period.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":
Add a recommendation that women should use first morning urine.

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by 5 days before the expected period. In this study, all samples from pregnant women tested positive by 2 days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because it is sometimes difficult to exactly predict the day of the expected period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

(b)(4)

Moyer, Vicki

From: Kolakowsky, Stephen [Stephen.Kolakowsky@churchdwight.com]
Sent: Tuesday, June 02, 2009 4:25 PM
To: Moyer, Vicki
Subject: K083716
Attachments: image005.png

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department - Building 100, Princeton, NJ 08543

June 2, 2009

Via eMail and FedEx®

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

This is in response to your eMail of earlier today, which is reproduced below in italic type and followed with our reply to your inquiry.

June 1, 2009 FDA eMail

Thank you very much for your helpful response. I have a follow-up question regarding the inclusion of a weak negative sample hCG concentration (b)(4) [redacted] as part of your stability, product release, and post-market testing programs. Do I understand it correctly that device lots that have (b [redacted] or more positive results a (b [redacted] (b)(4) [redacted] would not meet your acceptance criteria? For example, would lots (b)(4) [redacted] pass your criteria? These particular lots had about (b)([redacted] of positive results as interpreted by the consumers with Immulite values in the 2-3 (b)(4) [redacted] range.

RESPONSE → (b)(4) [redacted]

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Stephen C. Kolakowsky
Director, Regulatory Affairs

The information contained in this message may be confidential and/or subject to legal privilege, and is for the use of the intended addressee only. Any unauthorized use, dissemination or copying of the information in this message is strictly prohibited. If you have received this message in error, please notify the sender immediately and delete this message.

(b)(4)

(b)(4)

Lakshman were in attendance.

The performance of the device demonstrates that the consumers could detect hCG in samples 5 days before the expected period. (b)(4) [redacted] This was identified as a concern in our AI letter (see attached) and the sponsor disagreed that this is an issue (see attached) *If Church and Dwight give us some assurance that they have* (b)(4) [redacted] (b)(4) [redacted] *we would feel comfortable about an SE with stronger labeling (still needs to be worked on).*
<< File: Hold AI LETTER-k083716.pdf >> << File: Response k083716-S1 AI (04.23.09).pdf >>

Stronger labeling is warranted because this device detects concentrations of hCG much lower than other cleared devices. The stronger labeling would include truthful information that some women may not test positive 5 days before expected period, if you are over xx years, you may test positive....

If the above issue can be satisfactorily addressed by the sponsor and they are willing to reconsider their position, we don't think a panel opinion is needed.

If the do not adequately address the concern and label appropriately, we won't SE.

Carol, et al, does this accurately reflect our conclusions?
Courtney, do you support this approach? How should we communicate this to the sponsor?

Vicki

Moyer, Vicki

From: St. Pierre, Don J.
Sent: Friday, May 29, 2009 9:39 AM
To: Harper, Courtney C; Gutierrez, Alberto
Cc: Benson, Carol; Moyer, Vicki; Danishefsky, Avis
Subject: RE: Labeling and Intended use proposal k083716 (05 28 09) (3).doc

Fine by me.

From: Harper, Courtney C
Sent: Thursday, May 28, 2009 8:19 PM
To: St. Pierre, Don J.; Gutierrez, Alberto
Cc: Benson, Carol; Moyer, Vicki; Danishefsky, Avis
Subject: Labeling and Intended use proposal k083716 (05 28 09) (3).doc

Don and Alberto -

Here is an update on the Church and Dwight submission. The team has been working to see if there is anything we can offer the company to do to not go to panel. They have requested some information (new analysis of old data) but have not yet heard back from them. Supposing they get it and it looks acceptable, theye would like to move forward with SE and black box warning. The suggestions for labeling the team has come up with for that scenario are attached.

<< File: Labeling and Intended use proposal k083716 (05 28 09) (3).doc >>

If the data analysis show too much lot variability in this one particular study, then the group would not support SE and would prefer tpo NSE or go to panel.

Let me know if you have strong feelings about this approach one way or the other. If not, I will keep you posted.

Thanks,

Courtney

Moyer, Vicki

From: Harper, Courtney C
Sent: Thursday, May 28, 2009 8:19 PM
To: St. Pierre, Don J.; Gutierrez, Alberto
Cc: Benson, Carol; Moyer, Vicki; Danishefsky, Avis
Subject: Labeling and Intended use proposal k083716 (05 28 09) (3).doc

Attachments: Labeling and Intended use proposal k083716 (05 28 09) (3).doc

Don and Alberto -

Here is an update on the Church and Dwight submission. The team has been working to see if there is anything we can offer the company to do to not go to panel. They have requested some information (new analysis of old data) but have not yet heard back from them. Supposing they get it and it looks acceptable, theye would like to move forward with SE and black box warning. The suggestions for labeling the team has come up with for that scenario are attached.

Labeling and Intended use prop...

If the data analysis show too much lot variability in this one particular study, then the group would not support SE and would prefer tpo NSE or go to panel.

Let me know if you have strong feelings about this approach one way or the other. If not, I will keep you posted.

Thanks,

Courtney

Draft 5/28/09

First Response Early Pregnancy Test (k083716)
Idea for on the box if we proceed with SE:

Changes from current box

- Remove "Early results 6 days sooner" in very large font
- Remove (b)(4) [redacted]
- Add the following language and make it more prominent (not very small on side of box).

This test detected pregnancy (hCG) **5 days before the expected period in approximately half of women tested**. Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again in a few days after your missed period using the first morning sample.

If you are near age 40 or older, or are nearing menopause: there is a chance you may test positive (pregnant) with this test even if you are **not** pregnant. This is because women at ages nearing menopause who are not pregnant have low levels of a compound called "pituitary hCG" which may give a positive result with this test. If pregnancy is suspected, you should see your health care provider.

Intended use:
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 detects hCG in some women, as early as 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.

Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again in a few days (one week) after your missed period using the first morning sample.

There is a small chance that this test will give positive results in the absence of pregnancy.

Moyer, Vicki

From: Danishefsky, Avis
Sent: Thursday, May 28, 2009 2:00 PM
To: Moyer, Vicki
Cc: Ramamurthy, Lakshman; Benson, Carol; Phillips, Tracy; Harper, Courtney C
Subject: Labeling and Intended use proposal k083716 (05 28 09).doc
Attachments: Labeling and Intended use proposal k083716 (05 28 09).doc

Vicki
I think the labeling you sent gets across the main points we wanted. A few small suggestions are tracked within. As we discussed, I'm not sure where this all goes on the box label, and if they specifically need a black box (on the product box), if they have the other suggested language.
If possible, I think the explanation - that the 5 days does not refer to everyone - should be near (or as prominent as) the promotional "5 days".

Also, as we discussed, I morphed some of the suggested label wording to be more similar to your black box wording.

Avis

First Response Early Pregnancy Test (k083716)
Idea for on the box if we proceed with SE:

Changes from current box

- Remove "Early results 6 days sooner" in very large font
- Remove (b)(4)
- Add the following language and make it more prominent (not very small on side of box).

This test detected ~~(hCG?)~~pregnancy (hCG) **5 days before the expected period in half ~~(or some similar language)~~ of women tested**. Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again a few days after your missed period.
~~But some women may not test positive at that early date. **If you test negative before your expected period, but think you may still be pregnant, you should re-test again a few days (one week) after your missed period.**~~

Formatted: Border: Top: (No border), Bottom: (No border), Left: (No border), Right: (No border)

If you are near age 40~~aged ?~~ or older, or are nearing menopause: there is a chance you may test positive (pregnant) with this test even if you are **not** pregnant. This is because women at ages nearing menopause have low levels of a compound called "pituitary hCG" which may interact with this test.

Intended use:
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 cutoff detects hCG, in some cases, as early as 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.

Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again a few days (one week) after your missed period.

There is a small risk that this test will give positive results in the absence of pregnancy.

~~If you believe you are pregnant and if your test is positive, you should seek the advice of a medical provider prior to taking medications or scheduling medical procedures.~~

Moyer, Vicki

From: Danishefsky, Avis

Sent: Wednesday, May 27, 2009 3:37 PM

To: Moyer, Vicki

Subject: possible other questions

Vicki,
My questions are in blue below. The first one is for you. The next 2 may be for the sponsor, if you think it's appropriate. Thanks. Avis

Vicki, in the document regarding response to protocols the sponsor describes (b conceptive cycles. *Did they later add more to reach* (b)(4)

(b)(4)

Panel members recommended that women with urine hCG concentrations samples above 2 - 5 mIU/mL (depending on the panel member) are likely to be pregnant. This implies that samples below 2-5 mIU/mL should read negative. This test reads some samples at (b)(4) as positive. *What criteria is the sponsor using to ensure that samples at these low levels will not read positive?*

One benefit cited by the panel members is that someone could plan early, or avoid procedures. But, if the test is negative early on, and a woman thinks she may be pregnant, she should still avoid procedures, anyway. The risk would be if the woman assumes she is NOT pregnant because of misunderstanding the test claim.

Moyer, Vicki

From: Moyer, Vicki
Sent: Wednesday, May 27, 2009 4:21 PM
To: 'Kolakowsky, Stephen'
Cc: Harper, Courtney C
Subject: k083716 consumer study and library questions

Hello Mr. Kolakowsky,
We have a few more questions which we think would be helpful in understanding the performance of the First Response pregnancy test under review (k083716).

(b)(4)

[redacted]

2) Please provide a summary of the results of the conceptive cycle study (Tables 1 and 2, page 19 of submission) by lot, for the (b)(4) of devices in the study.

Please provide this information at your earliest convenience. Thank you in advance for your assistance. If you have any questions, please feel free to contact me.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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Moyer, Vicki

From: Moyer, Vicki
Sent: Friday, May 29, 2009 10:30 AM
To: 'Kolakowsky, Stephen'
Cc: Harper, Courtney C; Moyer, Vicki
Subject: k083716 S1 response

Dear Mr. Kolakowsky-

Can you please provide a few additional pieces of information regarding your response to item 1 of the February 25, 2009 hold letter?

On page 2 of your response, you state
(b)(4)
[redacted]

Please clarify "stability protocol and product release/acceptance criteria." Do you intend to include (b)(4) (b)(4) sample with acceptance criteria for performance in your stability protocol alone? Or does this mean that you intend to include a (b)(4) sample in your product specifications/manufacturing criteria and or post-manufacturing quality control criteria?

On page 3 you explained that any lot to lot inconsistency shown in the consumer variability study may be due to the variability of (b) consumers reading the devices in the study. In order for us to have a more balanced understanding of the device performance, please provide a summary of the conceptive cycle study as interpreted by the study monitor for each lot of devices tested. In following up from my e-mail to you on Wednesday, May 27, 2009, please provide both the consumer and study monitor interpretation for the data on page 19 Tables 1 and 2 of your submission, summarized by lot.

Please provide this information at your earliest convenience. Thank you in advance for your assistance. If you have any questions, please feel free to contact me.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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(b)(4)

Moyer, Vicki

From: Harper, Courtney C
Sent: Monday, May 18, 2009 9:25 AM
To: Danishefsky, Avis ; St. Pierre, Don J.; Benson, Carol; Moyer, Vicki
Cc: Gutierrez, Alberto
Subject: RE: Church and Dwight

We will meet to discuss. In addition to labeling, we may have some analytical concerns with lot variability and measurement at low hCG concentrations.

We can meet Thursday in our already scheduled time. Carol, since you will not be in Thursday, please let one of us know if you have thoughts/suggestions.

Thanks,

Courtney

From: Danishefsky, Avis
Sent: Monday, May 18, 2009 9:23 AM
To: St. Pierre, Don J.; Harper, Courtney C; Benson, Carol; Moyer, Vicki
Cc: Gutierrez, Alberto
Subject: RE: Church and Dwight

I suggest we reconsider labeling.

(b)(4)

[redacted]

(b)(4)

Church & Dwight Co., Inc.
c/o Mr. Stephen Kolakowsky
469 North Harrison Street
Princeton, NJ 08543

Decision making
4/29/09 Response

Re: k083716
Trade Name: FIRST RESPONSE® Early Result Pregnancy Test
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Kolakowsky,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the additional information outlined below.

1. FDA continues to be concerned about the performance of the device in measuring (b)(4) (b)(4)

   (b)(4) FDA recommended that you modify your stability study protocol and acceptance criteria to include a (b)(4) (b)(4) FDA continues to be concerned that your previously stated criteria are not adequate to control stability trends over time and (b)(4) You indicated in a recent email to FDA that a sample with hCG concentration (b)(4) (b)(4) is tested as part of your stability and lot release protocols. The acceptance criterion is that the test device must produce a (b)(4) (b)(4) We disagree that inclusion of a sample at (b)(4) is adequate to mitigate our concerns because a sample of this concentration does not represent a (b)(4) sample. The hCG level of this type of sample should reflect a concentration where lab professionals and/or lay users should get a negative result. We consider a weak negative to be a sample that produces a negative result 95% of the time. You may find the CLSI "User Protocol for Evaluation of Qualitative Test Performance" EP12-A2 helpful when evaluating the performance of your device. Please note, instead of the term "weak negative" the protocol uses the term C_5. The C_5-C_{95} interval is defined as the range of analyte such that observed results outside of the interval are consistently negative ($<C_5$) or consistently positive ($>C_{95}$).

   At the request of FDA you provided a summary of the Consumer Readability Study for the (b)(4) of test devices and with sample hCG concentrations by rank order. There appears to be significant performance differences between the (b)(4) tested. We are particularly concerned that for (b)(4) that (b) of samples in the range of (b)((b)(4) were interpreted as Positive, while for the other (b)(4) (b)(4) of samples in this same concentration range were interpreted as Positive. For this same lot, (b) of samples with concentration in the range of (b)(4) were

interpreted as Positive. Additionally, (b) samples with hCG concentrations (b)(4) (b)(4) were interpreted as positive for (b)(4) while (b)(4) samples were interpreted as positive for (b)(4). (Note: following your response, we identified two other observations where the specimen had hCG (b)(4) specimen (b)(4) interpreted the result as positive using (b) (b)(4)

These data suggest that the performance of the device in detecting very low levels of hCG is not well characterized and that manufacturing in-process testing criteria to ensure lot to lot consistency may not be adequate.

Please perform studies with multiple lots of test devices to determine at what concentration of hCG a weak negative result is achieved. Please revise your stability protocols to include a weak negative sample. Additionally please address how you plan to resolve issues of lot to lot variability.
See Church and Dwight's response. They have identified that (b)(4) is a weak negative in the test but have not added it to part of their stability protocol. They don't seem to understand the need for a weak negative.

They disagree that they have a lot to lot problem. Other lot to lot studies they previously performed do not show the same variability, but were performed by lab professionals (see examples in template). With that being said, ***the data "speaks".***

2. With regard to the validation studies in support of the use of the (b)(4) to quantitatively measure hCG in urine, in an e-mail dated January 9, 2009, FDA asked for additional detail on the study performed to evaluate the limit of quantitation. Specifically we asked for the criteria for acceptable precision and trueness. In your response, you referred to the (b)(4) validation protocol provided as exhibit III and stated that studies were performed based on the recommendations of CLSI EP17-A "Protocols for Determination of Limits of Detection and Limits of Quantitation;" however, we still have questions about your acceptance criteria and data analysis. In order for us to better understand the conclusions of the validaton study including the limit of blank and limit of quantitation please provide the line data for these studies.
See Church and Dwight's response. I don't really understand what they are saying. The fact is that when the standard is spiked it (b)(4) the recovery as measured on the (b)(4) ranges from (b)(4) They claim the LOQ is (b)(4) The (b)(4) reports values (b)(4) Based on their study, I'm unsure of the accuracy at the very low end (b)(4)

3. On page 15 of your submission, you included a completed Indications for Use form, however, this is not the most current version of the form. Please obtain the current version of the form that can be found at The Office of In Vitro Diagnostic Evaluation and Safety website: http://www.fda.gov/cdrh/oivd/indicationsforuse.html, complete it and resubmit it

with your response. Additionally, please add "up to 5 days before the expected period" to the existing language.

4. In the Questions and Answers section of the device labeling, you describe that "about 2% of women (all over the age of 47) had very low levels of hCG" using your device. However, in a study performed by testing the urine of (b)(4) [redacted] (b)(4) [redacted] In a similar study testing urines from (b)(4) [redacted] (b)(4) [redacted] Please revise the Questions and Answers section to reflect the actual test results obtained for both the (b)(4) [redacted] (b)(4) [redacted]

   Church and Dwight: "As explained in our telephone conference call, the Division has previously approved for competitive products now in the marketplace the language structure we use in our labeling statement. We believe the Company should be allowed to use the same language structure as that cleared previously for other OTC pregnancy test devices."

   (b)(4) [redacted]

   The labeling does include the typical warnings about what the result could mean or not mean, but it is appropriate that this device have more information about likelihood of false-positive results.

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html
You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device

(b)(4)

(b)(4)

Moyer, Vicki

From: Moyer, Vicki
Sent: Thursday, April 30, 2009 3:53 PM
To: Harper, Courtney C; Benson, Carol
Cc: Danishefsky, Avis
Subject: Church and Dwight k083716-S1 response

Attachments: k083716 dec. summary draft.doc; Response k083716-S1 AI (04.23.09).pdf; K3-AI LETTER-k083716-04.30.09.DOC

Hello-
I have reviewed the sponsor's response to our concerns and discussed many of the concerns with Avis. The AI letter, our draft template with all of the data, and the sponsor's response are attached for your reference. In formulating these thoughts, I considered the most recent concerns as well as previous discussions with management ([redacted] on the performance of this device and whether or not it is substantially equivalent to other similar devices, as well as statements from experts (homework assignment) and clinical laboratorians.

Here are my comments:

- Consumers appear to be able to read and interpret hCG in their urine 5 days before the expected period. This claim is supported. Many interpret results even before this date.
- The actual cut-off of the device appears to vary in the hands of consumers and from lot to lot (conceptive cycle consumer study). The cut-off (50/50) appears to be in the [redacted] range if read by consumers.
- We did not request to see this latest study as read by professionals summarized by lot or by rank order as we did the consumer results. Previous studies with lab professionals don't exhibit as much variability lot to lot. The cut-off (50/50) is less than [redacted] but not really known.

But pregnant

[redacted]

[redacted]

[redacted]

(b)(4)

[redacted]

Courtney, Carol-We only have about 10 days left to make our decision. Should I set-up a meeting to discuss or do you have a clear idea of the path we should follow?

k083716 dec. summary draft.doc.. | Response 83716-S1 AI (04.23 | K3-AI ER-k083716-04.30.

Vicki

OIVD Add-to-File ROUTE SLIP

Due Date is 30th Day: Oct 30, 2009

510(k) No.: K083716/A009	Reviewer: VYM
Applicant: Church & Dwight Co.	Re-Assigned: _____
Date Received in DMC: 9-30-09	
Branch: CHTB	PostMarket Database: _____

OIVD Action:			
Date:	Action:	Initials:	Logout Date:
10-2-09	Logged In	JMM	
10/21/09	NR	VYM	
2-3-10	Rcvd. 2-3-10	CCB	2-3-10

File given to Renita in error.

