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APR 23 1996

**MiniClinic Ovulation Predictor for Consumer Use**

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Prepared: January 8, 1996

**510(k) Summary of Product Safety and Effectiveness**

The trade name of this device is *MiniClinic* Ovulation Predictor. It is a qualitative visual test system for the detection of human Luteinizing Hormone (hLH) in urine as an indicator of ovulation and would be classified as a Human Luteinizing Hormone Test System.

Vanguard Biomedical Corporation considers the *MiniClinic* Ovulation Predictor to be substantially equivalent to other comparable FDA-approved products in intended use, test procedure, and test principles.

**INTENDED USE**

The *MiniClinic* Ovulation Predictor is a monoclonal antibody-based immunoassay intended for the visual qualitative detection of human Luteinizing Hormone (hLH) in urine. This test is used to detect the mid-cycle LH surge which occurs approximately 24 hours prior to ovulation. By predicting ovulation, conception can be planned most effectively. Its intended use is identical to that of several over-the-counter (OTC) products currently available for home use.

These include: **Conceive**® Ovulation Predictor

Quidel  
10165 McKellar Court  
San Diego, CA 92121

Clearplan Easy One Step Ovulation Predictor

Whitehall Labs, Inc.  
New York, N.Y.

**PRINCIPLES AND PROCEDURES**

The urine sample is applied to a paper reservoir which is in contact with a pad containing a dried conjugate of colloid gold-monoclonal antibody (reddish in color). The urine sample will then reconstitute the dried conjugate. If hLH is present in the sample, it will react with the monoclonal antibody to form a complex of colloid gold-monoclonal antibody-hLH. This complex migrates up in a membrane strip chromatographically and through a band of immobilized goat anti-hLH (the test line). Because the antibody of this immobilized goat anti-hLH is able to bind the hLH molecule of the migrating complex, a visible reddish band is formed along the exact location of the immobilized goat anti-hLH antibody. The amount of color seen on the test line is proportional to the amount of hLH present in the urine sample.

Further up the membrane, past the anti-hLH test line, is a control line consisting of a band of immobilized goat anti-mouse IgG. This band of antibody will bind only conjugate and form a colored line, regardless of whether hLH is present in the urine or not. The concentration of goat anti-mouse IgG and colloid gold-antibody conjugate are adjusted to give a color response against which the test line can be compared. Levels of hLH above baseline values will produce color on the test line which is darker than the control line. By observing the appearance of the two lines the user can determine the status of their LH surge.

JAN 18 12:38 PM '96