DIRECT ACCESS DIAGNOSTICS

K962521 JUL 29 1996

510(k) SUMMARY per 21CFR 807.92(c)

June 14, 1996

Trade name - FactPLUS® One Step Pregnancy Test

Common name - Consumer Use Home Pregnancy Test

Classification name- Human Chorionic Gonadotropin (hCG) Test System

Statement

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule..."*510(k) Summaries and 510(k) Statements.*" (21CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

- Modified device name: FactPLUS® One Step Pregnancy Test
- Predicate device name: ADVANCE® Pregnancy Test

Intended Use

The FactPLUS® One Step Pregnancy Test is an over-the-counter *in vitro* diagnostic immunoassay intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine. This device is the same device as ADVANCE® Pregnancy Test, with a labeling modification that provides for reading the test in three minutes without affecting the accuracy, sensitivity or specificity of the test.

Indications

FactPLUS One Step Pregnancy Test is indicated for consumer use to detect pregnancy as early as first day of a missed period, using a direct urine stream sampling mode. Test results can be read after three minutes. Some positives appear as soon as one minute, negative results are confirmed in three minutes.

Safety

Home pregnancy tests for detection of hCG in urine have been safely used and in commercial distribution for over two decades. *In vitro* diagnostic hCG urine tests which do not come in contact with the body are not generally associated with safety issues. Home-use pregnancy tests are categorized as "waived" status under the 1988 Clinical Laboratory and Improvement Amendment (CLIA).

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XI. 510(k) SUMMARY (continued)

Device Description

The FactPLUS One Step Pregnancy Test is an elongated "*Test Stick*" constructed of two pieces of molded plastic which house the internal chemistry strip. The chemistry strip contains a conjugate site, an antibody reaction site and a test control site. There are three openings on the upper surface of the *Test Stick*:

- "*Urine Well*"
- "*Result Window*"
- "*Control Window*"

Urine is absorbed through the *Urine Well* and travels along the test membrane to the *Result Window* (reaction site) and finally to the *Control Window.* The conjugate (anti-α hCG antibody) present on the membrane is mobilized by the urine flow. If hCG molecules are present in the urine, an hCG/conjugate/complex is formed. The mobilized hCG/conjugate/ complex continues to migrate along the strip to the reaction site where it binds with the anti-β hCG antibody present on the vertical bar and the polyclonal antibody present on the horizontal bar causing both bars to turn pink. The appearance of pink color on both intersecting bars create the plus sign or "pregnant" result. This reaction generally appears within three minutes. Some positives appear as soon as one minute; however, negative results are confirmed in three minutes.

In the absence of hCG molecules, the conjugate remains unbound and attaches only to the antibody present on the horizontal bar, causing it to turn pink. The appearance of only one reaction bar constitutes the minus or ("not pregnant") result. The urine continues to migrate until it reaches the *Control Window* where it reacts with a special dye causing a red color to appear. The red color in the *CW* is an indication that enough urine was added to the device. It takes approximately five minutes after the addition of urine for the *Control Window* to turn red. A labeling modification and optimization of the test antibodies, enable the results to be read sooner than previous versions of the test and eliminates the restriction of waiting for red color in the *Control Window* before reading the results.

Substantial Equivalence

The FactPLUS® One Step is substantially equivalent to, and is the same device as, the currently marketed ADVANCE® Pregnancy Test with a modification to the labeling for reading the results sooner. Results obtained in three minutes and some positives as soon as 1 minute, per the FactPLUS One Step labeling are substantially equivalent to results obtained in five minutes per the current ADVANCE labeling.

The proposed and the marketed devices have the same intended use, technology, performance characteristics, chemistry, component materials, and test analyte. The device can be used the first day of missed period, any time of the day.

XI. 510(k) SUMMARY (continued)

Performance Data

Substantial equivalence was demonstrated in laboratory validation studies which tested for accuracy, specificity and sensitivity at the new time frame.

Accuracy was performed using hCG-positive and hCG-negative female clinical urine specimens across three different lots of marketed ADVANCE. Test results read according to the modified labeling directions at (three minutes) and according to the current labeling directions (five minutes), demonstrated 100% agreement. Test results read at the one minute time frame demonstrated 98% agreement. Results were confirmed by running another currently marketed pregnancy test simultaneously.

Additionally, laboratory testing for both sensitivity and specificity read according to the modified and current labeling directions, demonstrated 100% agreement.

Consumer Testing

A consumer clinical study was conducted to verify that consumers could obtain accurate test results when performing the FactPLUS One Step test according to modified directions for reading the test at three minutes. The consumer population consisted of 150 female volunteers recruited from a Central New Jersey location. The volunteers were between the ages of 18 to 45, from various income, educational and employment backgrounds. One hundred forty-seven (147) of one hundred fifty volunteers who were instructed to read the test results at three minutes, performed the test and interpreted the results correctly for an overall accuracy rate of 98%.

Conclusion

The FactPLUS Pregnancy Test with modified directions has been shown to be substantially equivalent to the currently marketed ADVANCE Pregnancy Test in laboratory validation testing for accuracy, sensitivity, specificity demonstrating 99%, 100% & 100% respectively.

Additionally, results of consumer clinical testing demonstrated that the FactPLUS One Step can be performed and correctly interpreted by consumers at three minutes with an overall accuracy rate of 98%.