ACTION CODES

AI	Additional Information Requested (K-3 Letter)
AN	Approved Evaluation of Auto Class III Designation
CS	CLIA Cat. - Substantially Equivalent
CC	Information requires CLIA categorization
CR	Applicant can't respond in 30 days (K-9 Letter)
DB	Forwarded to Drugs/Biologics
DD	Deleted/Duplicate
DE	Deleted
DN	Denied Evaluation of Automatic Class III Designation
DR	Drug/Biologic Review Required
EX	Exempted by Regulation
FB	Subject to 515(b) – Requires PMA
FR	Final Recision
GP	General Purpose Article
HD	Appeal is on HOLD
IC	Information Incomplete (call or fax)
K4	Closeout Letter Issued
KD	Substantially Equivalent – Kit and Drugs
NA	Not Actively Regulated
NC	CLIA K25 Letter
ND	Not a Device
NE	Not Substantially Equivalent
NF	Not a Finished Product
NK	Additional Information Requires a New 510(k) K30 letter
NR	No Response Necessary
NT	No change in 510(k) status k25 letter
OD	Unable to Determine Equivalence
ON	Other Evaluation of Auto Class III Designation
OT	Other Decision/Other Action – Explain in Detail on the Front of this Page
PE	Pre-Amendment Exempt
PR	Substantially Equivalent – Proposed Recision
PT	Substantially Equivalent – Subject to Tracking & PMS
RA	Refuse to Accept
RC	Reconditioner/Remanufacturer
RE	Rescind Substantially Equivalent
RN	Substantially Equivalent – Rescind Non-Substantial Equivalent
SA	Substantially Equivalent – Awaiting Device Approval
SC	Not Substantially Equivalent – Cannot Market
SD	Substantially Equivalent with Drug
SE	Substantially Equivalent (No CLIA needed)
SF	Substantially Equivalent – Awaiting Future Policies
SI	Substantially Equivalent – Market After Inspection
SK	Substantially Equivalent – Kit
SL	Not Substantially Equivalent – Improper Label
SN	Substantially Equivalent for Some Indications
SP	Substantially Equivalent – Post Market Surveillance Require
SS	Substantially Equivalent – Special Labeling
ST	Substantially Equivalent – Subject to Tracking Reg.
SU	Substantially Equivalent – with Limitations
SW	Substantially Equivalent – Awaiting Drug Approval
TH	Telephone HOLD
TR	Transitional Device
UB	Unable to Determine Equivalence – Outstanding Biologic Issue
UO	Unable to Determine Equivalence – Outstanding Drug Issue
UR	Not Substantially Equivalent – Unreliable Data
WD	Withdrawn by Applicant
XS	Not a Required Submission

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 10/1/09

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K083716/A9

To: Division Director: CH / DCTD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

✓ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

✓ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [signature]

Date: 10/21/09

PCC 2/4

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department - Building 100, Princeton, NJ 08543

K083716/A9

Via FedEx

September 29, 2009

U.S. Food and Drug Administration
Center for Devices and Radiological Heath
Office of In Vitro Diagnostic Device
Evaluation and Safety
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 30 2009
Received
K.62

ATTN: Vicki A. Moyer
Room 5629

Re: 510(k) #K083716
FIRST RESPONSE® Early Result
Pregnancy Test (OTC)

Dear Ms. Moyer:

In response to your 9/25/2009 eMail, in which you stated you were unable to print out a complete copy of the carton and package insert labeling attached to my 9/09/2009 eMail, we are submitting herewith, in duplicate, print outs of courtesy copies for FDA's file of the carton and insert draft labeling for the FIRST RESPONSE® Early Result Pregnancy Test for OTC use as previously cleared June 8, 2009, under K083716.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

Enclosures (2) – in duplicate

H:\data\ANSWER_1RESPONSE\Pregnancy\510(k)LIMBOHI\510k_K083716\Ltr092909Lblg.docx

SCANTIBODIES, VERSION 123D
2-13/16 X 1-3/16 X 7-1/4
PRINT SIDE

DRAFT

Proud to Support

march of dimes

The moment you know you're pregnant, the sooner you can start giving your baby a healthy start. FIRST RESPONSE® is proud to support March of Dimes, the leading nonprofit organization for pregnancy and baby health. With chapters nationwide and its premier event, March for Babies, March of Dimes works to improve the health of babies. For the latest resources and information, visit marchofdimes.com or marcheforbabies.org.
The March of Dimes does not endorse specific products or brands.

In one study, in 88% of the samples tested, pregnancy could be detected up to 6 days before the day of the missed period.
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.

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 retest 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 the test will give positive results even if you are not pregnant. Chances of this are greater for women nearing age 49 and older.
All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

FIRST RESPONSE® PREGNANCY

Pregnancy Test EARLY RESULT

Questions: Call toll-free 1.800.367.6027 M-F, 7am-5pm ET or visit www.firstresponse.com

FIRST RESPONSE® PREGNANCY

Pregnancy Test EARLY RESULT

2 TESTS

LOT
EXP. DATE

FDO 80%
0 22600 90125 2
0 00000 00000 0
FRFC 90125 275

This kit contains 2 FIRST RESPONSE® Early Result Pregnancy Test sticks and instructions (in English and Spanish).

- Follow complete instructions inside box. Instrucciones en Español adentro.
- Remove Overcap and place absorbent tip in urine stream for 5 seconds. Results in 3 minutes.
- Results interpreted right on the stick.

For in vitro diagnostic use. Not to be taken internally. Store at a dry place below 86°F (30°C). Do not freeze. Keep out of reach of children.

First Response and 1 are registered trademarks of Church & Dwight Co., Inc.

Manufactured by Scantibodies Laboratory, Inc., Santee, CA 92071.

Distributed by Church & Dwight Co., Inc., Princeton, NJ 08543.

US Patents 5,141,850; 6,319,676; 6,767,714; 7,045,342; D548,359; and patent pending.

Do not use this product after expiration date.

FIRST RESPONSE® PREGNANCY

Pregnancy Test EARLY RESULT

2 TESTS

DRAFT

FOLDS

8-3/4"

At-Home Test for the Detection of Pregnancy

INSTRUCTIONS AND USE

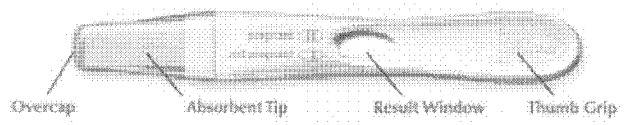
PLEASE READ ALL THE INFORMATION IN THIS LEAFLET BEFORE PERFORMING THE TEST.
Do not use after the expiration date stamped on the side of the carton. Store in a dry place below 86°F (30°C).
Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally.
If you have any questions, call us toll-free at 1-800-367-6022, Monday-Friday from 7:00 AM to 5:00 PM Eastern Time. Visit us online at www.firstresponse.com

When to use the FIRST RESPONSE® Early Result Pregnancy Test

The FIRST RESPONSE® test is so sensitive that it can detect hCG as early as 6 days before your missed period.
You can use the test anytime of the day. You do not have to use the first morning urine.
Generally, however, your first morning urine contains the highest level of the pregnancy hormone.

INSTRUCTIONS

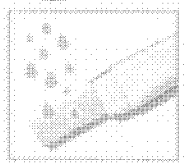
- Remove test stick from the foil wrapper and take off the **Overcap**.



STEP 1

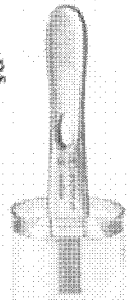
EITHER

- Holding the test stick by the **Thumb Grip** with the **Absorbent Tip** pointing downward and the **Result Window** facing away from your body, place the **Absorbent Tip** in your urine stream for 5 seconds only.



OR

- You may also collect your urine in a clean, dry cup and immerse the entire **Absorbent Tip** in the urine for 5 seconds only.



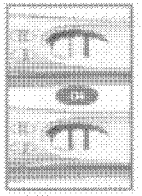
READING THE RESULT—READ YOUR RESULT AT 3 MINUTES

STEP 2

- With the **Absorbent Tip** still pointing downward, replace the **Overcap*** and lay stick on a flat surface with the **Result Window** facing up.
- You may soon see a pink color moving across the **Result Window** to indicate the test is working.
- Wait 3 minutes until reading results.

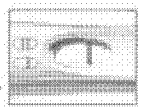
*Replacement of the Overcap is not necessary for the proper functioning of the test.

STEP 3



PREGNANT
TWO PINK LINES in the **Result Window.**
One line may be lighter than the other.
Appearance of the results may vary.

NOT PREGNANT
ONE PINK LINE in the **Result Window.**



QUESTIONS & ANSWERS

Q: How does the test work?
A: The FIRST RESPONSE® Early Result Pregnancy Test detects in urine the hormone your body makes during pregnancy: hCG (human chorionic gonadotropin).

Q: What do I do if the result is positive (pregnant)?
A: A positive (pregnant) test result shows that the pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant. Because this test detects very low levels of hCG, some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.

Q: What do I do if the result is negative (not pregnant)?
A: You may not be pregnant, or it may be too early to tell. If you do not get your period within 7 days, you should retest with another FIRST RESPONSE® Early Result Pregnancy Test. It is possible that you miscalculated the length of your cycle or your urine may not have had enough pregnancy hormone for the FIRST RESPONSE® Test to give a positive result. If you retest and again no hCG is found, and your period still has not started, you should call your doctor. See section below – "How accurate is the test?"

Q: How accurate is the test?
A: One study showed positive results for 68% of the samples by 6 days before the missed period. In this study, all samples from pregnant women tested positive by 4 days before the missed period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because some women sometimes have difficulty predicting the exact date of their next period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider.

Q: I have waited longer than 3 minutes, and still there are no lines in the Result Window. Is there anything wrong?
A: Your result should appear within 3 minutes. There should be at least one pink line in the **Result Window** at 3 minutes to indicate that the test is completed and you have done it correctly. If not, the test is invalid. This could be due to insufficient urine on the **Absorbent Tip** or not holding the device with the **Absorbent Tip** pointing downward while replacing the **Overcap**. You should retest with another device, carefully following all directions.

Q: Will the result change if left standing for a certain period of time?
A: The test result should be read as soon as possible after waiting the 3 minutes. A negative result should not be read after 10 minutes.

Q: Do any drugs or medications affect the test?
A: Only medications containing the pregnancy hormone (hCG) can affect the result (e.g., A.P.L.[1], Pregnyl[2], Profasi[4] and Pergonal[4]). The test should not be affected by hormone therapies containing Clomiphene citrate (e.g., Clomid[2] and Serophene[5]), alcohol, painkillers, antibiotics, or the contraceptive pill.

If you have any questions, call us toll-free at 1-800-367-6022, Monday-Friday from 7:00 AM to 5:00 PM Eastern Time.
Visit us online at www.tellsyourfirst.com

To increase your chances for a healthy pregnancy for you and your baby, you should consider the following:
- Maintain a well-balanced diet
- Stop smoking

From conception through the first three months of pregnancy is the most important time. You need to see your doctor immediately for proper care and nutrition counseling.

WARNING: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.

Trying to get pregnant...
Many women do not know that their most fertile days are the days leading up to ovulation (when your ovary releases an egg to be fertilized by the sperm). To become pregnant sooner, you should become more familiar with your ovulation cycle. The FIRST RESPONSE® Easy-Read Ovulation Test kit is an at-home, one-step test designed to predict ovulation by monitoring changes in your hormone levels. With the help of the FIRST RESPONSE® Easy-Read Ovulation Test kit, you can predict your peak fertility days and get pregnant sooner.

Distributed by Church & Dwight Co., Inc.,
Princeton, NJ 08543 ©1995, 2003
U.S. Patent Nos. 5,141,850; 5,359,676; 6,767,314; 7,045,340 and
U.S. patent pending FIRST RESPONSE is a registered trademark of
Church & Dwight Co., Inc.

1 A.P.L. is a registered trademark of Wyeth-Ayerst Laboratories Division of American Home Products Corp.
2 Clomid is a registered trademark of Merrell Pharmaceuticals Inc.
3 Pregnyl is a registered trademark of Organon USA, Inc.
4 Profasi and Pergonal are registered trademarks of Ares Trading S.A.
5 Serophene is a registered trademark of Serono Inc.

MANUFACTURER'S COPON | EXPIRES 12/07/

SAVE $1.00
On Any First Response®
Pregnancy Test

F.P.O. F.P.O.
s 22600 32076 s (8100) 0 13645

FPO

RETAILER: Only U.S. retail distributors of product listed or others specifically authorized by us may redeem coupon for face value plus 8¢ handling if terms of offer are met. Valid only for product stated. Limit 1 coupon per purchase. Consumer must pay any sales tax. Upon request, retailer must show invoices for enough stock to cover coupons presented. Void where prohibited, taxed, licensed, or restricted. Cash value 1/100¢.

Mail to: Church & Dwight Co., Inc.,
CMS Dept. #33200,
1 Fawcett Drive, Del Rio, Texas 78840
©2006 Church & Dwight Co., Inc.

MANUFACTURER'S COPON | EXPIRES 12/07/

SAVE $1.00
On Any First Response®
Easy-Read Ovulation Test

F.P.O. F.P.O.
s 22600 31076 s (8100) 0 13646

FPO

RETAILER: Only U.S. retail distributors of product listed or others specifically authorized by us may redeem coupon for face value plus 8¢ handling if terms of offer are met. Valid only for product stated. Limit 1 coupon per purchase. Consumer must pay any sales tax. Upon request, retailer must show invoices for enough stock to cover coupons presented. Void where prohibited, taxed, licensed, or restricted. Cash value 1/100¢.

Mail to: Church & Dwight Co., Inc.,
CMS Dept. #33200,
1 Fawcett Drive, Del Rio, Texas 78840
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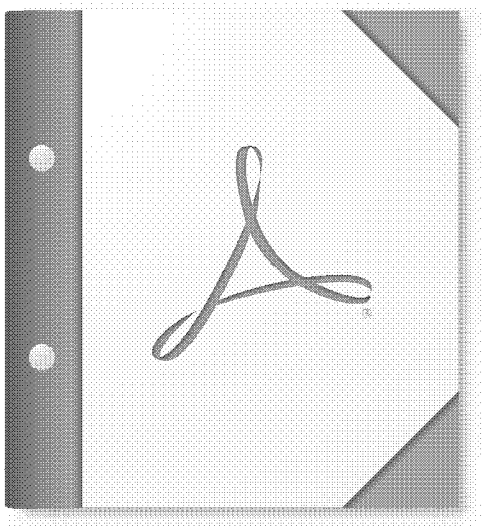
FBIN-90127-00



For the best experience, open this PDF portfolio in Acrobat 9 or Adobe Reader 9, or later.

Get Adobe Reader Now!

K083716/A1

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

January 9, 2009

Via FedEx

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC
JAN 12 2009
JAN 13 2009
Received
K34

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

Enclosed for the record is a copy of the eMail that I sent to you on January 9, 2009, in reply to your eMail of December 22, 2008.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

In Duplicate

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Kolakowsky, Stephen

From: Kolakowsky, Stephen
Sent: Friday, January 09, 2009 3:03 PM
To: 'Moyer, Vicki'
Subject: RE: First Response pregnancy test (k083716)

Importance: High
Sensitivity: Confidential

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration

Re: 510(k) #K083716 – FIRST RESPONSE® Early Result Pregnancy Test (OTC)

Dear Ms. Moyer:

This responds to your below eMail of December 22, 2008. We believe that we have fully provided the clarifications requested in your three inquiries and hope that you also find this to be the case. Following are your three inquiries in bold face serif black type with our response immediately following each inquiry in non-bold, non-serif red type.

(1) I have a few preliminary questions about Exhibit III, the (b)(4) validation studies and protocol (b)(4) For the limit of detection and limit of quantitation studies, was a sample at (b)(4) the only sample tested or were other levels of hCG tested also?

Yes, the (b)(4) level was the only level tested. As noted in the Method Validation Protocol (b)(4) beginning on page 103 of the 510(k) and as noted in the Validation Study Report beginning on page 98 of the 510(k), guidelines of the Clinical Laboratory Standards Institute as recommended by FDA were utilized.

(2) Can you please give me a little more detail on the criteria for defining the LoQ? What was the "acceptable precision and trueness" that is stated in the study report? For example, for some devices the LoQ is defined as the concentration where the %CV across many runs is 15% and where the device was shown to be accurate.

The "acceptable precision and trueness" cited in the study report is derived from recommendations given in CLSI-EP17A. The precision was the total standard deviation across all of test results utilized to generate the LoQ. The trueness, or bias, was the closeness of agreement between the average value of those test results and the accepted reference value of (b)(4)

The total error was defined by the equation given in section 3.2.3 of the (b)(4) Validation Protocol, and accounted for both the precision and trueness inherent within the system.

The calculated value for the total error was less than the LoD. Goals for total error are dependent upon intended usage (in our case a reference method), and

acceptable cutoffs are left to the discretion of the laboratory in which the method shall be utilized.

As per CLSI-EP-17A, if the total error is less than the goal for total error defined by the laboratory, than the procedure ensures that for samples with a true value equal to the LoQ (in this instance (b)(4) [redacted]) there is approximately 95% probability that the test result will be sufficiently accurate.

(3) For the accuracy study on page 3 of the study report, table 2 shows % accuracy and % cumulative accuracy. I want to make sure I understand the table. For (b)(4) [redacted] the stated accuracy is (b)(4) [redacted] Does this mean that (b)(4) [redacted] of the samples prepared to be a concentration of (b)(4) [redacted] were observed to be (b)(4) [redacted] when tested on the (b)(4) [redacted] method? Please explain.

For a given series of replicates at a given expected concentration, the mean value of those replicates would have the % accuracy stated in Table 2 relative to the expected value of the series. (The cumulative accuracy is the average of the individual values.) Therefore, in the example of the case of the (b)(4) [redacted] series, the calculated mean (b)(4) [redacted] of the replicates tested on the Immulite was (b)(4) [redacted] of the expected value of 5 mIU/mL.

We are currently addressing your second eMail request from January 8, 2009, for the consumer study values to be re-presented in mIU/mL rank order, and we expect to respond early next week to your second request.

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Monday, December 22, 2008 11:28 AM
To: Kolakowsky, Stephen
Subject: First Response pregnancy test (k083716)

Dear Mr. Kolakowsky,
We received your 510(k) for the First Response Early Result Pregnancy Test and it was assigned number k083716. I have been assigned again as lead reviewer for this device.

I have a few preliminary questions about Exhibit III, the (b)(4) [redacted] validation studies and protocol (b)(4) [redacted]
For the limit of detection and limit of quantitation studies, was a sample at (b)(4) [redacted] the only sample tested or were other levels of hCG tested also?

Can you please give me a little more detail on the criteria for defining the LoQ? What was the "acceptable precision and trueness" that is stated in the study report? For example, for some devices the LoQ is defined as the concentration where the %CV across many runs is 15% and where the device was shown to be accurate.

For the accuracy study on page 3 of the study report, table 2 shows % accuracy and % cumulative accuracy. I want to make sure I understand the table. For (b)(4) [redacted] the stated accuracy is (b)(4 [redacted] Does this mean that (b)(4) [redacted] of the samples prepared to be a concentration of (b)(4) [redacted] were observed to be (b)(4) [redacted] when tested on the (b)(4) [redacted] method? Please explain.

Thank you in advance.
Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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K083716/A2

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

January 13, 2009

Via FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH
JAN 14 2009
Received

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

Enclosed for the record is a copy of the eMail that I sent to you on January 13, 2009, in reply to your eMail of January 8, 2009.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

K7

In Duplicate
* Track #7972 4706 4614

H:\data\ANSWER_TRESPONSE\Pregnancy\510(k)LIMBOIII\510k_K083716\03.doc

Kolakowsky, Stephen

From: Kolakowsky, Stephen
Sent: Tuesday, January 13, 2009 2:45 PM
To: 'Moyer, Vicki'
Cc: Benson, Carol; Harper, Courtney C; Cooper, Jean M
Subject: RE: k083716 Consumer study results

Importance: High
Sensitivity: Confidential

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration

Re: 510(k) #K083716 – FIRST RESPONSE® Early Result Pregnancy Test (OTC)

Dear Ms. Moyer:

This responds to your below eMail request of January 8, 2009, wherein you requested a re-presentation of the data of Appendix 1 of Exhibit I of the 510(k) submission dated December 12, 2008, in order that you and your colleagues at FDA might better understand the results of our Consumer Readability Study. The re-presentation of data is provided in Table 2 below as requested with study values equal to or (b)(4) [redacted] in rank order and the number of positive and negative observations indicated.

We note that you make a comment in the opening paragraph of your below eMail that the (b)(4) [redacted] It is not at all clear to us why you might be raising this matter again at this time since we are under the understanding that this matter has been more than thoroughly discussed and settled; and furthermore, that the entire purpose of the Consumer Readability Study requested by FDA was the outcome of the discussion. Table 1 on page 8 of the 510(k) submission of December 12, 2008, presents the results of the Consumer Readability Study in terms of pregnancy detection prior to the expected menstrual period (EMP). Table 1 includes the presentation of the results in terms of positive test results per cycle day, which is the basis for the product claim. The product's performance claim is made in terms understandable to the lay consumer —days before the expected missed period — and technical scientific terms familiar to laboratory professions — e.g., sensitivity and mIU —are not utilized because they are meaningless to the lay consumer.

Table 2: FIRST RESPONSE® Early Result Pregnancy Test (OTC)
Consumer Readability Study
Results Verses hCG Values

hCG	(b)(4)												Total			
mIU	N	Neg	Pos	%Pos	N	Neg	Pos	%Pos	N	Neg	Pos	%Pos	**N**	**Neg**	**Pos**	**%Pos**
(b)(4)	70	70	0	0%	72	70	2	3%	72	71	1	1%	**214**	**211**	**3**	**1%**
	22	17	5	23%	24	19	5	21%	16	15	1	6%	**62**	**51**	**11**	**18%**
	20	9	11	55%	10	2	8	80%	14	10	4	29%	**44**	**21**	**23**	**52%**
	18	4	14	78%	18	2	16	89%	8	4	4	50%	**44**	**10**	**34**	**77%**
	6	2	4	67%	10	2	8	80%	12	1	11	92%	**28**	**5**	**23**	**82%**
	2	0	2	100%	2	0	2	100%	6	0	6	100%	**10**	**0**	**10**	**100%**

We hope that this additional information will allow you to complete your review and clear our 510(k).

