

k112870

5. 510(k) SUMMARY

DEC 10 2012

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Date Prepared: November 16th, 2012

Proprietary Name: Clearblue® Advanced Pregnancy Test with Weeks Estimator

Common Name: Over-the-Counter hCG Pregnancy Test Kit

Classification Name: Human chorionic gonadotropin (hCG) test system

Predicate Device: Clearblue® Easy Digital Pregnancy Test (now marketed as Clearblue® Digital Pregnancy Test)

Description of the Device: The Clearblue® Advanced Pregnancy Test with Weeks Estimator is a Class II in vitro diagnostic medical device product. It functions by way of a sandwich immunoassay employing monoclonal antibodies specific for hCG in the urine as an aid in the early diagnosis of pregnancy, and using chromatographic principles to separate bound and free coloured label. The test is indicated for use from four days before the expected period, which is equivalent to five days before the day of the missed period. In the case of a positive test the added "Weeks Estimator" feature provides the pregnant user with an estimation of the number of weeks since ovulation.

The device is in a ready-to-use format and consists of a plastic stick, which contains an absorbent tip that protrudes from the end of the device. The absorbent tip collects and delivers urine to reagents on test chips contained within the device. An optical detection system in the device measures the signals present on the test chips. The test is performed by placing the absorbent tip of the device downward in the urine stream for 5 seconds or by

immersing the absorbent tip into a container of urine for 20 seconds. On wetting, the urine travels along the absorbent section, and activates the device.

The detection of hCG in the urine sample above a threshold is indicated by the “Pregnant” result on the display and a “Weeks Estimator” result (“PREGNANT 3+”, “PREGNANT 2-3”, or “PREGNANT 1-2”). These numbers are an estimation of how many weeks since ovulation, where the ‘3+’ means more than three weeks since ovulation, ‘2-3’ means two and up to three weeks since ovulation and ‘1-2’ weeks means one to two weeks since ovulation. The test uses a semi-quantitative measurement of hCG concentration in urine to categorize each positive result into one of the three intervals. If the concentration of hCG in the sample is below the minimum detection threshold the display will show a “Not Pregnant” result. All results will continue to be shown on the display for approximately 24 hours.

Intended Use

The Clearblue Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).

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

This test contains a “Weeks Estimator.” The “Weeks Estimator” is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor’s clinical diagnosis. The ‘Weeks Estimator’ is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.

This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor’s determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.

Substantial Equivalence Data

Numerous laboratory and consumer performance studies were conducted to determine the substantial equivalence of the test to the Clearblue® Easy Digital Pregnancy Test for the early detection of pregnancy. These studies are as follows:

- A laboratory study to evaluate the accuracy of pregnancy determination of the Clearblue® Advanced Pregnancy Test with Weeks Estimator against quantitative determination of hCG concentration using urine samples submitted for pregnancy testing.
- A laboratory study to determine the performance of the Clearblue® Advanced Pregnancy Test with Weeks Estimator when tested on urine samples collected from a panel of non-pregnant women of pre-, peri- and post-menopausal age, where the concentration of hCG was determined in each individual urine sample by testing on a quantitative assay.

- An Early Pregnancy Study using urine samples from 135 pregnancy cycles was conducted to confirm the pregnancy detection rate of the test when used before the expected period.
- A Gestational Age study was completed to determine the performance of the “Weeks Estimator” feature when compared to reference methods for duration of pregnancy.
- Consumer usage studies conducted included the evaluation of: 1) consumer accuracy when compared to results obtained by trained technicians; 2) the ability of lay consumers to easily perform the test and interpret the results.
- Potentially interfering substances and cross-reactants were tested to ensure they do not interfere with the test’s performance.

The consumer performance and laboratory studies conducted demonstrate that the Clearblue® Advanced Pregnancy Test with Weeks Estimator is substantially equivalent in its intended use and performance in detecting pregnancy from four days before the expected period/five days before the missed period to the predicate test Clearblue® Easy Digital Pregnancy Test (now marketed as Clearblue® Digital Pregnancy Test) which is currently marketed in the USA.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

December 10, 2012

SPD Swiss Precision Diagnostics GMBH
c/o SPD Development Company Ltd.
Mark Gittins
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United Kingdom

Re: k112870

Trade/Device Name: Clearblue Advanced Pregnancy Test with Weeks Estimator
Regulation Number: 21 CFR §862.1155
Regulation Name: Human Chorionic Gonadotropin (HCG) Test system
Regulatory Class: Class II
Product Code: LCX
Dated: November 28, 2012
Received: December 3, 2012

Dear Mr. Gittins:

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of In Vitro Diagnostics and Radiological Health (OIR) has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the device's labeling:

1. Box Labeling:
 - a) Performance of the Weeks Estimator should not be displayed on your box labeling. Box labeling should instruct users to see the package insert for test instructions and for more information on the Weeks Estimator.
 - b) The terms "*Accurate or Accuracy*" should not be used on your box labeling.
2. Package Insert:

- a) Weeks Estimator results should not be expressed as “weeks pregnant” and should only be explained as the number of weeks that may have passed since ovulation.
- b) Weeks Estimator performance should only be presented as follows:

Result	Pregnant 1-2	Pregnant 2-3	Pregnant 3+
What does this mean?	Your result is Pregnant and you may be 1-2 weeks since ovulation	Your result is Pregnant and you may be 2 and up to 3 weeks since ovulation	Your result is Pregnant and you may be more than 3 weeks since ovulation
How your doctor may date your pregnancy (weeks pregnant)	3-4 weeks	4-5 weeks	5+ weeks

- The Weeks Estimator result is determined by the level of hCG in your urine. The level of hCG varies from woman to woman and therefore the Weeks Estimator may give misleading results. All results should be confirmed by your doctor, especially when making decisions about future medical care. Only your doctor can determine whether your pregnancy is healthy.
- Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate. Please note that the doctor may date your pregnancy differently from the information shown in this table, since pregnancy dating is dependent on the circumstances of the patient.
- Agreement of Weeks Estimator results with clinical findings ranged widely from 45-99%.

Furthermore, the following indications for use must be prominently displayed in all labelling, including pouch box, and carton labels, and instructions for use, in close proximity to the trade name, of a similar point size and in bold and shall be conveyed accurately – including any limitations -- in all promotional materials:

“The Clearblue Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).

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

This test contains a “Weeks Estimator.” The “Weeks Estimator” is meant solely as an estimate for the consumer and is not intended as a substitute for a doctor’s clinical diagnosis. The ‘Weeks Estimator’ is not intended for multiple pregnancies. The estimate provided by the device may be inaccurate in these cases.

This test cannot be used to determine the duration of pregnancy or to monitor the progression of pregnancy. Your doctor determines how many weeks pregnant you are based on the first day of your last menstrual period and ultrasound results. This test provides a different estimate that cannot be substituted for a doctor’s determination of gestational age. Only your doctor can provide a reliable estimate of gestational age and only your doctor can monitor pregnancy progression. You should seek qualified prenatal care if you suspect you are pregnant.”

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device’s labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

Alberto Gutierrez

Alberto Gutierrez, Ph.D.

Director

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): k112870

Device Name: Clearblue Advanced Pregnancy Test with Weeks Estimator

Indications for Use:

The Clearblue Advanced Pregnancy Test with Weeks Estimator is an over-the-counter urine hCG test which is intended for the detection of pregnancy. The test detects hCG in some cases from four days before the expected period (which is 5 days before the day of the missed period).

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

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

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

Alberto Gutierrez
2012.12.10 14:31:57 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k112870