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Thursday, January 08, 2009 11:52 AM
To: Kolakowsky, Stephen
Cc: Benson, Carol; Harper, Courtney C; Cooper, Jean M; Moyer, Vicki
Subject: k083716 Consumer study results

Dear Mr. Kolakowsky,
I have reviewed the consumer study data and need your help in helping me understand some of the results. You provided in Appendix 1 the observations of the study participants for each patient specimen tested (pregnant or not pregnant), along with the hCG value as determined by the (b)(4) method. You have stated that (b)(4)

Please summarize the study data for (b)(4) values (b)(4) in rank order and indicate the number of observations that were positive or not positive. Please present this data for each of the (b)(4 of kits included in the study as well as combined.

It is our goal to work with you interactively and keep the review process moving along. Therefore, please provide this requested information at you earliest convenience. I also look forward to receiving the response from Dr. Nazareth on my last set of questions.

If you have any questions, please do not hesitate to contact me.

Best wishes for the new year to you and your colleagues.
Regards,
Vicki

Vicki Moyer
Scientific Reviewer

111

Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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K083716/A3

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

February 5, 2009

Via FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC
FEB 6 2009
Received

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

Enclosed for the record is a copy of the eMail that I sent to you on February 5, 2009, in reply to your eMail of January 30, 2009, regarding the Acceptance Criteria for initial lot release and stability monitoring.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

In Duplicate
* Track #7973 1252 3432

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K25
105

Kolakowsky, Stephen

From: Kolakowsky, Stephen
Sent: Thursday, February 05, 2009 9:48 AM
To: 'Moyer, Vicki'
Subject: RE: First Response Items of Concern-k083716
Attachments: Stability_R1.doc

Importance: High
Sensitivity: Confidential

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration

Dear Ms. MOYER .....

In response to your eMail below, be advised that as recommended, the Acceptance Criteria for the FIRST RESONSE® Early Response Pregnancy Test has been revised to include the requirement for (b)(4) [redacted] for initial lot release and in the Stability Protocol. The attached table outlining our Stability Protocol is a revision of Exhibit 1 of our April 3, 2008 Additional Information submission on (b)(4) [redacted], a copy of which was sent to you last week on January 28, 2009.

..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, January 30, 2009 1:00 PM
To: Kolakowsky, Stephen
Cc: Moyer, Vicki
Subject: First Response Items of Concern-k083716

Dear Mr. Kolakowsky,
As part of the current review of k083716 for First Response pregnancy test, we also review any items of concern from previous relevant Not Substantially Equivalent decisions, (b)(4) [redacted]

Please explain how Church and Dwight will address concerns related to the stability protocol and lot release criteria outlined in our NSE letter. For your convenience the paragraph from our letter is inserted below:

We are concerned that the stability protocol used to support the 24-month shelf-life for the FIRST RESPONSE® Early Result Pregnancy Test is not adequate because the acceptance criteria are too broad. You have stated that the device is designed to give an unequivocal result at 8-10 mIU/mL in the hands of consumers. The protocol calls for testing (b)(4) (b)(4) The acceptance criteria state that the (b)(4) (b)(4) (b)(4) Based on these criteria you do not seem to have a mechanism to determine the concentration of hCG at which consumers should get a negative result. This concentration could vary by lot between (b)(4) and (b)(4) It will be difficult to track instability trends over time without characterizing the performance of the device (b)(4) Therefore, we recommend that you modify your stability study acceptance criteria to include performance requirements at (b)(4) (e.g., ((b)(4) over time. We are also concerned that your manufacturing lot release criteria may not be adequate to control (b)(4) for your claim of a consumer cutoff of (b)(4) (b)(4) We recommend that you include lot release testing requirements at (b)(4) (b)(4) as well.

If I can be of assistance, please do not hesitate to contact me.

Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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(b)(4)

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

K083716/4Y

February 13, 2009

Via FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

FDA CDRH DMC
FEB 17 2009
Received

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

Enclosed for the record is a copy of the eMail that I sent to you on February 13, 2009, in reply to your eMail of the same date, regarding interpretation of the summary data tables of the Consumer Readability Study.

Sincerely,

Stephen C. Kolakowsky
Director, Regulatory Affairs

In Duplicate
* Track #7973 3875 4172

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K30 101

Kolakowsky, Stephen

From: Kolakowsky, Stephen
Sent: Friday, February 13, 2009 2:45 PM
To: 'Moyer, Vicki'
Subject: RE: k083716-consumer study results clarification

Importance: High
Sensitivity: Confidential

February 13, 2009

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration

Re: K083716 FIRST RESPONSE® Early Result Pregnancy Test (OTC)

Dear Ms. MOYER:

This responds to your eMail message below.

1. Study samples were taken from a library of (b)(conceptive cycles. A segment of (b)(4) samples from each individual cycle was used in the study according to the selection criteria specified in the protocol. Each of (b)(4) samples was separately examined by (b)(4) in the Consumer Readability Study. Therefore, the (b cycles each read by (b)(4) represents a total of (b)(4 (b)(4) reading the test results.

   For example, refer to Appendix 1 — Consumer Reading Data beginning on page 22 of our December 12, 2008 submission. On page 23, the first table represents the first conceptive cycle — there are (b)(4) in this cycle ranging from (b)(4) (b)(4) separately read each of the (b samples of this cycle and their readings of the result of each test is listed in the table. Similarly, for each of the remaining (b) cycles (for a total of (b cycles) the results are presented for each of the (b)(4) per cycle for a total of (b)(4) panelists participating in the study.

   Therefore the link between the (b) cycles and the (b)(participants is that each of the specimens of the (b cycles was independently read by (b)(4) for a total of (b)(4)

2. Your second question appears to be in reference to Table 2 — (b)(4) (b)(4) that appears in Exhibit I – Study Report: (b)(4) (b)(4) on page 19 of our December 12, 2008 submission. As the title of Table 2

102

indicates, the table presents (b)(4) [redacted]
participants in the study. (b)(4) [redacted]
(b)(4) [redacted]

(b)(4) [redacted]

Please note that the consumer data pertinent to the FIRST RESPONSE® Early Result Pregnancy Test is summarized in Table 1 on page 19 and likewise in the table on page 8 of our December 12, 2008 submission. Following the two explanations above, one would note in both of these tables of consumer results that in the row identified as "# Positive Results per Cycle Day" (b)(4) [redacted] on the corresponding Cycle Day because (b)(4) [redacted]
(b)(4) [redacted]

..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, February 13, 2009 9:19 AM
To: Kolakowsky, Stephen
Cc: Moyer, Vicki
Subject: k083716-consumer study results clarification

Good morning Mr. Kolakowsky-
Can you please help me with a few questions regarding the (b)(4) [redacted] who participated and tables 1 and 2 of the conceptive cycle testing? I know you explained the testing protocol many times in the submission, but I am still having a little difficulty with the numbers:

I understand that (b) [redacted] conceptive cycles were tested, but I don't understand the link between the (b)([redacted] (b)(4) [redacted] and the (b) [redacted] conceptive cycles. Are the samples from the different women pooled? Why is there exactly half?

Also, Please remind me why in the tables (row called Positive results/cycle day) the denominator is not always (b)(4) For example, the denominator for the (b)(4) samples tested positive. I understand that 8-10 samples were collected for each cycle. Is this the explanation? For example, for (b)(4) collect a specimen on this cycle day?

I'm sure these are pretty basic and no problem for you to explain. Thanks in advance!
Regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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K083716/A6

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

June 2, 2009

Via eMail and FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC
JUN 3 2009
Received

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

This is in response to your eMail of earlier today, which is reproduced below in italic type and followed with our reply to your inquiry.

K79

June 1, 2009 FDA eMail

Thank you very much for your helpful response. I have a follow-up question regarding the inclusion of a weak negative sample hCG concentration (b)(4) *as part of your stability, product release, and post-market testing programs. Do I understand it correctly that device lots that have* (b)(4) *or more positive results at* (b)(4) *would not meet your acceptance criteria? For example, would lots* (b)(4) *pass your criteria? These particular lots had about* (b)(4) *of positive results as interpreted by the consumers with Immulite values in the* (b)(4) (b)(4)

*FedEx #7976 4588 5222

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S2

RESPONSE → (b)(4) [redacted]

If I can be of further assistance, please do not hesitate to contact me.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

K083716/A6

June 1, 2009

Via eMail and FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

K49

FDA CDRH DMC
JUN 3 2009
Received

Attn: Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Ms. Moyer:

This is in response to your eMails of Wednesday, May 27, 2009 and of Friday, May 29, 2009. Each eMail is addressed separately below. The text of each eMail is reproduced below in *italic type* followed by our response to the inquiry.

Wednesday, 5/27/2009 FDA eMail

1) Regarding the library of conceptive cycle samples, on page 3 of your June 11, 2008 pre-IDE response, you state t (b)(4) [redacted] (b)(4) [redacted] *Can you further explain this occurrence? Was the reason for* (b)(4) [redacted] *known? Were the* (b)(4) [redacted] *or was there some other reason? How many of the samples from the library* (b)(4) [redacted] *from the study because of this criterion?*

RESPONSE → (b)(4) [redacted]

2) Please provide a summary of the results of the conceptive cycle study (Tables 1 and 2, page 19 of submission) by lot, for the (b)(4) [redacted] *of devices in the study.*

RESPONSE → The summary results presented in Tables 1 (b)(4) [redacted] and 2 (b)(4) [redacted] on page 19 of our December 12, 2008, 510(k) Submission are represented below broken out by lot for the (b)(4) [redacted] of devices used in the study.

Summary of Consumer Reading Results

(b)(4) [redacted]

Summary of Monitor Reading Results

(b)(4)

[redacted]

Friday, 5/29/2009, FDA eMail

Can you please provide a few additional pieces of information regarding your response to item 1 of the February 25, 2009 hold letter?

On page 2 of your response, you state

(b)(4)

[redacted]

Please clarify (b)(4) [redacted] *Do you intend to include* (b)(4) [redacted]

(b)(4) *protocol alone? Or does this mean that you intend to include* (b)(4) *and or* (b)(4) *criteria?*

RESPOSE → (b)(4)

On page 3 you explained that any (b)(4) *shown in the consumer variability study may be due to the variability of* (b)(*consumers reading the devices in the study. In order for us to have a more balanced understanding of the device performance, please provide a summary of the conceptive cycle study as interpreted by the study monitor for each lot of devices tested. In following up from my e-mail to you on Wednesday, May 27, 2009, please provide both the consumer and study monitor interpretation for the data on page 19 Tables 1 and 2 of your submission, summarized by lot.*

RESPONSE → As described in the Consumer Readability Study protocol, the (b)(4) used in the study were not tested using the (b)(4) samples, and therefore, no conclusions on (b)(4) can be drawn. Also, each (b)(4) (to preclude FDA's reading bias concern), and therefore, a device from each lot (b)(4) (b)(4) participating in the study. Thus the variability contributed by (b)(4) reading the devices in the study preclude any conclusions regarding (b)(4) As we have previously explained, the Consumer Readability Study was designed, as requested by FDA in their April 28, 2008 letter, with the objective (b)(4) (b)(4) (b)(4) And although (b)(4) of product were included as requested by FDA, the Consumer Readability Study was not designed as a (b)(4) (b)(4) to look at possible (b)(4) of the product.

The summary of the conceptive cycle study as interpreted by the study monitor for each lot tested is provided in our response above to the

second question of FDA's May 27, 2009 eMail. Likewise, the information requested in FDA's May 27, 2009 eMail is provided above.

As also noted in our earlier correspondence and meetings, the lots of products as they are produced will be required to meet strict quality control and release standards. These standards are already in place and have been satisfactorily used to release this same product for sale in the EU, Canada and Australia.

We believe that our replies above fully respond to each of your inquiries. We look forward to a quick and amicable resolution of these issues.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

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

Device Name: FIRST RESPONSE® Early Result Pregnancy Test

Indication For Use:

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.

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

510(k) K083716

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

March 20, 2009

CHURCH & DWIGHT CO., INC.
469 NORTH HARRISON STREET
PRINCETON, NEW JERSEY 08543
UNITED STATES
ATTN: STEPHEN C. KOLAKOWSKY

510k Number: K083716

Product: FIRST RESPONSE EARLY RESULT PR

Extended Until: 04/27/2009

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department - Building 100, Princeton, NJ 08543

March 18, 2009

Via FedEx*

FDA CDRH DMC

MAR 19 2009

Received

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)
Request for Extension

Dear Sirs or Madam:

FDA in its letter dated February 25, 2009, requested additional information regarding the above referenced 510(k) notification. We have arranged a conference call with the reviewing division on Friday, March 27, 2009, in order to clarify the additional information requested. Until at least after that conference call takes place, we will be unable to begin to prepare our response to FDA's request for additional information, and therefore, we will request additional time beyond the initial 30 days provided for a response to FDA's February 25, 2009, request.

If there is any question regarding the above request, please contact me by telephone at 609-279-7748 or by eMail at STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM.

Sincerely,

Stephen C. Kolakowsky

Stephen C. Kolakowsky
Director, Regulatory Affairs

In Duplicate

K39

* Track # 7964 3957 2960

H:\data\ANSWER_1RESPONSE\Pregnancy\510(k)LIMBOIII\510k_K083716\07X10.docx

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Church & Dwight Co., Inc.
c/o Mr. Stephen Kolakowsky
469 North Harrison Street
Princeton, NJ 08543

FEB 25 2009

Re: k083716
Trade Name: FIRST RESPONSE® Early Result Pregnancy Test
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Kolakowsky,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the additional information outlined below.

1. FDA continues to be concerned about the performance of the device in measuring (b)(4) (b)(4)

   (b)(4) FDA recommended that you modify your stability study protocol and acceptance criteria to include a (b)(4) (b)(4) FDA continues to be concerned that your previously stated criteria are not adequate to control stability trends over time and (b)(4) You indicated in a recent email to FDA that a sample with hCG concentration (b)(4) a (b)(4) is tested as part of your stability and lot release protocols. The acceptance criterion is that the test device must produce a (b)(4) (b)(4) We disagree that inclusion of a sample at (b)(4) is adequate to mitigate our concerns because a sample of this concentration does not represent a (b)(4) sample. The hCG level of this type of sample should reflect a concentration where lab professionals and/or lay users should get a negative result. We consider a weak negative to be a sample that produces a negative result 95% of the time. You may find the CLSI "User Protocol for Evaluation of Qualitative Test Performance" EP12-A2 helpful when evaluating the performance of your device. Please note, instead of the term "weak negative" the protocol uses the term C_5. The C_5-C_{95} interval is defined as the range of analyte such that observed results outside of the interval are consistently negative ($<C_5$) or consistently positive ($>C_{95}$).

   At the request of FDA you provided a summary of the Consumer Readability Study for the (b)(4) of test devices and with sample hCG concentrations by rank order. There appears to be significant performance differences between the (b)(4) tested. We are particularly concerned that for (b)(4) that (b)(4 of samples in the range of (b)(

(b)(4) by the (b)(4) method were interpreted as Positive, while for the other (b)(4) (b)(4) of samples in this same concentration range were interpreted as Positive. For this same lot, (b)(4) of samples with concentration in the range of (b)(4), were interpreted as Positive. Additionally, (b)(4) samples with hCG concentrations (b)(4) (b)(4) were interpreted as positive for (b)(4) while (b)(4) samples were interpreted as positive for lot (b)(4) (Note: following your response, we identified (b) other observations where the specimen had hCG (b)(4), specimen (b)(4) (b)(4) and (b)(4) interpreted the result as positive using (b)(4)

(b)(4)

2. With regard to the validation studies in support of the use of the (b)(4) to quantitatively measure hCG in urine, in an e-mail dated January 9, 2009, FDA asked for additional detail on the study performed to evaluate the limit of quantitation. Specifically we asked for the criteria for acceptable precision and trueness. In your response, you referred to the (b)(4) validation protocol provided as exhibit III and stated that studies were performed based on the recommendations of CLSI EP17-A "Protocols for Determination of Limits of Detection and Limits of Quantitation;" however, we still have questions about your acceptance criteria and data analysis. In order for us to better understand the conclusions of the validaton study including the limit of blank and limit of quantitation please provide the line data for these studies.

3. On page 15 of your submission, you included a completed Indications for Use form, however, this is not the most current version of the form. Please obtain the current version of the form that can be found at The Office of In Vitro Diagnostic Evaluation and Safety website: http://www.fda.gov/cdrh/oivd/indicationsforuse.html, complete it and resubmit it with your response. Additionally, please add "up to 5 days before the expected period" to the existing language.

4. In the Questions and Answers section of the device labeling, you describe that "about 2% of women (all over the age of 47) had very low levels of hCG" using your device. However, in a study performed by testing the urine of (b)(4) (b)(4) In a similar study testing urines from (b)(4) observations (b)(4). Please revise the Questions and Answers section to reflect the actual test

results obtained for both the (b)(4) [redacted]
(b)(4) [redacted]

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at:
http://www.fda.gov/cdrh/modact/leastburdensome.html

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "Guidance for Industry and FDA Staff: Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs, and BLA Supplements" at www.fda.gov/cdrh/ode/guidance/1655.html.

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and
Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Vicki Moyer at (240) 276-0698. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

December 15, 2008

CHURCH & DWIGHT CO., INC.
469 NORTH HARRISON STREET
PRINCETON, NEW JERSEY 08543
UNITED STATES
ATTN: STEPHEN C. KOLAKOWSKY

510k Number: K083716
Received: 12/15/2008
Product: FIRST RESPONSE EARLY RESULT PR

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see www.fda.gov/cdrh/elecsub.html.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"

(http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural questions, or want information on how to check on the status of your submission, please contact DSMICA at (240) 276-3150 or its toll-free number (800)638-2041, or at their Internet address
http://www.fda.gov/cdrh/dsmamain.html or the 510k staff at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

CH/DCTD

CHURCH & DWIGHT CO., INC. K083716

469 North Harrison Street, Law Department - Building 100, Princeton, NJ 08543

December 12, 2008

Via FedEx

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

K-34

Re: **510(k) Notification**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Received
DEC 15 2008
FDA CDRH DMC

Dear Sirs:

Reference is made to (b)(4) (b)(4) and (b)(4) (b)(4) which contain information and data previously reviewed by FDA regarding the above referenced medical device product that is also the subject of this 510(k) notification submission. Reference is also made to (b)(4) and our (b)(4) with FDA and to the (b)(4) protocol dated (b)(4) (b)(4) and submitted under (b)(4) to FDA on (b)(4) that was discussed at those times. With regard to the (b)(4), it was agreed that, provided the data are acceptable and do not raise new issues of safety and effectiveness, the consumer study discussed would meet FDA's evidentiary needs for a finding of substantial equivalence of the above referenced medical device product.

As agreed, therefore, this 510(k) submission includes general information elements and the report of the consumer study conducted under the referenced protocol; all other elements of the 510(k) are incorporated by reference to (b)(4) (b)(4) which contain information and data previously reviewed by FDA regarding the 510(k)-subject device.

We look forward to FDA's rapid review of the enclosed information and FDA's clearance to market the 510(k)-subject device. I may be contacted by phone at (609)279-7748 or by e-mail at STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM

Sincerely,

Stephen C. Kolakowsky
Director, Regulatory Affairs

Enclosure

H:\data\ANSWER_1RESPONSE\Pregnancy\510(k)LIMBOIII\510k\01.doc

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

December 12, 2008

Via FedEx

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

Re: **510(k) Notification**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Sirs:

Reference is made to FDA file [redacted] (b)(4) and [redacted] (b)(4), which contain information and data previously reviewed by FDA regarding the above referenced medical device product that is also the subject of this 510(k) notification submission. Reference is also made to our [redacted] (b)(4) and our [redacted] (b)(4) with FDA and to the [redacted] (b)(4) protocol dated [redacted] (b)(4) and submitted under [redacted] (b)(4) to FDA on [redacted] (b)(4), that was discussed at those times. With regard to the [redacted] (b)(4), it was agreed that, provided the data are acceptable and do not raise new issues of safety and effectiveness, the consumer study discussed would meet FDA's evidentiary needs for a finding of substantial equivalence of the above referenced medical device product.

As agreed, therefore, this 510(k) submission includes general information elements and the report of the consumer study conducted under the referenced protocol; all other elements of the 510(k) are incorporated by reference to FDA file # [redacted] (b)(4) and [redacted] (b)(4) which contain information and data previously reviewed by FDA regarding the 510(k)-subject device.

We look forward to FDA's rapid review of the enclosed information and FDA's clearance to market the 510(k)-subject device. I may be contacted by phone at (609)279-7748 or by e-mail at STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM

Sincerely,

Stephen C. Kolakowsky
Director, Regulatory Affairs

Enclosure

H:\data\ANSWER_FRESPONSE\Pregnancy\510(k)LIMBOH\510k01.doc

510(k) Premarket Notification

Church & Dwight Co., Inc.

FIRST RESPONSE® Early Result Pregnancy Test (OTC)

December 12, 2008

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

CONTENTS

- Cover Letter
- Cover Page

I. Medical Device User Fee Cover Sheet — Form FDA 3601 1

II. Certification of Compliance with Requirements of Clinical Trials.gov Data Bank — Form FDA 3674 2

III. Truthful and Accurate Statement 3

IV. General Information 4

V. 510(k) Summary 5

VI. Description of Device 6

VII. Statement of Substantial Equivalence 7

Table of Similarities & Differences 9

VIII. Labeling 10

IX. Indications for Use Statement 15

Exhibit I — Consumer Readability Study Report 17

Exhibit II — Consumer Readability Study Protocol 79

Exhibit III — hCG Assay Method Validation Report 98

Exhibit IV — hCG Assay Method Validation Protocol 102

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6039753-956733** Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
CHURCH AND DWIGHT CO INC 469 NORTH HARRISON STREET PRINCETON NJ 08543 US	Karen Vescovi 2.1 E-MAIL ADDRESS karen.vescovi@churchdwight.com 2.2 TELEPHONE NUMBER (include Area code) 609-279-7715
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 134996950	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 609-497-7179

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$3,693.00 13-Nov-2008

Form FDA 3601 (01/2007)

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Church & Dwight Co. Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Dec 12, 2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
469 North Harrison Street
Princeton, NJ 08543

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 609-279-7748
(Fax) 609-497-7179

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

FIRST RESPONSE® Early Result Pregnancy Test (OTC)

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Stephen C. Kolakowsky

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Stephen C. Kolakowsky
(Title) Director, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
469 North Harrison Street
Princeton, NJ 08543

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 609-279-7748
(Fax) 609-47-97-7179

15. DATE OF CERTIFICATION
Dec 5, 2008

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090

Truthful and Accurate Statement

I certify, in my capacity as Research Fellow, Global Women's Health Research & Development at Church & Dwight Co., Inc., to the best of my knowledge, that all data and information submitted in this 510(k) Premarket Notification Submission is truthful and accurate and that no material fact has been omitted.

Albert Nazareth, PhD
Research Fellow
Global Women's Health Research & Development

General Information

A. Submitter's Name and Address

Church & Dwight Co., Inc.
469 North Harrison Street
Princeton, NJ 08543

B. Contact Person

Stephen C. Kolakowsky
Director, Regulatory Affairs
Phone: (609) 279-7748
Fax: (609) 497-7179
eMail: STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM

C. Establishment Registration Number of Sponsor

#2280705

D. Contract Manufacturing Facility

Scantibodies Laboratory, Inc.
9336 Abraham Way
Santee, CA 92071
Est. Reg: No. 2020808

E. Device Name

Proprietary Name: FIRST RESPONSE® Early Result Pregnancy Test
Common Name: At-home Pregnancy Test
Classification Name: Human chorionic gonadotropin (hCG) test system

F. Device Classification

Class II [Clinical Chemistry Test System, 21 CFR Part 862, §862.1155], 75 LCX

G. Action Taken to Comply with Section 514 of the Act

The Commissioner has not to date issued any regulation promulgated in accordance with Sec. 514(b) of the FFD&C Act concerning the development of performance standards for products of this product type. Therefore, no action has been taken to comply with any such performance standard. The sponsor of this 510(k) Notification makes no statement of conformance with any standard recognized under the authority of Sec. 514(c) as an alternative means of compliance with the 510(k) requirements pertinent to the 510(k)-subject device.

H. Reason for 510(k) Submission

Product modification, including directions for use labeling / claim for time of use of device.

I. Predicate Device

FIRST RESPONSE® Early Result Pregnancy Test — 510(k) #K030258 and #K992232

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
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

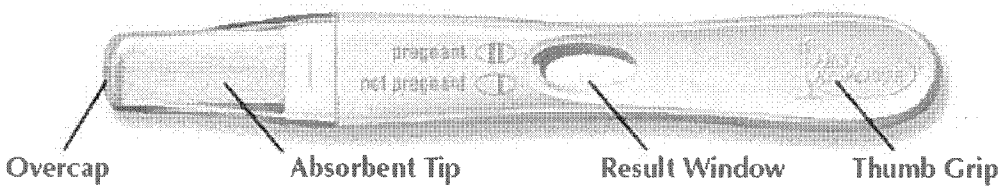
Description of Device: The FIRST RESPONSE® Early Result Pregnancy Test is a human chorionic gonadotropin (hCG) test system. It is a screening device intended for early detection of pregnancy by the lay user for the qualitative measurement of hCG in urine as early as six (6) days before the day of the 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 test device intended for the early detection of pregnancy by the lay user as early as six (6) days before the day of the missed period.

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.

Description of Device

The FIRST RESPONSE® Early Result Pregnancy Test is an at-home test for the detection of hCG as an indication of pregnancy.



- Under FDA's device classification, it is a Class II human chorionic gonadotropin (hCG) test system.
- It is a device intended for early detection of pregnancy by the lay user.
- It can detect hCG in urine as early as six (6) days before the day of the missed period (*i.e.,* five (5) days before the expected period). *
- The device detects hCG utilizing a series of immunochemical reactions with component reagents that are striped onto a chromatographic strip contained within a plastic housing.

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* "hCG can be detected in urine or serum in minute quantities ...5 days before the expected menstruation."
[*Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s*; July 22, 2000, HHS, FDA, CDRH.]

Statement of Substantial Equivalence

The purpose of this 510(k) Notification is to describe the modifications intended to be implemented into the currently marketed FIRST RESPONSE® Early Result Pregnancy Test, which was cleared under 510(k) #K030258; reference is also made to 510(k) #K992232 cleared by the Center December 21, 1999. The modified 510(k)-subject device does not represent a change in technology, only an enhancement, and is thus substantially equivalent to the predicate device. The following provides the rationale for this determination. (Reference is also made to (b)(4) for additional information previously submitted to and reviewed by FDA.)

Intended Use

The 510(k)-subject FIRST RESPONSE® Early Result Pregnancy Test has the same intended use as the predicate FIRST RESPONSE® Early Result Pregnancy Test. Both products are single-use test devices marketed over-the-counter (OTC) to lay consumers for the at-home rapid qualitative detection of human chorionic gonadotropin (hCG) in urine as an aid in the determination of pregnancy. Both tests can be used any time of the day in either urine midstream or dip format. The two devices differ in that the 510(k)-subject device can be used as early as six (6) days before the day of the missed period, while the predicate FIRST RESPONSE® Early Result Pregnancy Test can be used as early as five (5) days before the day of the missed period, that is, the 510(k)-subject device may be used one (1) day sooner than the predicate device when pregnancy is suspected.

Principles of Operation

The 510(k)-subject FIRST RESPONSE® Early Result Pregnancy Test is a lateral flow device. It has the same technological characteristics in its principles of operation as the predicate FIRST RESPONSE® Early Result Pregnancy Test. (b)(4)

(b)(4)

(b)(4) Thus, with a successful test, the presence of hCG is detected by the formation of two pink lines (||) in the Result Window. If no hCG is detected, only one pink line (|) develops and is shown in the Result Window. (See figure on previous page.)

Limitations of the Test

The labeling of both the 510(k)-subject device and the predicate instructs consumers to follow the instructions carefully, and to repeat the test in a few days if pregnancy is not detected and the expected period has not started. Consumers are also advised that the test is not meant to replace a visit to the doctor.

Supporting Information & Data

Information and data in support of the performance characteristics of the 510(k)-subject device have been previously submitted and reviewed by FDA and are contained in (b)(4) and (b)(4) which are incorporated by reference.

The information and data in the exhibits that follow pertain to the consumer readability study requested by FDA and described in the protocol previously submitted to FDA under Pre-IDE #I080286. In (b)(4) FDA stated that to gain 510(k) clearance, Church & Dwight needed to "perform studies with (b)(4) (b)(4) to demonstrate that the device can be safely and effectively used for the early detection of pregnancy up to 6 days before the missed period." FDA also expressed (b)(4) (b)(4) therefore, according to the protocol, (b)(4) in the consumer readability study. Samples tested in this study with the (b)(4) were not intended to provide separate statistically analyzable subsets of data (b)(4) but rather were provided to, and do adequately demonstrate (b)(4) (b)(4) The results of the consumer readability study are summarized in the following table.

Table 1: Detection of hCG in Conceptive Cycles Relative to Expected Menstrual Period and Ovulation Using 510(k)-Subject FIRST RESPONSE® Early Result Pregnancy Test as Read by Consumers

Day relative to EMP	(b)(4)	EMP -5	(b)(4)	EMP -2	EMP -1	EMP	EMP +1
(b)(4)							
# Positive Results per Cycle Day	(b)(4)	69/102	(b)(4)	102/102	102/102	102/102	102/102
% Positive Results per Cycle Day		68%		100%	100%	100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of the Missed Period EMP-# = Day # Before the Expected Period

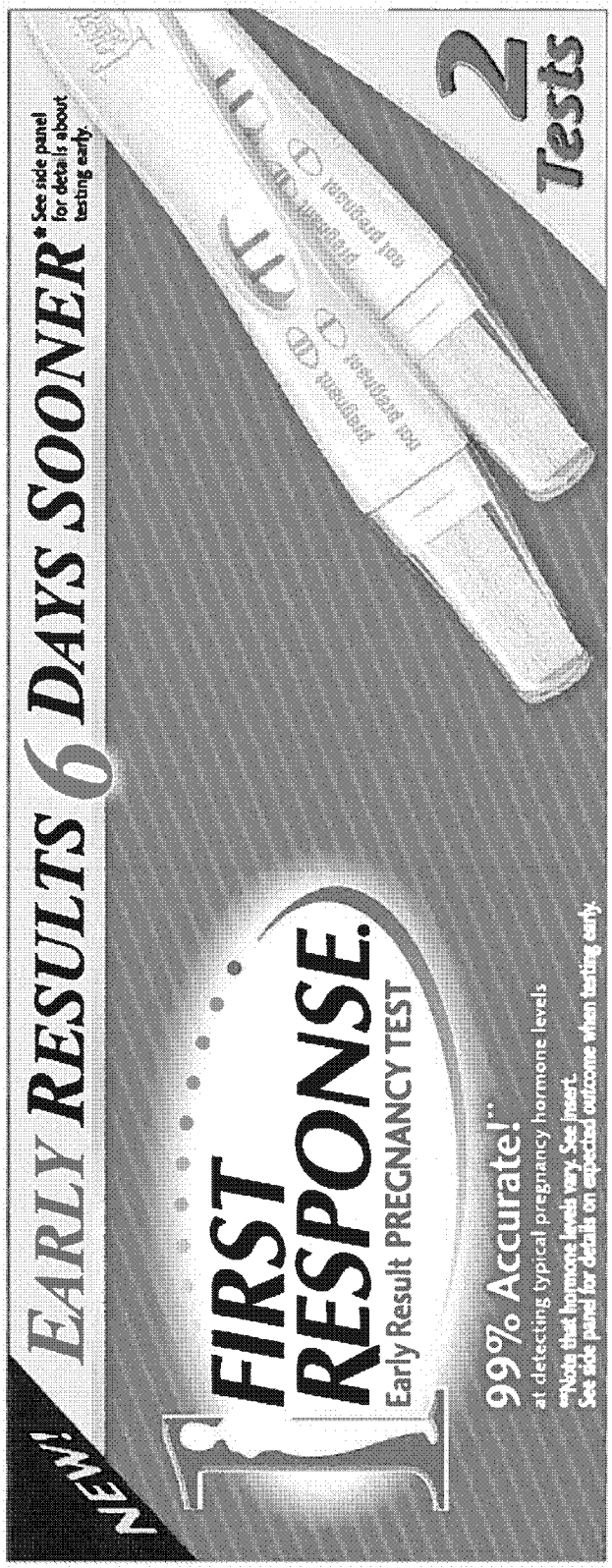
We conclude that the data presented in the enclosed study report, along with information previously submitted to the FDA in the referenced 510(k) submissions, substantiate an early intended use claim. These findings also support our contention that the FIRST RESPONSE® Early Result Pregnancy Test can qualitatively detect hCG levels in the urine of pregnant women, and the results can be read by consumers five days earlier than the day of the expected menstrual period, that is, six days before the missed period.

Table 2: Summary of Similarities and Differences

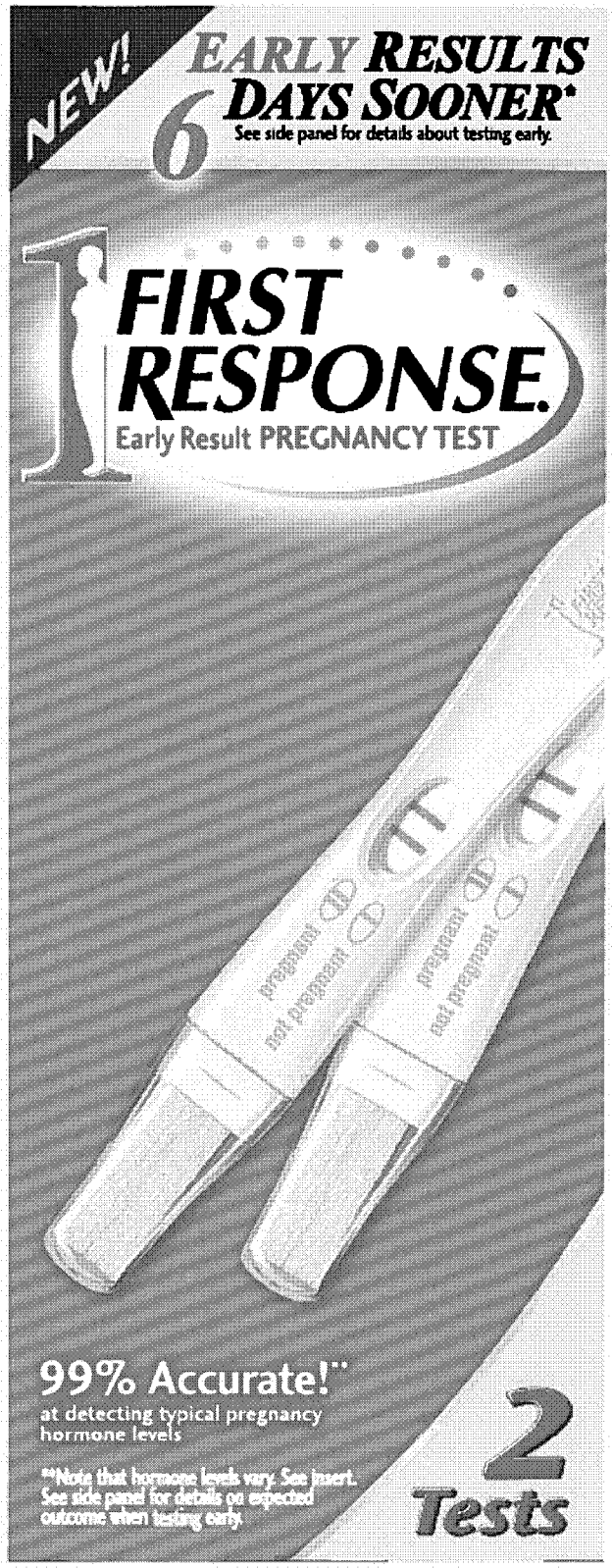
CONFIDENTIAL

Item	Predicate	510 (k)-Subject Device
Product Name	FIRST RESPONSE® Early Result Pregnancy Test	FIRST RESPONSE® Early Result Pregnancy Test
Intended Use	Detection of hCG as an indication of pregnancy	Same
Sample Matrix	Urine (Midstream or Dip)	Same
Principle/Methodology	• Lateral Flow Chromatographic Immunoassay	Same
	(b)(4) [redacted]	
Detection Level		8–10 mIU hCG/mL
Sampling Time	5 seconds in urine stream or cup	Same
Time to Result	3 minutes	Same
Device Housing	Undecorated	• "Pregnant (| |)" and "Not Pregnant (|)" embossed next to result window • Anti-flooding design on interior surface
Primary Conjugate	(b)(4) [redacted]	
Intermediate Conjugate		
Trap		
Pregnancy Detection	As early as four (4) days before expected period	As early as five (5) days before expected period
Results	2 pink lines = Positive 1 pink line = Negative	Same
Laboratory Accuracy	> 99%	Same

Principal (Front) Display Panel



Alternate (Rear) Display Panel



Carton — Side Panel A

FIRST RESPONSE® Early Result PREGNANCY TEST and March of Dimes® Saving babies, together.

Working Together to Promote Healthy Babies†

†The March of Dimes does not endorse specific products or brands.

First Response is a proud partner of the March of Dimes and is proud to be a part of improving the health of mothers and babies nationwide. For additional information on First Response products and on maintaining good health, visit www.firstresponse.com

*FIRST RESPONSE® detects the pregnancy hormone 6 days sooner than the day of your missed period (5 days before day of expected period).

Things to Know about Testing Early....

FIRST RESPONSE® is 99% accurate at detecting the pregnancy hormone. However, some pregnant women may not have detectable amounts of the pregnancy hormone in their urine on the day they use the test. The amount of pregnancy hormone increases as pregnancy progresses. In clinical testing, FIRST RESPONSE® detected the hormone levels in ___% of women 5 days before their expected period, in ___% of women 4 days before their expected period, in ___% of women 3 days before their expected period, and in ___% of women 2 days before their expected period.

100%

89%

98%

68%

Carton — Side Panel B

This kit contains 2 FIRST RESPONSE® Early Result Pregnancy Test sticks and instructions (in English and Spanish).

- Follow complete instructions inside box. Instrucciones en Español adentro.
- Remove overcap and place absorbent tip in urine stream for 5 seconds.
- Results in 3 minutes.
- Results interpreted right on the stick.

For in-vitro diagnostic use. Not to be taken internally. Store in a dry place below 86°F (30°C). Do not freeze. Keep out of reach of children.

LIVE UPC ADDED DURING SEPARATIONS 80% Version A

0 22600 90125 9

FRCT-50125-21

First Response and ™ are registered trademarks of Church & Dwight Co., Inc.

Manufactured by Scantibodies Laboratory, Inc., Santee, CA 92071.

Distributed by Church & Dwight Co., Inc., Princeton, NJ 08543.

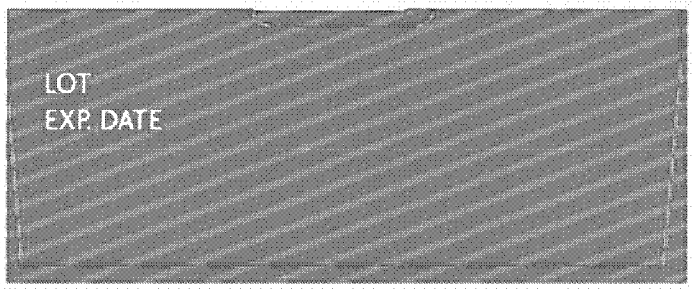
US Patent No. 5,141,850, 6,319,676, C,767,714 and 7,045,342.

Other patents pending.

Do not use this product after expiration date.

Carton — Left End-Flap

Carton — Right End-Flap



Insert (Page 1 of 2)

FIRST RESPONSE.
Early Result PREGNANCY TEST

At-Home Test for the Detection of Pregnancy

INSTRUCTIONS AND USE

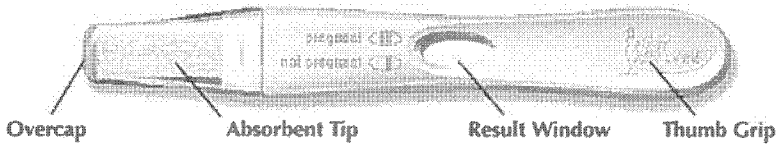
PLEASE READ ALL THE INFORMATION IN THIS LEAFLET BEFORE PERFORMING THE TEST.
Do not use after the expiration date stamped on the side of the carton. Store in a dry place below 86°F (30°C).
Do not freeze. Keep out of reach of children. For in-vitro diagnostic use. Not to be taken internally.
If you have any questions, call us toll-free at 1-800-367-6022, Monday-Friday from 7:00 AM to 5:00 PM Eastern Time. Visit us online at www.firstresponse.com

When to use the FIRST RESPONSE® Early Result Pregnancy Test

The FIRST RESPONSE® test is so sensitive that it can detect hCG as early as 5 days before your expected period.
You can use the test any time of the day. You do not have to use the first morning urine.
Generally, however, your first morning urine contains the highest level of the pregnancy hormone.

INSTRUCTIONS

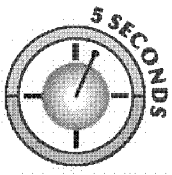
- Remove test stick from the foil wrapper and take off the **Overcap**.

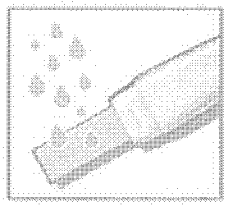


STEP 1

EITHER

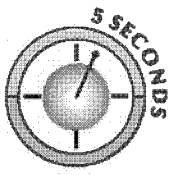
- Holding the test stick by the **Thumb Grip** with the **Absorbent Tip** pointing downward and the **Result Window** facing away from your body, place the **Absorbent Tip** in your urine stream for 5 seconds only.

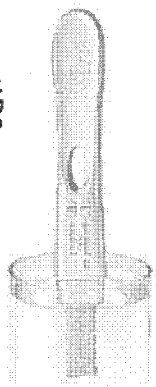




OR

- You may also collect your urine in a clean, dry cup and immerse the entire **Absorbent Tip** in the urine for 5 seconds only.

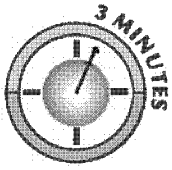




READING THE RESULT—READ YOUR RESULT AT 3 MINUTES

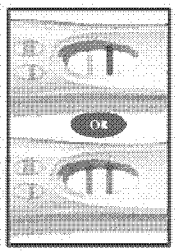
STEP 2

- With the **Absorbent Tip** still pointing downward, replace the **Overcap*** and lay the stick on a flat surface with the **Result Window** facing up.
- You may soon see a pink color moving across the **Result Window** to indicate the test is working.
- Wait 3 minutes until reading results.



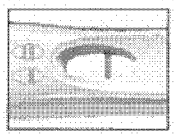
*Replacement of the Overcap is not necessary for the proper functioning of the test.

STEP 3



PREGNANT
TWO PINK LINES in the **Result Window.**
One line may be lighter than the other.
Appearance of the results may vary.

NOT PREGNANT
ONE PINK LINE in the **Result Window.**



Insert (Page 2 of 2)

(b)(4 (b)(4) (b)(4 68%

QUESTIONS & ANSWERS

Q: How does the test work?

A: The FIRST RESPONSE® Early Result Pregnancy Test detects in urine the hormone your body makes during pregnancy: hCG (human chorionic gonadotropin). The FIRST RESPONSE® Test is so sensitive that it can detect hCG as early as 5 days before your expected period. The amount of pregnancy hormone increases as pregnancy progresses. In clinical testing, FIRST RESPONSE® detected the hormone levels in % of women 5 days before their expected period, in % of women 4 days before their expected period, in % of women 3 days before their expected period, and in % of women 2 days before their expected period.

Q: What do I do if the result is positive (pregnant)?

A: A positive (pregnant) test result shows that the pregnancy hormone (hCG) was detected. See your doctor to confirm that you are pregnant.

Q: What do I do if the result is negative (not pregnant)?

A: You may not be pregnant, or it may be too early to tell. If you do not get your period within 7 days, you should retest with another FIRST RESPONSE® Early Result Pregnancy Test. It is possible that you miscalculated the length of your cycle or your urine may not have had enough pregnancy hormone for the FIRST RESPONSE® Test to give a positive result. If you retest and again no hCG is found, and your period still has not started, you should call your doctor.

Q: How accurate is the test?

A: In laboratory studies of the FIRST RESPONSE® Early Result Pregnancy Test with urine samples from pregnant and non-pregnant women, the accuracy was 99% at detecting the pregnancy hormone. However, some pregnant women may not have detectable amounts of pregnancy hormone in their urine on the first day of their missed period or may have miscalculated the first day of their period. In a study of pre-, peri- and post-menopausal aged, non-pregnant women, about 2% of the women (all over age 47) had very low levels of hCG that gave positive test results. If you are in this category of women and get a positive result, you need to have your result confirmed by your doctor.

Q: I have waited longer than 3 minutes, and still there are no lines in the Result Window. Is there anything wrong?

A: Your result should appear within 3 minutes. There should be at least one pink line in the **Result Window** at 3 minutes to indicate that the test is completed and you have done it correctly. If not, the test is invalid. This could be due to insufficient urine on the **Absorbent Tip** or not holding the device with the **Absorbent Tip** pointing downward while replacing the **Overcap**. You should retest with another device, carefully following all directions.

Q: Will the result change if left standing for a certain period of time?

A: The test result should be read as soon as possible after waiting the 3 minutes. A positive result will last for at least 48 hours. A negative result should not be read after 10 minutes.

Q: Do any drugs or medications affect the test?

A: Only medications containing the pregnancy hormone (hCG) can affect the result (e.g., A.P.L.[1], Pregnyl[3], Profasi[4] and Pergonal[4]). The test should not be affected by hormone therapies containing Clomiphene citrate (e.g., Clomid[2] and Serophene[5]), alcohol, painkillers, antibiotics, or the contraceptive pill.

If you have any questions, call us toll-free at **1-800-367-6022**, Monday-Friday from 7:00 AM to 5:00 PM Eastern Time.
Visit us online at **www.firstresponse.com**

To increase your chances for a healthy pregnancy for you and your baby, you should consider the following:

- Maintain a well-balanced diet
- Stop smoking

From conception through the first three months of pregnancy is the most important time. You need to see your doctor immediately for proper care and nutrition counseling.

WARNING: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.

Trying to get pregnant...

Many women do not know that their most fertile days are the days leading up to ovulation (when your ovary releases an egg to be fertilized by the sperm). To become pregnant sooner, you should become more familiar with your ovulation cycle. The FIRST RESPONSE® Easy-Read Ovulation Test kit is an at-home, one-step test designed to predict ovulation by monitoring changes in your hormone levels. With the help of the FIRST RESPONSE® Easy-Read Ovulation Test kit, you can predict your peak fertility days and get pregnant sooner.

Distributed by Church & Dwight Co., Inc.,
Princeton, NJ 08543 ©1995, 2003
U.S. Patent Nos. 5,141,850, 6,319,676, 6,767,714, 7,045,342 and U.S. patent pending
FIRST RESPONSE is a registered trademark of Church & Dwight Co., Inc.

1 A.P.L. is a registered trademark of Wyeth-Ayerst Laboratories Division of American Home Products Corp.
2 Clomid is a registered trademark of Merrell Pharmaceuticals Inc.
3 Pregnyl is a registered trademark of Organon USA, Inc.
4 Profasi and Pergonal are registered trademarks of Ares Trading S.A.
5 Serophene is a registered trademark of Serono Inc.

MANUFACTURER'S COUPON | EXPIRES 12/31/10

SAVE $1.00

On Any First Response®
Pregnancy Test

F.P.O. F.P.O.

5 22600 32076 5 (8100) 0 13645

RETAILER: Only U.S. retail distributors of product stated or others specifically authorized by us may redeem coupon for face value plus 8¢ handling if terms of offer are met. Valid only for product stated. Limit 1 coupon per purchase. Consumer must pay any sales tax. Upon request, retailer must show invoices for enough stock to cover coupons presented. Void where prohibited, taxed, licensed, or restricted. Cash value 1/100¢.

Mail to: Church & Dwight Co., Inc.,
CMS Dept. #33200,
1 Fawcett Drive, Del Rio, Texas 78840
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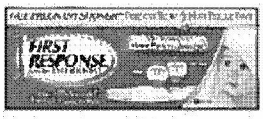
MANUFACTURER'S COUPON | EXPIRES 12/31/10

SAVE $1.00

On Any First Response®
Easy-Read Ovulation Test

F.P.O. F.P.O.

5 22600 31076 6 (8100) 0 13646



RETAILER: Only U.S. retail distributors of product stated or others specifically authorized by us may redeem coupon for face value plus 8¢ handling if terms of offer are met. Valid only for product stated. Limit 1 coupon per purchase. Consumer must pay any sales tax. Upon request, retailer must show invoices for enough stock to cover coupons presented. Void where prohibited, taxed, licensed, or restricted. Cash value 1/100¢.

Mail to: Church & Dwight Co., Inc.,
CMS Dept. #33200,
1 Fawcett Drive, Del Rio, Texas 78840.
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FRIN-90127-15

Indications for Use Statement

510(k) Number: _____

Device Name: FIRST RESPONSE® Early Result Pregnancy Test

Indications for Use: The FIRST RESPONSE® Early Result Pregnancy Test is an *in vitro* diagnostic test device intended for the early detection of pregnancy by the lay user up to six (6) days sooner than the day of the missed period

Prescription Use _____ OR Over-the-Counter Use ___X___
(Per 21 CFR Part 801 Subpart D) *(Per 21 CFR Part 801 Subpart C)*

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____

Exhibits

I. (b)(4) [redacted] Study Report

II. [redacted] Study Protocol

III. (b)(4) [redacted] Validation Report

IV. [redacted] Validation Protocol

Exhibit I

STUDY REPORT

Consumer Readability Study with First Response® Early Result Pregnancy Test Using Early Pregnancy Urines

INTRODUCTION

The First Response® Early Result Pregnancy Test has previously demonstrated in clinical use the necessary sensitivity to detect low levels of the hCG hormone in early pregnancy urine samples, five days earlier than the day of the expected period (see (b)(4)

Prior studies using this device in clinical testing have correlated well with the scientific literature in that hCG levels generally increase 7-11 days after ovulation, and pregnancy kits with sensitivity of at least 25 mIU/mL may show positive test results in urine days earlier than the date the period is due.

This study is intended to supplement previous data generated for the (b)(4) (b)(4) by demonstrating the lay consumer's ability to read low levels of hCG found in genuine early pregnancy clinical samples.

MATERIALS AND METHODS

PROTOCOL

(b)(4)

SAMPLES

(b)(4)

(b)(4) For each conceptive cycle, the day of ovulation and days of expected and missed period were determined by accepted methods described in

protocol #238. All cycles were collected prior to this study and comprise a sample library that is owned, maintained, and controlled by Church & Dwight.

(b)(4) [redacted]

TEST DEVICES

Three approved manufacturing lots, (b)(4) [redacted] and (b)(4) [redacted] were utilized in this study.

TESTING PROCEDURE

(b)(4) [redacted]

RESULTS

Consumer Results

Table 1 summarizes the reading results from (b)(4) [redacted] with samples from the cycle segments organized by the (b)(4) [redacted] and by the day relative to the expected menstrual period (EMP). Sixty-eight percent (68%) of the women were able to read the positive result 5 days before the expected menstrual period (EMP-5), which correlates to 6 days before the missed period. The reading percentages increase to (b) [redacted]

and (b) on days (b)(4) respectively, and climb to (b)(4) from EMP-2 to EMP+1. The individual consumer reading results are included in the Appendix I. In addition and as requested by the FDA, the consumer reading results are also provided separately for each of the (b)(4) used in the study. These are included in Appendix II, III and IV.

TABLE 1. Summary of Consumer Reading Results

Day Relative to EMP	(b)(4)	EMP-5	(b)(4)	EMP-2	EMP-1	EMP	EMP+1
(b)(4)		(b)(4)		(b)(4)			
Positive results / cycle day		69/102		102/102	102/102	102/102	102/102
% positive results / cycle day		68%		100%	100%	100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of Missed Period

(b)(4)

(b)(4)

DISCUSSION

From each conceptive cycle used in the study, a 'cycle segment' was identified for the actual testing, that included a window of transition from undetectable levels of hCG to detectable levels (around the time of implantation) and ending one day after the day of expected menstrual period.

Since (b)(4) [redacted] samples from conceptive cycles were used in this study, the results produced by devices during testing of these cycle segments were highly representative of the results that the consumer would typically experience when testing themselves for early pregnancy. All samples in the cycle segments were randomized prior to testing to minimize any potential learning bias in reading by the consumer.

Overall, 68% of consumers read positive results at EMP-5, (b)(4) [redacted] (b)(4) [redacted] These data are consistent with the data provided in (b)(4) [redacted]

CONCLUSION

We conclude the data presented in this report, along with information previously submitted to the FDA (b)(4) [redacted] substantiates an early intended use claim. These findings also support our contention that the First Response® Early Result Pregnancy Test can qualitatively detect hCG levels in the urine of pregnant women, and the results can be read by consumers five days earlier than the day of the expected menstrual period, or six days before the missed period.

PREPARED:

Henry Bell Date

REVIEWED & APPROVED:

Principal investigator:

Yea-Shun Cheng, Ph.D. Date

Program Manager:

Shang Li, Ph.D. Date

Research Fellow

Albert Nazareth, Ph.D. Date

APPENDIX I

(b)(4)
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(b)(4)

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(b)(4)

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13.0 PROTOCOL APPROVAL

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ATTACHMENT 2

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Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vicki Moyer

Subject: 510(k) Number K083716/S1

To: The Record

Please list CTS decision code SECS

VMoy 6/8/09

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☒ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			✓
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?		✓	
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Rev. 7/2/07

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number	Class*	Product Code
21CFR 862.1155	Class II	LCX

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: (Branch Chief) DGD (Branch Code) 06/08/2009 (Date)

Final Review: (Division Director) 6/8/09 (Date)

(cdh/cch edits)

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k083716

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

Church and Dwight

F. Proprietary and Established Names:

FIRST RESPONSE® Early Result Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   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.

3. Special conditions for use statement(s):

   For over the counter use

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

4. Special instrument requirements:

   None

I. Device Description:

The FIRST RESPONSE® Early Result Pregnancy Test kit consists of two chromatographic test strips enclosed in plastic housing and the package insert. The test strips contain avidin-biotin chemistry and mouse monoclonal and goat anti-mouse polyclonal antibodies.

The device is intended to detect pregnancy, in some cases, as early as 6 days before the missed period (5 days before the expected period). The 'expected period' is defined as Day 0 of a woman's menstrual cycle while "missed period" is defined as Day 1 of the menstrual cycle.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FIRST RESPONSE® Early Result Pregnancy Test

2. Predicate K number(s):

   k030258, k992232

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Early detection of pregnancy
Sample matrix	Same	Urine (midstream or dip)
Time to result	Same	3 minutes

Differences		
Item	Device	Predicate
Intended Use	Maybe be used up to 5 days before the expected period	Maybe be used up to 4 days before the expected period

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The test principle is lateral flow chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   The sponsor performed two studies with lay user consumers where they were asked to interpret test results from masked samples containing varying

concentrations of hCG. In the first study the urine samples were prepared from a negative urine pool and also spiked with purified hCG at (b)(4) (b)(4) In the second study urine samples were prepared from a negative urine pool and also spiked with purified hCG at lower hCG concentrations of (b)(4) Study participants were asked to interpret the result of the FIRST RESPONSE® Early Result Pregnancy test as either positive or negative using the instructions provided with the test.
The results are summarized in the table below.

Samples with hCG	Results
Study 1 (b)(4) consumers)	
(b)(4) mIU/mL (n=104)	104/104 negative
mIU/mL (n=104)	101/104 positive (97%)
mIU/mL (n=104)	101/104 positive (97%)
mIU/mL (n=104)	104/104 positive (100%)
Study 2 (b)(4) consumers)	
mIU/mL (n=104)	104/104 negative
(b)(4) mIU/mL (n=102)	5/102 positive (5%)
mIU/mL (n=104)	40/104 positive (38%)

b. *Linearity/assay reportable range:*

The effect of high dose hCG on the test was evaluated using hCG standards (WHO 4th IS) ranging from 1,000 mIU/mL to 500,000 mIU/mL. All samples yielded the expected positive results.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The test is calibrated against the WHO 4th I.S. for hCG.

The stability testing protocol used to support the shelf life was reviewed. The sponsor claims a 24-month shelf life for the test when stored below 86°F (30°C).

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Various prescription and OTC drugs (acetaminophen, acetylsalicylic acid, ascorbic acid, caffeine, gentisic acid, atropine, phenothiazine, phenylpropanolamine , ampicillin tetracycline, all at 10 µg/mL), potential endogenous interferants (glucose and albumin at 20 mg/mL, hemoglobin,

bilirubin, estriol at 10 μg/mL) and homologous hormones (hLH and hFSH at 1000 mIU/mL and hTSH at 1 mIU/mL) were added to aliquots of non-pregnant urine pool at hCG levels of 0 and 25 mIU/mL. These samples were run on the FIRST RESPONSE® Early Results Pregnancy Test and in each case, no effect on the performance of the test was observed. All samples produced negative results at 0 mIU hCG/mL and positive results at 25 mIU hCG/mL.

f. Assay cut-off:
This device is intended to detect pregnancy 5 days before the expected menstrual period. See the precision section above for performance at different concentrations of hCG.

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the subject device was compared to the predicate test of the same name, FIRST RESPONSE® Early Result Pregnancy Test. Urine samples from clinically determined pregnant and non-pregnant women were tested on both the predicate device and (b)(4) of the device under review. All non-pregnant samples were negative and all pregnant samples were positive.

(b)(4)

(b)(4)

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
A study was performed to determine the incidence of positive results in urine from non-pregnant females when tested with FIRST RESPONSE® Early Result Test. Urine specimens from non-pregnant women in pre-menopausal (ages 18-40) peri-menopausal (41-55 years) and post-menopausal (>55 years) age groups were evaluated. Testing was performed with (b)(4) of devices.

The results are summarized in the table below.

Age Group	Urine specimens (n)	Positive results (%)
18-40 years	(b)(4)	(b)(4) (0%)
41-55 years		(4.2%)
>55 years		(1.3%)

Detection of hCG in Early Pregnancy Clinical Samples

An early pregnancy study was performed to support the sponsor's claim that the device detects hCG in urine up to five (5) days before the expected period. Urine specimens were collected daily by women attempting to conceive. In all (b)(individual conceptive cycle sample panels were evaluated each having urine samples from 7 days prior to and 2 days after the first day of the expected menstrual period (day 0). A total of (b)(women consumers participated in the study to evaluate and interpret the samples from the conceptive cycles. The samples were randomized and tested individually using (b)(4) of the First Response devices. Each sample was tested twice and each result recorded independently.

When performed and interpreted by the consumer participants, the FIRST RESPONSE® Early Result Pregnancy Test detected a positive result in 68% of the cycles 5 days before the expected menstrual period, (b)(4) (b)(4) (b)(4) 100% of the cycles 2 days before the EMP, and 100% of the cycles 1 days before the EMP.

Summary of Consumer Reading Results

Day Relative to EMP	(b)(4)	EMP-5	(b)(4)	EMP-2	EMP-1	EMP	EMP+1
Positive results / cycle day		69/102		102/102	102/102	102/102	102/102
% positive results / cycle day		68%		100%	100%	100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of Missed Period

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k083716

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin (hCG)

D. Type of Test:

Qualitative

E. Applicant:

Church and Dwight

F. Proprietary and Established Names:

FIRST RESPONSE® Early Result Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:
   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.

3. Special conditions for use statement(s):

   For over the counter use

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

4. Special instrument requirements:

   None

I. Device Description:

The FIRST RESPONSE® Early Result Pregnancy Test kit consists of two chromatographic test strips enclosed in plastic housing and the package insert. The test strips contain avidin-biotin chemistry and mouse monoclonal and goat anti-mouse polyclonal antibodies.

The device is intended to detect pregnancy, in some cases, as early as 6 days before the missed period (5 days before the expected period). The 'expected period' is defined as Day 0 of a woman's menstrual cycle while "missed period" is defined as Day 1 of the menstrual cycle.

Comment [c1]: Vicki/Avis – make sure this is correct.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   FIRST RESPONSE® Early Result Pregnancy Test

2. Predicate K number(s):

   k030258, k992232

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Early detection of pregnancy
Sample matrix	Same	Urine (midstream or dip)
Time to result	Same	3 minutes

Differences		
Item	Device	Predicate
Intended Use	Maybe be used up to 5 days before the expected period	Maybe be used up to 4 days before the expected period

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

The test principle is lateral flow chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   The sponsor performed two studies with lay user consumers where they were asked to interpret test results from masked samples containing varying

concentrations of hCG. In the first study the urine samples were prepared from a negative urine pool and also spiked with purified hCG at (b)(4) (b)(4) In the second study urine samples were prepared from a negative urine pool and also spiked with purified hCG at lower hCG concentrations of (b)(4) Study participants were asked to interpret the result of the FIRST RESPONSE® Early Result Pregnancy test as either positive or negative using the instructions provided with the test.
The results are summarized in the table below.

Samples with hCG	Results
Study 1 ((b consumers)	
(mIU/mL (n=104)	104/104 negative
b mIU/mL (n=104)	101/104 positive (97%)
(b mIU/mL (n=104)	101/104 positive (97%)
)(mIU/mL (n=104)	104/104 positive (100%)
Study 2 ((b)(consumers)	
(b) IU/mL (n=104)	104/104 negative
(b)(mIU/mL (n=102)	5/102 positive (5%)
(b)(mIU/mL (n=104)	40/104 positive (38%)

b. *Linearity/assay reportable range:*

The effect of high dose hCG on the test was evaluated using hCG standards (WHO 4th IS) ranging from 1,000 mIU/mL to 500,000 mIU/mL. All samples yielded the expected positive results.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

The test is calibrated against the WHO 4th I.S. for hCG.

The stability testing protocol used to support the shelf life was reviewed. The sponsor claims a 24-month shelf life for the test when stored below 86°F (30°C).

d. *Detection limit:*

Not applicable

e. *Analytical specificity:*

Various prescription and OTC drugs (acetaminophen, acetylsalicylic acid, ascorbic acid, caffeine, gentisic acid, atropine, phenothiazine, phenylpropanolamine , ampicillin tetracycline, all at 10 µg/mL), potential endogenous interferants (glucose and albumin at 20 mg/mL, hemoglobin,

bilirubin, estriol at 10 μg/mL) and homologous hormones (hLH and hFSH at 1000 mIU/mL and hTSH at 1 mIU/mL) were added to aliquots of non-pregnant urine pool at hCG levels of 0 and 25 mIU/mL. These samples were run on the FIRST RESPONSE® Early Results Pregnancy Test and in each case, no effect on the performance of the test was observed. All samples produced negative results at 0 mIU hCG/mL and positive results at 25 mIU hCG/mL.

f. *Assay cut-off:*
This device is intended to detect pregnancy 5 days before the expected menstrual period. See the precision section above for performance at different concentrations of hCG.

2. Comparison studies:

a. *Method comparison with predicate device:*

The performance of the subject device was compared to the predicate test of the same name, FIRST RESPONSE® Early Result Pregnancy Test. Urine samples from clinically determined pregnant and non-pregnant women were tested on both the predicate device and (b)(4) of the device under review. All non-pregnant samples were negative and all pregnant samples were positive.

(b)(4)

b. *Matrix comparison:*
Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*
Not applicable

b. *Clinical specificity:*
Not applicable

17

c. Other clinical supportive data (when a. and b. are not applicable):
A study was performed to determine the incidence of positive results in urine from non-pregnant females when tested with FIRST RESPONSE® Early Result Test. Urine specimens from non-pregnant women in pre-menopausal (ages 18-40) peri-menopausal (41-55 years) and post-menopausal (>55 years) age groups were evaluated. Testing was performed with (b)(4) of devices.

The results are summarized in the table below.

Age Group	Urine specimens (n)	Positive results (%)
18-40 years	(b)(4)	(b)(4) (0%)
41-55 years		(4.2%)
>55 years		(1.3%)

Detection of hCG in Early Pregnancy Clinical Samples

An early pregnancy study was performed to support the sponsor's claim that the device detects hCG in urine up to five (5) days before the expected period. Urine specimens were collected daily by women attempting to conceive. In all, (b) individual conceptive cycle sample panels were evaluated each having urine samples from 7 days prior to and 2 days after the first day of the expected menstrual period (day 0). A total of (b) women consumers participated in the study to evaluate and interpret the samples from the conceptive cycles. The samples were randomized and tested individually using (b)(4) of the First Response devices. Each sample was tested twice and each result recorded independently.

When performed and interpreted by the consumer participants, the FIRST RESPONSE® Early Result Pregnancy Test detected a positive result in 68% of the cycles 5 days before the expected menstrual period, (b)(4) (b)(4) (b)(4) 100% of the cycles 2 days before the EMP, and 100% of the cycles 1 days before the EMP.

Summary of Consumer Reading Results

Day Relative to EMP	(b)(4)	EMP-5	(b)(4)	EMP-2	EMP-1	EMP	EMP+1
Day relative to OV		OV+10		OV+13	OV+14	OV+15	OV+16
Positive results / cycle day		69/102		102/102	102/102	102/102	102/102
% positive results / cycle day		68%		100%	100%	100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of Missed Period

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

   Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Other Supportive Device and Instrument Information:

"Laboratory sensitivity" by lab prof.

The sponsor performed a study using spiked samples at hCG concentrations of (b)(4) (b)(4) Three lots of devices were tested. All samples were tested n=5. The study was performed and interpreted by laboratory professionals. All replicates tested with the standards at (b)(4) and above were positive, and all replicates tested with the (b)(4) standard were negative. (b)(4)

Laboratory Sensitivity

(b)(4)

"Consumer readability test"

Since the device is being cleared based on performance by consumers, the results from lab professionals will not be shown in the template. This is the same as the data in the precision section of the template.

A study was performed with spiked urines at (b)(4) These results of the pre-assayed samples were interpreted by (b)(consumers and then the study monitor also recorded the result. There were (b)(results for each sample. All samples (b)(4) read by the study monitor were positive and all (mIU/mL samples were interpreted as negative. The consumers interpreted all (b) samples at (b)(4) samples as negative and all samples at (b)(4) as positive. They interpreted 101 out of 104 samples at the (b)(4) levels as positive (97%). (b)(4)

	Consumer	Monitor
(b) (4) mIU/mL (n (b)(4)	(b)(4) negative	(b)(4) negative
nIU/mL	positive (97%)	(b)(4) positive (100%)
mIU/mL	positive (97%)	positive (100%)
mIU/mL	positive (100%)	positive (100%)

A study was performed with spiked urines at (b)(4) consumers were recruited to perform the testing and interpret the results. A study monitor interpreted the results of each device also (b)(4)

	Consumer	Monitor
(b mIU/mL (n= (b)(4	(b)(4) negative	100% negative
(b) (4) mIU/mL	(b)(4) positive (5%)	(b)(4) positive (72%)
mIU/mL	(b)(4) positive (38%)	positive (100%)

For analytical specificity (section e above) studies for qualitative devices, we typically want data around the true cut-off, which for this device in the hands of consumers is about (b)(4) (where device is 95% positive) and/or where 50% of results are positive and 50% negative (which would be (b)(4)). Because of the unusual history of this device and in the way it was reviewed, this type of study was not performed nor was it requested by FDA. Based on our experience with these types of devices, these interferences are rather low risk.

Additional accuracy data

Additionally, (b) hCG-positive urine samples with pre-determined hCG levels ranging from (b)(4) (b)(4) were tested by in-house laboratory professionals using 510(k)-subject devices. The results are presented in Table 3 below. (k080103)

Table 3: Laboratory Accuracy with Clinical Specimens at Defined hCG Levels

hCG Range (mIU/mL)	Lot #1		Lot #2		Lot #3	
	Negative Result	Positive Result	Negative Result	Positive Result	Negative Result	Positive Result
(b)(4)						
(b)(4)						
Total	(b)(4)					

Other clinical supporting data

In another study, the ability of the consumers to perform the test with their own urine samples was evaluated. Non-pregnant (b)(4) and pregnant (b) females between the ages of 18 and 45 were recruited. Each subject was given the package insert to read thoroughly before performing the test. The subjects were given the choice of either performing the test using the mid-stream or dip method. (b)(4) (b)(4) method. The test was read in the presence of a study monitor at the same time as the consumer recorder her own result. All (b) subjects performed the test correctly and obtained valid results.

Consumer self-test using their own urine. Mid stream (b)(4) of consumers, (b)(4) [redacted]

	Consumer	Monitor
Pregnant (b)	100% positive	100% positive
Not pregnant (b)(4)	100% negative	100% negative

(b)(4) [redacted]

Conceptive cycle data summarized by lot and by quantified value on Immulite

(b)(4) [redacted]

Study with non-pregnant samples:

Another study was conducted at Church & Dwight with a separate panel of 100 urine samples from nonpregnant women (ages 18-40), and they were found to have a mean hCG value of <1 mIU/mL. When these samples were tested with FIRST RESPONSE® Early Result Pregnancy Test (three combined lots) by a trained laboratory technician, the incidence of positive results from the population was 0% (0/300). The results from this study are summarized below in Table 17

(b)(4) [redacted]

Q. Administrative Information:

1. Applicant contact information:

   a. Name of applicant:

   Church & Dwight Co., Inc.

   b. Mailing address:
   469 North Harrison Street
   Princeton, NJ 08543

   c. Phone #:

   (609) 279-7748

   d. Fax #:

   (609) 497-7179

   e. E-mail address (optional):

   STEPHEN.KOLAKOWSKY@CHURCHDWIGHT.COM

   f. Contact:
   Stephen C. Kolakowsky
   Director, Regulatory Affairs

2. Review documentation:

(b)(4)

[redacted]

The review team included Vicki Moyer, Avis Danishefky (reviewer), Carol Benson, DCTD Associate director, and Courtney Harper, Acting DCTD Director and previously Jean Cooper, former DCTD director. After extensive thought and discussion, the OIVD review team decided to make a substantially equivalent decision, but recommended a black box warning in the indications for use of the

device. The review team worked with medical officer Patricia Beaston on the IFU as well as the labeling that would accompany the device. OIVD made specific recommendations to the sponsor for the labeling since we believed 1) it was necessary to ensure the safety of the device and 2) so the claims associated with the device very clear and truthful for over the counter users.

3. Substantial Equivalence Discussion:

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	x		If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

a. *Explain how the new indication differs from the predicate device's indication:*

N/A

b. *Explain why there is or is not a new effect or safety or effectiveness issue:*

N/A

c. *Describe the new technological characteristics:*

N/A

d. *Explain how new characteristics could or could not affect safety or effectiveness:*

N/A

e. *Explain how descriptive characteristics are not precise enough:*

Descriptive characteristics are not adequate for making an SE determination for an IVD as the performance characteristics of a device must be characterized and compared to the predicate device or reference method.

f. *Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:*

N/A

g. *Explain why existing scientific methods can not be used:*

N/A

h. *Explain what performance data is needed:*

analytical sensitivity, method comparison, specificity. See section M

i. *Explain how the performance data demonstrates that the device is or is not substantially equivalent:*

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. See the decision summary template section M.

R. Reviewer Name and Signature:

Vicki Moyer 6/8/09
Vicki Moyer
CDRH/OIVD/DCTD

Note: the postmarket database was reviewed and no related signals or compliance issues were found.
6/8/09 vm

Memo

To: Memo to File

From: Vicki Moyer, Scientific Reviewer, CDRH/OIVD/DCTD 6/8/09

Date: June 5, 2009

Re: k083716 Church and Dwight First Response pregnancy test Vicki Moyer

---

On Friday morning June 5 Ron Caiazza, General Counsel, Church and Dwight, contacted OIVD to discuss their desire to have the 99% Accuracy claim on the box labeling.

Vicki Moyer and Courtney Harper participated on the call, as well as Steve Kolakowsky from Church and Dwight.

(b)(4)

[redacted]

26

Moyer, Vicki

From: Kolakowsky, Stephen [Stephen.Kolakowsky@churchdwight.com]
Sent: Monday, June 08, 2009 1:46 PM
To: Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test
Attachments: 11-Indiicatn4Use_A.doc; 11_Summary_A.doc

VICKI .....

Our file server is back on line. Attached are the Indications Statement and the Summary with the corrections you requested.

..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:Vicki.Moyer@fda.hhs.gov]
Sent: Friday, June 05, 2009 2:44 PM
To: Kolakowsky, Stephen
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Hi Steve-
I made 2 small changes consistent with what we discussed. Can you please review the changes and accept them if they are ok, then resend the corrected version?

Thank you!
Vicki

Vicki Moyer
OIVD-FDA

From: Kolakowsky, Stephen [mailto:Stephen.Kolakowsky@churchdwight.com]
Sent: Friday, June 05, 2009 1:11 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Dr. Harper .....

Attached per the request contained in your earlier eMail below are revised versions of our Intended Use Statement and our 510(k) Summary incorporating the language suggested in your attached "Labeling and Intended Use Modifications" document.

This will also serve to confirm our agreement to the "Labeling and Intended Use Modifications" as discussed earlier today.

27

Indication for Use

510(k) Number (if known): k083716

Device Name: FIRST RESPONSE® Early Result Pregnancy Test

Indication For Use:

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.

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

510(k) 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

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.

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 1:17 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test

Thank you very much for this prompt response. We will let you know if we have any questions as we prepare our final documentation.

Regards,

Courtney

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
2098 Gaither Rd.
Rockville, MD 20850
Ph 240-276-0694
Fax 240-276-0651
courtney.harper@fda.hhs.gov

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From: Kolakowsky, Stephen [mailto:Stephen.Kolakowsky@churchdwight.com]
Sent: Friday, June 05, 2009 1:11 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Dr. Harper .....

Attached per the request contained in your earlier eMail below are revised versions of our Intended Use Statement and our 510(k) Summary incorporating the language suggested in your attached "Labeling and Intended Use Modifications" document.

This will also serve to confirm our agreement to the "Labeling and Intended Use Modifications" as discussed earlier today.

It is our understanding that the above now clears the way for clearance of the 510(k) and avoidance of the need for a Panel meeting.

Stephen C. Kolakowsky

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 11:26 AM
To: St. Pierre, Don J.; Gutierrez, Alberto; Benson, Carol; Moyer, Vicki; Danishefsky, Avis ; Beaston, Patricia; Phillips, Tracy
Subject: Church and Dwight update

Church and Dwight have accepted our labeling requests. They plan to come back in to get some of the claims we did not get them (b)(4) [redacted] Therefore a panel meeting will not be necessary.

Tracy - Don't do anything to cancel the meeting until we actually sign out the 510(k) (hopefully Monday). Just in case anything changes in the meantime.

Thanks all,

Courtney

32

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, June 05, 2009 8:41 AM
To: Moyer, Vicki; Danishefsky, Avis
Cc: Benson, Carol
Subject: RE: k083716 - First Response Early Pregnancy Test

They will likely put it on the insert based on what we asked them. Let's see first if they agree to put it at all...

From: Moyer, Vicki
Sent: Friday, June 05, 2009 8:15 AM
To: Harper, Courtney C; Danishefsky, Avis
Cc: Benson, Carol
Subject: RE: k083716 - First Response Early Pregnancy Test

I thought of this on the way in this morning...
Do we want the black box warning on the box packaging? Or prominently at the start of the test instructions? I don't think we specified this.
Most of the information does appear throughout the labeling, however some does not (such as intended for home use....)

Vicki

From: Harper, Courtney C
Sent: Thursday, June 04, 2009 5:00 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test

Mr. Kolakowsky –

Thank you very much for responding so quickly to our request. It is very helpful as we try to resolve this issue. We have carefully considered your proposed modifications and believe that some of them are acceptable. However, there are a few of your suggestions that do not address our concerns. We have tracked our modified requests for the labeling changes based on your proposed modifications.

If you agree to modify your labeling, indications for use form, and 510(k) summary in accordance with our requests, please let us know and we will let the panel members know that the panel is not necessary. If, however, you do not agree with our requests, we will be happy to obtain our panel experts' input on this new type of device.

Thank you again for your prompt response,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices

Moyer, Vicki

From: Harper, Courtney C
Sent: Thursday, June 04, 2009 5:00 PM
To: 'Kolakowsky, Stephen'
Cc: Benson, Carol; Moyer, Vicki
Subject: RE: k083716 - First Response Early Pregnancy Test
Attachments: Labeling and Intended use modifications k083716 6 4 09.doc

Mr. Kolakowsky –

Thank you very much for responding so quickly to our request. It is very helpful as we try to resolve this issue. We have carefully considered your proposed modifications and believe that some of them are acceptable. However, there are a few of your suggestions that do not address our concerns. We have tracked our modified requests for the labeling changes based on your proposed modifications.

If you agree to modify your labeling, indications for use form, and 510(k) summary in accordance with our requests, please let us know and we will let the panel members know that the panel is not necessary. If, however, you do not agree with our requests, we will be happy to obtain our panel experts' input on this new type of device.

Thank you again for your prompt response,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
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From: Kolakowsky, Stephen [mailto:Stephen.Kolakowsky@churchdwight.com]
Sent: Thursday, June 04, 2009 3:10 PM
To: Harper, Courtney C
Cc: Benson, Carol; Moyer, Vicki
Subject: FW: k083716 - First Response Early Pregnancy Test
Importance: High

Dr. HARPER .....

Thank you for your input on our proposed labeling. We are able to agree to the majority of the revisions that you recommend and have incorporated our comments and other revisions to the proposed labeling for your consideration. See the attached file "10Lblg.doc". (Your original file is attached.) If you would like to discuss our comments, I can arrange a conference call this afternoon or tomorrow morning.

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Harper, Courtney C [mailto:Courtney.Harper@fda.hhs.gov]
Sent: Thursday, June 04, 2009 9:26 AM
To: Kolakowsky, Stephen
Cc: Benson, Carol; Moyer, Vicki
Subject: k083716 - First Response Early Pregnancy Test
Importance: High

Dear Mr. Kolakowsky -
Per your conversation with Don St.Pierre regarding the planned public panel meeting for your First Response device (k083716), the review team has worked hard to determine whether there are potential solutions to our review questions that would allow clearance in lieu of a panel meeting. We very much appreciate that you have quickly responded to our recent requests for additional analyses of data.

(b)(4)

[redacted]

Please let us know if you agree to these changes and submit modified labeling, indications for use form, and 510(k) summary that reflect these changes. Because of the scheduled panel meeting, we need this information very quickly (i.e., if the meeting is to be canceled, it must be done this week). Therefore, please send us your response to this proposal by COB today or early Friday, June 5. We apologize for the quick turn-around that is necessary.

In the meantime, please let us know if you have any questions on this and we will be happy to address them.
Thank you,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
2098 Gaither Rd.

35

Rockville, MD 20850
Ph 240-276-0694
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courtney.harper@fda.hhs.gov

<<Labeling and Intended use modifications k083716.doc>>

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First Response Early Pregnancy Test (k083716)

6/4/09

Change to Intended use with black boxed information:

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 65 days before the ~~expected~~ missed period.

Comment [c1]: This recommendation is for the labeling. We request that for the indications for Use form for the submission that you also insert to read: "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:
~~Many~~ Some pregnant women will not be able to detect hCG in their urine 65 days before the expected period. If you test negative before your ~~expected~~ 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~~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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute (This full statement may be on the side if it fits better. An asterisk should not be used.):

"Early results. In ~~half~~ one study, in 68% of the samples tested, pregnancy could be detected up to 65 days ~~prior to~~before the day of the ~~expected~~ missed period."

- Remove (b)(4) [redacted] ~~because this is not the accuracy at 5 days before the missed period.~~ There is not sufficient data for us to conclude that your test is (b)(4) [redacted] in the hands of the intended users ~~(both pregnant and not pregnant)~~ (both pregnant and not pregnant). This may be because of the (b)(4) [redacted] for your device which affects this performance metric.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":

We recommend you aAdd ~~a recommendation that women should use first morning urine.~~the following statement (or similar): "Your first morning urine contains the highest concentration of pregnancy hormone. However, you may test at any time of the day."

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by ~~5~~6 days before the ~~expected~~ missed period. In this study, all samples from pregnant women tested positive by 3~~2~~ days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because some women sometimes have difficulty predicting the exact ~~date~~date of their next ~~it is sometimes difficult to exactly predict the day of the expected~~ period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

Moyer, Vicki

From: Harper, Courtney C
Sent: Thursday, June 04, 2009 9:26 AM
To: 'stephen.kolakowsky@churchdwight.com'
Cc: Benson, Carol; Moyer, Vicki
Subject: k083716 - First Response Early Pregnancy Test

Importance: High

Attachments: Labeling and Intended use modifications k083716.doc

Dear Mr. Kolakowsky -

Per your conversation with Don St.Pierre regarding the planned public panel meeting for your First Response device (k083716), the review team has worked hard to determine whether there are potential solutions to our review questions that would allow clearance in lieu of a panel meeting. We very much appreciate that you have quickly responded to our recent requests for additional analyses of data.

(b)(4)

[redacted]

Please let us know if you agree to these changes and submit modified labeling, indications for use form, and 510(k) summary that reflect these changes. Because of the scheduled panel meeting, we need this information very quickly (i.e., if the meeting is to be canceled, it must be done this week). Therefore, please send us your response to this proposal by COB today or early Friday, June 5. We apologize for the quick turn-around that is necessary.

In the meantime, please let us know if you have any questions on this and we will be happy to address them.

Thank you,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
FDA, CDRH, OIVD (HFZ-440)
2098 Gaither Rd.
Rockville, MD 20850
Ph 240-276-0694
Fax 240-276-0651
courtney.harper@fda.hhs.gov

First Response Early Pregnancy Test (k083716)

6/4/09
Proposal

Change to Intended use with black boxed information:

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 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:
Many pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected 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 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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute:
"Early results. In half the samples tested, pregnancy could be detected up to 5 days prior to the day of the expected period."

- Remove (b)(4) because this is not the accuracy at 5 days before the missed period.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":
Add a recommendation that women should use first morning urine.

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged 41-55 showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by 5 days before the expected period. In this study, all samples from pregnant women tested positive by 2 days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because it is sometimes difficult to exactly predict the day of the expected period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

Moyer, Vicki

From: Harper, Courtney C
Sent: Wednesday, June 03, 2009 5:49 PM
To: Moyer, Vicki; Danishefsky, Avis
Cc: Benson, Carol; Beaston, Patricia
Subject: Labeling and Intended use proposal k083716 (06 02 09)).doc

Attachments: Labeling and Intended use proposal k083716 (06 02 09)).doc

Vicki and Avis -

I wanted to mark up the label, but I see that without a word copy that will be impossible. I edited this to be more definitive and less tentative. We need to add the ages of the perimenopausal subjects. Please take a look and see what you think:

Labeling and Intended use prop...

Courtney

47

First Response Early Pregnancy Test (k083716) 6/3/09

Change to Intended use with black boxed information:

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 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:
Many pregnant women will not be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected 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 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.

Other Changes to the Box:

- Remove "Early results 6 days sooner". Substitute:
"Early results. In half the samples tested, pregnancy could be detected up to 5 days prior to the day of the expected period."

- Remove (b)(4) because this is not the accuracy at 5 days before the missed period.

- Remove study results on the side of the box, because it's not clear that this study represents conditions of home use testing. The study results to be described in more detail in the Q&A section of the package insert.

Changes to the package insert information:

Under "instructions and use":
Add a recommendation that women should use first morning urine.

Changes to "Q and A" section:

How does the test work?
[No change recommended to the beginning of this statement, but the study information should be moved to a separate question – specifically, How accurate is the test (below).]

What does it mean if the result is positive (pregnant)?
[Change to: "A positive (pregnant) result shows that pregnancy hormone (hCG) was detected. You should see your doctor to confirm that you are pregnant.

Because this test detects very low levels of hCG some women may test positive even if they are not pregnant. For example, a study of women aged ?-? showed that 4 out of 100 women tested positive even though they were not pregnant. Such "false positive" results in women in this age group are generally due to a hormone called pituitary hCG.]

Comment [c1]: Need to add ages

What does it mean if the result is negative (not pregnant)
[Add: "See section below – How accurate is the test?" to the end of current statement]

How accurate is the test?
[The current text should be replaced with the following:
"One study showed positive results for 68% of the samples by 5 days before the expected period. In this study, all samples from pregnant women tested positive by 2 days before the expected period. However, it is important to note that your results may vary, and that some women may not have detectable amounts of pregnancy hormone in their urine until after the missed period. This is because hCG levels vary between women, and because it is sometimes difficult to exactly predict the day of the expected period. If test results are negative, but you still believe you may be pregnant, you should retest a few days after your missed period. If the test is negative, but you still believe you may be pregnant, consult with your healthcare provider."

No changes to other sections in the Q and A.

(b)(4)

(b)(4)

Moyer, Vicki

From: Harper, Courtney C
Sent: Friday, May 29, 2009 10:03 AM
To: Moyer, Vicki; Ramamurthy, Lakshman; Benson, Carol; Danishefsky, Avis
Cc: Phillips, Tracy
Subject: RE: Church and Dwight k083716-Internal meeting summary

OK. Please ask for this information by COB today.

Thanks,

Courtney

From: Moyer, Vicki
Sent: Friday, May 29, 2009 8:42 AM
To: Harper, Courtney C; Ramamurthy, Lakshman; Benson, Carol; Danishefsky, Avis
Cc: Phillips, Tracy
Subject: RE: Church and Dwight k083716-Internal meeting summary

Good morning-
I would like to ask the company for more information, in addition to what we already requested:

First, the company's position is that the apparent lot to lot variability is due to the differences in (b)(4) [redacted] interpreting the line, not due to the manufacturing inconsistency of the device. For the consumer study, (b)(4) [redacted] (b)(4) according to their protocol. I would like to request the data (b)(4) [redacted] summarized for the (b)(4) since this presumably should have much less variability and could make our case stronger or at least give us more information.

Second, I plan to ask them for clarification on one item in their response to item 1 of our AI letter. They say they will add (b)(4) [redacted] but then later say they think there is not a (b) (b)(4) [redacted] problem and its a postmarket issue. Since they use the words "product release" in the stability response I have interpreted that to mean they will add (b)(4) [redacted] and (b)(4) [redacted] but using their words "product release" seems to imply manufacturing. I'd like them to clarify this point before we go to them again and say they have not addressed our concern about manufacturing inconsistency.

Still no acknowledgement of my email earlier this week. Don says he is going to contact them.

Vicki

From: Harper, Courtney C
Sent: Thursday, May 28, 2009 1:16 PM
To: Moyer, Vicki; Ramamurthy, Lakshman; Benson, Carol; Danishefsky, Avis
Cc: Phillips, Tracy
Subject: RE: Church and Dwight k083716-Internal meeting summary

have you gotten the lot data you wanted?

From: Moyer, Vicki
Sent: Thursday, May 28, 2009 12:43 PM
To: Ramamurthy, Lakshman; Benson, Carol; Danishefsky, Avis ; Harper, Courtney C
Cc: Phillips, Tracy
Subject: Church and Dwight k083716-Internal meeting summary

Hello all:
Here is a summary of our conclusions at the meeting this morning. Vicki, Avis, Carol, Tracy (by phone), and

47

Lakshman were in attendance.

The performance of the device demonstrates that the consumers could detect hCG in samples 5 days before the expected period. (b)(4) [redacted] This was identified as a concern in our AI letter (see attached) and the sponsor disagreed that this is an issue (see attached) *If Church and Dwight give us some assurance that they* (b)(4) [redacted] (b)(4) [redacted] *we would feel comfortable about an SE with stronger labeling (still needs to be worked on).*
<< File: Hold AI LETTER-k083716.pdf >> << File: Response k083716-S1 AI (04.23.09).pdf >>

Stronger labeling is warranted because this device detects concentrations of hCG much lower than other cleared devices. The stronger labeling would include truthful information that some women may not test positive 5 days before expected period, if you are over xx years, you may test positive....

If the above issue can be satisfactorily addressed by the sponsor and they are willing to reconsider their position, we don't think a panel opinion is needed.

If the do not adequately address the concern and label appropriately, we won't SE.

Carol, et al, does this accurately reflect our conclusions?
Courtney, do you support this approach? How should we communicate this to the sponsor?

Vicki

(b)(4)

(b)(4)

First Response Early Pregnancy Test (k083716) 5/28/09
Idea for on the box if we proceed with SE:

Changes from current box

- Remove "Early results 6 days sooner" in very large font
- Remove (b)(4) [redacted]
- Add the following language and make it more prominent (not very small on side of box).

This test detected pregnancy (hCG) **5 days before the expected period in approximately half of women tested**. Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again in a few days after your missed period using the first morning sample.

If you are near age 40 or older, or are nearing menopause: there is a chance you may test positive (pregnant) with this test even if you are **not** pregnant. This is because women at ages nearing menopause who are not pregnant have low levels of a compound called "pituitary hCG" which may give a positive result with this test. If pregnancy is suspected, you should see your health care provider.

Intended use:
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 detects hCG in some women, as early as 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.

Not all pregnant women will be able to detect hCG in their urine 5 days before the expected period. If you test negative before your expected period, but think you may still be pregnant, you should re-test again in a few days (one week) after your missed period using the first morning sample.

There is a small chance that this test will give positive results in the absence of pregnancy.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Vicki Moyer

Subject: 510(k) Number K083716

To: The Record

Vicki Moyer 2/25/09

Please list CTS decision code AI

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page needs new form	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement. ok	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf) no			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.) page 2			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Carol C Benson (Branch Chief) DCTD (Branch Code) February 25, 2009 (Date)

Final Review:
(Division Director) (Date)

Memo

To: Memo to File

From: Vicki Moyer, Scientific Reviewer, CDRH/OIVD/DCTD

Date: February 25, 2009

Re: k083716 Church and Dwight First Response pregnancy test

Vicki Moyer
2/25/09

Several meetings were held to discuss concerns relating to the performance of this device. See meeting notes and emails dated 1/7/09 and 2/10/09.

In order to fully understand and evaluate all of the data Church and Dwight has submitted for this device, including the data submitted under (b)(4) and (b)(4) a draft decision summary template was prepared and is included in this file. FDA has requested that the sponsor submit a hard copy of the content of (b)(4) to include in the current submission.

We identified several concerns and they have been compiled into a request for additional information. See attached. The sponsor will be sent an AI letter and emailed the questions as well.

80

Church & Dwight Co., Inc.
c/o Mr. Stephen Kolakowsky
469 North Harrison Street
Princeton, NJ 08543

Draft

Re: k083716
Trade Name: FIRST RESPONSE® Early Result Pregnancy Test
Dated: December 12, 2008
Received: December 15, 2008

Dear Mr. Kolakowsky,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require the additional information outlined below.

1. FDA continues to be concerned about the performance of the device in measuring (b)(4) (b)(4)

   (b)(4) FDA recommended that you modify your stability study protocol and acceptance criteria to include a (b)(4) (b)(4) FDA continues to be concerned that your previously stated criteria are not adequate to control stability trends over time and (b)(4) You indicated in a recent email to FDA that a sample with hCG concentration (b)(4) a (b)(4) is tested as part of your stability and lot release protocols. The acceptance criterion is that the test device must produce a (b)(4) (b)(4) is tested. We disagree that inclusion of a sample at (b)(4) is adequate to mitigate our concerns because a sample of this concentration does not represent a (b)(4) sample. The hCG level of this type of sample should reflect a concentration where lab professionals and/or lay users should get a negative result. We consider a weak negative to be a sample that produces a negative result 95% of the time. You may find the CLSI "User Protocol for Evaluation of Qualitative Test Performance" EP12-A2 helpful when evaluating the performance of your device. Please note, instead of the term "weak negative" the protocol uses the term C_5. The C_5-C_{95} interval is defined as the range of analyte such that observed results outside of the interval are consistently negative ($<C_5$) or consistently positive ($>C_{95}$).

   At the request of FDA you provided a summary of the Consumer Readability Study for the (b)(4) of test devices and with sample hCG concentrations by rank order. There appears to be significant performance differences between the (b)(4) tested. We are particularly concerned that for (b)(4) that (b) of samples in the range of (b)((b)(4) were interpreted as Positive, while for the other (b)(4) (b)(4 and (b) of samples in this same concentration range were interpreted as Positive. For this same lot, (b) of samples with concentration in the range of (b)(4) were

Draft

interpreted as Positive. Additionally, (b)(samples with hCG concentrations (b)(4) (b)(4) were interpreted as positive for (b)(4) while (b)(4 samples were interpreted as positive for (b)(4) (Note: following your response, we identified two other observations where the specimen had hCG (b)(4) specimen (b)(4) interpreted the result as positive using (b) (b)(4)

These data suggest that the performance of the device in detecting very low levels of hCG is not well characterized and that manufacturing in-process testing criteria to ensure lot to lot consistency may not be adequate.

Please perform studies with multiple lots of test devices to determine at what concentration of hCG a weak negative result is achieved. Please revise your stability protocols to include a weak negative sample. Additionally please address how you plan to resolve issues of lot to lot variability.

2. With regard to the validation studies in support of the use of the (b)(4) to quantitatively measure hCG in urine, in an e-mail dated January 9, 2009, FDA asked for additional detail on the study performed to evaluate the limit of quantitation. Specifically we asked for the criteria for acceptable precision and trueness. In your response, you referred to the (b)(4) validation protocol provided as exhibit III and stated that studies were performed based on the recommendations of CLSI EP17-A "Protocols for Determination of Limits of Detection and Limits of Quantitation;" however, we still have questions about your acceptance criteria and data analysis. In order for us to better understand the conclusions of the validaton study including the limit of blank and limit of quantitation please provide the line data for these studies.

3. On page 15 of your submission, you included a completed Indications for Use form, however, this is not the most current version of the form. Please obtain the current version of the form that can be found at The Office of In Vitro Diagnostic Evaluation and Safety website: http://www.fda.gov/cdrh/oivd/indicationsforuse.html, complete it and resubmit it with your response. Additionally, please add "up to 5 days before the expected period" to the existing language.

4. In the Questions and Answers section of the device labeling, you describe that "about 2% of women (all over the age of 47) had very low levels of hCG" using your device. However, in a study performed by testing the urine of (b)(4) (b)(4) In a similar study testing urines from (b)(4) (b)(4) Please revise the Questions and Answers section to reflect the actual test results obtained for both the (b)(4) (b)(4)

Moyer, Vicki

From: Moyer, Vicki
Sent: Tuesday, February 10, 2009 4:52 PM
To: Harper, Courtney C
Cc: Benson, Carol; Danishefsky, Avis ; Moyer, Vicki
Subject: RE: Church and Dwight k083716

Courtney-
Carol, Avis and I met to discuss the data.

Overall, we concluded that the consumer data new to this submission and the other clinical and analytical studies may support their claims, however we identified some concerns.

- We still do not have consistent data demonstrating where the device produces a negative result in the presence of know quantities of hCG. The laboratory sensitivity study presented in section M. 1.d. of the draft template shows that quantities of hCG as low as (b)(4) [redacted] produce positive results (b)(4 [redacted] of the time, whereas the study on page 5 shows that the same concentration gives a positive result (b)(4 [redacted] of the time.
- The consumer study results when summarized by lot of device shows that the device performance varies significantly. It does appear that consumers can interpret a sample in the range of (b)(4) [redacted] as positive (b)(4) [redacted] of the time but samples as low as (b)(4) [redacted] were also interpreted as positive.
- In our NSE letter we asked that they include a weak negative sample (b)(4) [redacted] in their stability and lot release criteria. They have done this however the acceptance criterion is of concern. The devices must produce a "weak positive" result at (b)(4) [redacted] The sponsor has not defined "weak positive". We wonder what would happen if the result during testing was a strong positive. Would this meet their criterion?
- The indications for use should be revised to include the phrase "up to 5 days before the expected period" in addition to the "6 days before the missed period." We are concerned about using the language "sooner" and this has apparently been discussed with the sponsor before (according to previous records).
- The labeling currently averages the studies using perimenopausal and postmenopausal specimens from women to state that the rate for false positives is (b)([redacted] The data should accurately be stated. The False pos. rate for perimenopausal samples was about (b)(4 [redacted] and (b)(4 [redacted] for post menopausal. We think the perimen. false pos. rate is particularly important.
- There are a few more minor clarifications on the data also needed.

Please let us know if you have additional concerns not covered here and if you would like me to arrange a time for us all to discuss. The current version of the draft decision summary contains all the data submitted by Church and Dwight, but will certainly need to worked on further should we proceed with an SE decision. If we feel there are still major concerns, we need to next consider how we will present the issues to the sponsor.

Vicki

From: Harper, Courtney C
Sent: Monday, February 09, 2009 4:41 PM
To: Moyer, Vicki
Subject: RE: Church and Dwight k083716

Vicki -

We have a potential class I recall that has come up and the meeting for that has to be at this time. Would you work out a proposal with Carol and Avis. You can brief me on it afterwards.

Thanks,

Courtney

From: Moyer, Vicki
Sent: Friday, February 06, 2009 8:23 AM
To: Benson, Carol; Danishefsky, Avis ; Harper, Courtney C; Moyer, Vicki

83

Subject: Church and Dwight k083716
When: Tuesday, February 10, 2009 11:00 AM-12:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: TBD

When: Tuesday, February 10, 2009 11:00 AM-12:00 PM (GMT-05:00) Eastern Time (US & Canada).
Where: TBD

~~*~*~*~*~*~*~*~*~*

Meeting to discuss next steps for this submission. A decision summary with be sent prior to the meeting.

**Carol-I could not view your calendar, so if another time is better, please let me know.

Moyer, Vicki

Subject:	Church and Dwight k083716
Location:	Carol's office
Start:	Wed 1/7/2009 2:00 PM
End:	Wed 1/7/2009 2:30 PM
Recurrence:	(none)
Meeting Status:	Meeting organizer
Required Attendees:	Moyer, Vicki; Harper, Courtney C; Benson, Carol

Updated time

Hi Carol and Courtney,
I would like to discuss Church and Dwight's latest submission for the First Response Early Pregnancy test, specifically the results of the consumer study and the data they provided the serve as validation for (b)(4) (quantitative hCG with urine). I have concerns that their consumer study does not show what they claimed, that consumers can not read a line (b)(4) Some consumers reported a + result for samples as little as ((b)(4) Also, the validation data they provided for the (b)(4) is minimal and not adequate in my opinion.

Sorry but I couldn't schedule this meeting during Carol's office hours in the afternoon.
If you need any additional info. prior to the meeting please let me know.

Vicki

85

Moyer, Vicki

From: Kolakowsky, Stephen [Stephen.Kolakowsky@churchdwight.com]
Sent: Wednesday, February 25, 2009 9:07 AM
To: Moyer, Vicki
Subject: RE: k083716 additional supporting data

VICKI .....
I sent a CD via FedEx overnight and it should arrive this AM at the Corporate Document Center.
..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, February 20, 2009 10:23 AM
To: Kolakowsky, Stephen
Cc: Harper, Courtney C
Subject: k083716 additional supporting data

Dear Mr. Kolakowsky-
In your submission k083716 for the First Response Early pregnancy test, reference is made to related 510(k) submissions which were previously determined to be not substantially equivalent, but contain many studies that apply to the submission under review.

In order for our records to be complete for the current submission k083716, please submit the content of (b)(4) supplements and add to files) either electronically or by sending a hard copy add-to-file to the document mail center. I realize that you have at my request sent me this information already (thank you again) however, to ensure that there is no misunderstanding about the studies supporting the current submission, we think this is the best route. There is no need to incorporate the studies into k083716 or reformat the current submission, just simply submit file with all contents again and indicate it is in support of k083716.

Thank you in advance.
Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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86

Moyer, Vicki

From: Kolakowsky, Stephen [Stephen.Kolakowsky@churchdwight.com]
Sent: Tuesday, February 24, 2009 10:57 AM
To: Moyer, Vicki
Subject: RE: k083716 additional supporting data

Ms. Moyer .....

I was out of the office, and will be reassembling (b)(4) as an Add-to-File to K083716.

..... STEVE

Stephen C. Kolakowsky
Director, Regulatory Affairs
Church & Dwight Co., Inc.
Tel: (609) 279-7748
Fax: (609) 497-7179

From: Moyer, Vicki [mailto:vicki.moyer@fda.hhs.gov]
Sent: Friday, February 20, 2009 10:23 AM
To: Kolakowsky, Stephen
Cc: Harper, Courtney C
Subject: k083716 additional supporting data

Dear Mr. Kolakowsky-
In your submission k083716 for the First Response Early pregnancy test, reference is made to related 510(k) submissions which were previously determined to be not substantially equivalent, but contain many studies that apply to the submission under ew.

In order for our records to be complete for the current submission k083716, please submit the content of (b)(4) (including supplements and add to files) either electronically or by sending a hard copy add-to-file to the document mail center. I realize that you have at my request sent me this information already (thank you again) however, to ensure that there is no misunderstanding about the studies supporting the current submission, we think this is the best route. There is no need to incorporate the studies into k083716 or reformat the current submission, just simply submit file with all contents again and indicate it is in support of k083716.

Thank you in advance.
Best regards,
Vicki

Vicki Moyer
Scientific Reviewer
Office of In Vitro Diagnostic Devices
Evaluation and Safety
Food and Drug Administration
Phone (240) 276-0698
vicki.moyer@fda.hhs.gov

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87

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

Draft
2/25/09

A. 510(k) Number:

k083716

B. Purpose for Submission:

New device

C. Measurand:

Human chorionic gonadotropin

D. Type of Test:

Qualitative

E. Applicant:

Church and Dwight

F. Proprietary and Established Names:

FIRST RESPONSE® Early Result Pregnancy Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1155

2. Classification:

   Class II

3. Product code:

   LCX

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The FIRST RESPONSE® Early Result Pregnancy Test is an *in vitro* diagnostic test device intended for the early detection of pregnancy by the lay user up to six (6) days sooner than the day of the missed period.

3. Special conditions for use statement(s):

   For over the counter use

   For in vitro diagnostic use

4. Special instrument requirements:

   None

I. Device Description:

J. Substantial Equivalence Information:

1. Predicate device name(s):

2. Predicate K number(s):

3. Comparison with predicate:

Similarities		
Item	Device	Predicate

Differences		
Item	Device	Predicate

Differences		
Item	Device	Predicate

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle:

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   See detection limit

   b. *Linearity/assay reportable range:*

   The effect of high dose hCG on the test was evaluated using hCG standards ranging from 1,000 mIU/mL to 500,000 mIU/mL. All samples yielded the expected positive results.

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

   The test is calibrated against the WHO 4th I.S. for hCG.

(b)(4)

[redacted]

1.

90

(b)(4)

FDA questions: Are we concerned that a "weak positive" is rather subjective? What if the (b)(4) standard produces a strong positive result instead of a weak positive? What is the course of action? Do we also want them to include a standard with low hCG that produces a negative result?

d. Detection limit:

(b)(4)

(b)(4)

(b)(4)

(b)(4)

	Consumer	Monitor
(b)(4) mIU/mL (n=104)	(b)(4) negative	100% negative
mIU/mL	positive (97%)	(b)(4) positive (100%)
mIU/mL	positive (97%)	positive (100%)
mIU/mL	positive (100%)	positive (100%)

91

A study was performed with spiked urines at (b)(4) (b)(4) were recruited to perform the testing and interpret the results. A study monitor interpreted the results of each device also. (b)(4)

	Consumer	Monitor
(mIU/mL (n=(b)(4	(b)(4) negative	100% negative
(b)(4) mIU/mL	(b)(4) positive (5%)	(b)(4) positive (72%)
(4) mIU/mL	(b)(4) positive (38%)	positive (100%)

e. *Analytical specificity:*

Various prescription and OTC drugs (at 10 µg/mL), potential endogenous interferants (see the list below), and homologous hormones (hLH and hFSH at 1000 mIU/mL and hTSH at 1 mIU/mL) were added to aliquots of non-pregnant urine pool at hCG levels of 0 and 25 mIU. These samples were run on the FIRST RESPONSE® Early Results Pregnancy Test and in each case, no effect on the performance of the test was observed. All samples produced negative results at 0 mIU hCG/mL and positive results at 25 mIU hCG/mL.

DRUGS
Acetaminophen
Acetylsalicylic Acid
Ascorbic Acid
Caffeine
Gentisic Acid
Atropine
Phenothiazine
Phenylpropanolamine
Ampicillin
Tetracycline

Endogenous interferants	**QUANTITIES**
Human Albumin	20 mg/mL
Glucose	20 mg/mL
Hemoglobin	10 µg/mL
Bilirubin	10 µg/mL
Estriol	10 µg/mL

f. *Assay cut-off:*

See detection limit

2. Comparison studies:

92

a. Method comparison with predicate device:

The performance of the subject device was compared to that of the currently marketed FIRST RESPONSE® Early Result Pregnancy Test to determine laboratory accuracy. A total of (b)(urine samples, clinically determined pregnant and non-pregnant, were tested on both devices. The results showed no discrepancies between the two devices. All (b) non-pregnant samples were negative and all (b) pregnant samples were positive, resulting in an overall agreement of 100%. (b)(4) [redacted]

Urine Sample	Number of Samples	Predicate Device Correct Results (Accuracy)	510(k)-Subject Device Correct Results (Accuracy)
Non-Pregnant	103	103/103 (100%)	103/103 (100%)
Pregnant	50	50/50 (100%)	50/50 (100%)
Total	153	153/153 (100%)	153/153 (100%)

Samples from 150 clinically determined pregnant and non-pregnant, were tested with 2 additional lots of devices. (k080103)

Table 2: FIRST RESPONSE® Early Result Pregnancy Test Laboratory Accuracy

Urine Sample	Number of Samples	Lot # 2	Lot # 3	Total
Non-pregnant	100	100/100 (100%)	100/100 (100%)	200/200 (100%)
Pregnant	50	50/50 (100%)	50/50 (100%)	100/100 (100%)

Additionally, 101 hCG-positive urine samples with pre-determined hCG levels ranging from 6.1 to 188 mIU hCG/mL (determined using Immulite 1000 Immunoassay Analyzer) were tested by in-house laboratory professionals using 510(k)-subject devices. The results are presented in Table 3 below. (k080103)

Table 3: Laboratory Accuracy with Clinical Specimens at Defined hCG Levels

hCG Range (mIU/mL)	Lot #1		Lot #2		Lot #3	
	Negative Result	Positive Result	Negative Result	Positive Result	Negative Result	Positive Result
(b)(4) [redacted]	0/13	13/13	0/13	13/13	0/13	13/13
	0/21	21/21	0/21	21/21	0/21	21/21
	0/15	15/15	0/15	15/15	0/15	15/15
	0/12	12/12	0/12	12/12	0/12	12/12
	0/12	12/12	0/12	12/12	0/12	12/12
	0/17	17/17	0/17	17/17	0/17	17/17
	0/11	11/11	0/11	11/11	0/11	11/11
Total	0/101	101/101	0/101	101/101	0/101	101/101

b. *Matrix comparison:*

Not applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

b. *Clinical specificity:*

In a study conducted by Church & Dwight to determine the incidence of positive results with FIRST RESPONSE® Early Result Test, (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] When samples collected from the perimenopausal women were tested with FIRST RESPONSE® Early Result Pregnancy Test (three combined lots) by a trained laboratory technician, the incidence of positive results from the population was 4.2% (13/312). The results from this study are summarized below in Table 8 and the complete study report is provided in Exhibit 1. (b)(4) [redacted]

Table 8: Laboratory Performance — Perimenopausal Urines

Age Group	Urine Samples (n)	(b)(4)	Positive Results
41-55	104		13/312 (4.2%)

(b)(4)

In a study conducted by Church & Dwight to determine the incidence of positive results with FIRST RESPONSE® Early Result Test, (b)(4)

(b)(4)

When urine samples collected from the postmenopausal-age women were tested with FIRST RESPONSE® Early Result Pregnancy Test (three combined lots) by a trained laboratory technician, the incidence of positive results from the population was 1.3% (4/312). The results from this study are summarized below in Table 9 and the complete study report is provided in Exhibit 1. (b)(4)

Table 9: Laboratory Performance — Postmenopausal urines

Age Group	Urine Sample (n)	(b)(4)	Positive Results
56-75	104		4/312 (1.3%)

(b)(4)

c. Other clinical supportive data (when a. and b. are not applicable):

Consumer self-test using their own urine. Mid stream 75% of consumers, 25% cup. (b)(4)

	Consumer	(b)(4)	
Pregnant (3)	100% positive		
Not pregnant (101)	100% negative		

Pregnant: 2 confirmed by physician, 1 by another hCG OTC test

Detection of hCG in Early Pregnancy Clinical Samples, study 1 (k063335)

Early pregnancy studies were performed with approximately (b)(4) from a total of (b)(4) conceptive cycles. The testing segment in each cycle commenced with the two consecutive negative samples followed by the first sample demonstrating a rise in hCG, and the testing segment ended with the sample collected 3 days after the expected menstrual period (EMP).

When performed and interpreted by lab professionals, The FIRST RESPONSE® Early Result Pregnancy Test detected the hCG rise in (b)(of the cycles 5 days before the expected menstrual period, (b) of the cycles 4 days before the EMP, (b) of the cycles 3 days before the EMP, (b)(4) of the cycles 2 days before the EMP, and (b)(4) of the cycles 1 days before the EMP.

Detection of hCG in Conceptive Cycles Relative to Expected Menstrual Period and (b)(4) Using 510(k)-Subject FIRST RESPONSE® Early Result Pregnancy Test

Day relative to expected period	(b)(4)	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
(b)(4)		(b)(4)						
# Cycles positive for hCG		41/50	45/50	44/45	48/48	49/49	47/47	50/50
Cumulative % Cycles positive for hCG		(b)(4)					100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of the Missed Period.

The data were recalculated to include those samples from the 52 conceptive cycles that tested positive for hCG with the subject device and had quantitative hCG values of (b)(4) (in order to model how consumers would interpret the results), relative to the day of the expected menstrual period. After this adjustment, the FIRST RESPONSE® Early Result Pregnancy Test detected the hCG rise in (b)(4 of the cycles 5 days before the EMP, (b)(4) of the cycles 4 days before the EMP (b)(4) of the cycles 3 days before the EMP, (b) of the cycles 2 days before the EMP, and (b)(4) of the cycles 1 days before the EMP.

Cycles Testing Positive with 510(k)-Subject FIRST RESPONSE® Early Result Pregnancy Test with Samples ≥ 8 mIU hCG/mL

Day relative to expected menstrual period	(b)(4) [redacted]	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
(b)(4) [redacted]								
# Cycles positive for hCG	[redacted]	31/50	39/50	39/45	47/48	49/49	47/47	50/50
Cumulative % Cycles positive for hCG	[redacted]	(b)(4) [redacted]					100%	100%

Note: EMP = Expected Menstrual Period EMP+1 = Day of the Missed Period

Detection of hCG in Early Pregnancy Clinical Samples, study 2 (k083716)

Early pregnancy studies were performed with over 500 samples from a total of 51 individual conceptive cycles. They were collected daily by women attempting to conceive. The specimens were delivered to collection facilities, then characterized for cycle length, hCG (b)(4) [redacted] and LH quantitative values. The study was performed according to protocol 238 which was reviewed by FDA in pre-IDE I080286.

A total of 102 women participated in the study to evaluate the samples from the conceptive cycles. The samples were randomized and tested individually. The samples were tested using the First Response test using 2 devices. (b)(4) [redacted] (b)(4) [redacted] then the devices were presented to 2 consumers separately and the results recorded. (b)(4) [redacted] were utilized in the study, each lot tested with about 17 conceptive cycles.

(b)(4) [redacted]

Day Relative to EMP	(b)(4) [redacted]
(b)(4) [redacted]	
Positive results/cycle day	
% positive results / cycle day	

Note: EMP = Expected Menstrual Period EMP+1 = Day of Missed Period

When performed and interpreted by the consumer participants, the FIRST RESPONSE® Early Result Pregnancy Test detected the hCG rise in 68% of the cycles 5 days before the expected menstrual period, 89% of the cycles 4 days before the EMP, 100% of the cycles 3 days before the EMP, 100% of the cycles 2 days before the EMP, and 100% of the cycles 1 days before the EMP.

15 missed 16

Summary of Consumer Reading Results

Day Relative to EMP	EMP-10	EMP -9	EMP - 8	EMP-7	EMP-6	EMP-5	EMP-4	EMP-3	EMP-2	EMP-1	EMP	EMP+1
(b)(4) [redacted]												
Positive results / cycle day	0/2	0/28	0/74	8/100	30/102	69/102	91/102	100/102	102/102	102/102	102/102	102/102
% positive results / cycle day	0%	0%	0%	8%	29%	68%	89%	98%	100%	100%	100%	100%

Note: EMP = Expected Menstrual Period

EMP+1 = Day of Missed Period

(b)(4) [redacted]

(b)(4) [redacted]

hCG	(b)(4) [redacted]												Total			
mIU	N	Neg	Pos	%Pos	N	Neg	Pos	%Pos	N	Neg	Pos	%Pos	N	Neg	Pos	%Pos
(b)(4)	70	70	0	0%	72	70	2	3%	72	71	1	1%	**214**	**211**	**3**	**1%**
	22	17	5	23%	24	19	5	21%	16	15	1	6%	**62**	**51**	**11**	**18%**
	20	9	11	55%	10	2	8	80%	14	10	4	29%	**44**	**21**	**23**	**52%**
	18	4	14	78%	18	2	16	89%	8	4	4	50%	**44**	**10**	**34**	**77%**
	6	2	4	67%	10	2	8	80%	12	1	11	92%	**28**	**5**	**23**	**82%**
	2	0	2	100%	2	0	2	100%	6	0	6	100%	**10**	**0**	**10**	**100%**

(b)(4) [redacted]

4. Clinical cut-off:

   Not applicable

5. Expected values/Reference range:

(b)(4) [redacted]

(b)(4) [redacted]

Table 16: Laboratory Performance — Non-Pregnant Urine Samples

Age Group	Urine Sample (n)	(b)(4) [redacted]	Negative Results	Positive Results
18-40	63		189/189 (100%)	0/189 (0%)

(b)(4) [redacted]

Another study was conducted at Church & Dwight with a separate panel of 100 urine samples from nonpregnant women (ages 18-40), and they were found to have a mean hCG value of <1 mIU/mL. When these samples were tested with FIRST RESPONSE® Early Result Pregnancy Test (three combined lots) by a trained laboratory technician, the incidence of positive results from the population was 0% (0/300). The results from this study are summarized below in Table 17

Table 17: Laboratory Performance – Non-Pregnant Urine Samples

Urine Samples (n)	Device Lot #	Negative Results	Positive Results
100	1	100/100	0/100
100	2	100/100	0/100
100	3	100/100	0/100

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

2. The petition for Evaluation of Automatic Class III Designation for this device is accepted. The device is classified as Class II under regulation 21 CFR 8xx.xxxx with special controls. The special control guidance document "xyzxyzxyzxyzxyz" will shortly be available shortly.

3. The petition for Evaluation of Automatic Class III Designation for this device is accepted. The device is classified as Class II under regulation 21 CFR 8xx.xxxx with special controls. The special control guidance document "xyzxyzxyzxyzxyz" is available at www.fda.cdrh..... (Insert the URL to the Special Control guidance document here).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

April 24, 2009

CHURCH & DWIGHT CO., INC.
469 NORTH HARRISON STREET
PRINCETON, NEW JERSEY 08543
UNITED STATES
ATTN: STEPHEN C. KOLAKOWSKY

510k Number: K083716

Product: FIRST RESPONSE EARLY RESULT PR

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department – Building 100, Princeton, NJ 08543

K083716/S1

April 23, 2009

Via FedEx*

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd
Rockville, MD 20850

FDA CDRH DMC
APR 24 2009
Received

Attn: Courtney C. Harper, PhD
Acting Director, Div Chem & Tox
Office of In Vitro Diagnostic Devices
Evaluation and Safety (HFZ-440)

Re: **510(k) Notification K083716**
FIRST RESPONSE® Early Result Pregnancy Test (OTC)

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR §20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §20.61(c) AND §807.95

Dear Dr. Harper:

This is in reply to the Food and Drug Administration letter of February 25, 2009, which raised four issues concerning which you requiring additional information in determining the substantial equivalency of the above referenced medical device, the FIRST RESPONSE® Early Result Pregnancy Test for OTC use. Reference is also made to our telephone conference call with the Division of March 27, 2009. The four items raised in the letter are addressed below in the same order as in the letter.

* Track # 7965 4496 9278

60
K30

FDA Issue #1 (b)(4) [redacted]

[1] Please perform studies with multiple lots of the device to determine at what concentration of hCG a weak negative result is achieved. [2] Please revise your stability protocols to include (b)(4) [redacted] *[3] Additionally please address how you plan to resolve issues of* (b)(4) [redacted].

[1] With respect to determining a weak negative result:

As defined in your letter a "weak negative" is a sample that produces a negative result 95% of the time. We have determined that the (b)(4) [redacted]

[2] With respect to the stability protocols:

(b)(4) [redacted]

[3] With respect to lot-to-lot consistency:

We believe this comment to be inappropriate because the lot-to-lot consistency of the product is primarily a post-market manufacturing issue, subject to FDA's regulation under the Quality System Regulation (21 C.F.R. Part 820) rather than an issue subject to premarket review. We have established and maintain procedures in our quality system that ensure lot-to-lot consistency. We have a heritage of manufacturing OTC pregnancy tests since 1978 and of manufacturing professional use pregnancy tests and other

IVD products for many years prior. No significant issue was ever raised by any FDA inspector regarding the lot-to-lot consistency of the FIRST RESPONSE® Early Result Pregnancy Test. We have continued this heritage of high quality production as exemplified by the Company's marketing history with this device. The Company has marketed over two million of the same devices in the EU, Canada, and in Australia since 2007 without any stability issues. (b)(4) [redacted]
(b)(4) [redacted]

Even if lot-to-lot consistency were an appropriate issue for premarket review, as discussed during our March 27 call with the Division, this product *does* perform consistently from lot-to-lot. The variability in results — alluded to in your letter regarding the Consumer Readability Study as suggesting a lack of lot-to-lot consistency — is actually (b)(4) [redacted]
(b)(4) [redacted]

(b)(4) [redacted]

FDA Issue #2. *The Division questions the validation of the* (b)(4) *assay used to quantify the hCG in the samples used in the Consumer Readability Study and requests the line data in order to better understand the conclusion of the validation study including the limit of blank and limit of quantitation.*

We have provided the line item data utilized to generate the Limit of Blank (LoB), Limit of Detection (LoD), and Limit of Quantitation (LoQ) in DD Protocol (b)(4) [See Attachment 1.]

The Limit of Blank (LoB) was determined by using (b)(4) (b)(4) (b)(4) Following DD Protocol (b)(4), the LoB from the data generated by those (b)(4) was calculated to be (b)(4)

The Limit of Detection (LoD) was determined by using the (b)(4) (b)(4) points. Following DD Protocol (b)(4) the LoD from the data generated by those (b) replicates was calculated to be (b)(4) which in the (b)(4) Validation Report was set at (b)(4)

The Limit of Quantitation (LoQ) was established using (b)(4) following the recommendation from CLSI-EP-17A, which defines the LoQ as the "lowest amount of analyte that can be quantitatively determined with acceptable precision and trueness, under stated experimental conditions". (b)(4) (b)(4) (b)(4) The trueness, or bias, was the closeness of agreement between the average value of those test results and the accepted reference value of 2 mIU/mL (established by the WHO 4TH IS hCG standard).

The total error was defined by the equation given in section (b)(4) Validation Protocol (derived from Section 5.2 of CLSI-EP-17A), and accounted for both the precision and trueness inherent within the system. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] We also respectfully note the following:

- The (b)(4) [redacted] has been previously cleared via 510(k) by the FDA for clinical use by professionals, which also included the qualitative detection of hCG in urine. It was never the intent of DD Protocol (b)(4) [redacted] for quantitative use by professionals or clinicians outside of Church & Dwight. The intent of the validation study was to validate the (b)(4) [redacted] Church & Dwight's intended usage: quantitative detection of hCG in clinical urine samples to assign reference values to those samples during development. (b)(4) [redacted] (b)(4) [redacted] (b)(4) [redacted] The qualitative results returned by the pregnancy test are completely independent of any and all data generated by the Immulite, and there is an immense body of data that supports that the subject device is safe in the hands of the consumer.

- (b)(4) [redacted]

(b)(4) [redacted]

- The validation protocol was generated following the intent and purpose of the CLSI documents recommended by the Division in previous communications during the review process. Church & Dwight had reservations about following the recommended documents, as not only were they too detailed for our intended usage, but overall they are subject to different interpretation surrounding cutoffs, bias, precision, total error, and so forth. Ultimately, the Company attempted to work in good faith by following the intent of the recommended CLSI documents to validate the (b)(4) [redacted] following a protocol that reflected our intended usage during product development.
- As per CLSI-EP17A, goals for total error are dependent upon intended usage, which in our case is a quantitative detection of hCG in clinical urine samples to assign reference values to those samples during development. Also note that in Section 5 of CLSI-EP-17A, it clearly states that: "Establishing goals for total error is beyond the scope of this document". We believe that our good faith approach to using this standard is clearly supported by the fact that the reference document which was recommended by the Division states that it is left to the discretion of the laboratory performing the validation to set those goals.

<u>FDA Issue #3</u> *The completed Indications for Use form on page 15 of your submission is not the most current version of the form, which should be submitted, and add "up to 5 days before the expected period" to the existing language.*

We have copied the latest Intended Use form from the OIVD website http://www.fda.gov/cdrh/oivd/indicationsforuse.html and revised the intended use statement as now requested by the Division. [See Attachment 2.]

FDA Issue #4 *The Question and Answers section of the device labeling should be revised to reflect the actual test results obtained for* (b)(4) [redacted]
(b)(4) [redacted]

The Division requests the revision of our package insert labeling relating to the results of our Study of Non-Pregnant Women of Pre-, Peri-, and Post-Menopausal Age conducted and submitted (b)(4) [redacted]
(b)(4) [redacted] This issue was not raised during the review of

As explained in our telephone conference call, the Division has previously approved for competitive products now in the marketplace the language structure we use in our labeling statement. We believe the Company should be allowed to use the same language structure as that cleared previously for other OTC pregnancy test devices.

We believe that our responses above and in the enclosed attachments complete address the requests for addition information made in your letter of January 25, 2009.

Sincerely,

Stephen C. Kolakowsky
Director, Regulatory Affairs

Attachments (2)

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

[redacted]

Indication for Use

510(k) Number (if known): K083716

Device Name: FIRST RESPONSE® Early Result Pregnancy Test

Indication For Use: The FIRST RESPONSE® Early Result Pregnancy Test is an *in vitro* diagnostic test device intended for the early detection of pregnancy by the lay user up to six (6) days sooner than the day of the missed period (5 days before the expected period)

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

510(k)_____