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

A. 510(k) Number:
k032563

B. Analyte:
hCG

C. Type of Test:
Qualitative immunochromatographic test cassette analyzed on the Clinitek Status analyzer

D. Applicant:
Bayer Healthcare, LLC

E. Proprietary and Established Names:
Clinitest hCG Pregnancy Test

F. Regulatory Information:

1. Regulation section:
   21 CFR § 862.1155
2. Classification:
   Class II
3. Product Code:
   JHI
4. Panel:
   75 Clinical Chemistry

G. Intended Use:

1. Indication(s) for use:

   The Bayer Healthcare Clinitest hCG Pregnancy Test is for in vitro diagnostic use as a qualitative method in the rapid detection of human chorionic gonadotrophin (hCG) in urine specimens. The test is utilized with the Clinitek Status analyzer and is intended for near patient (point of care) and centralized laboratory locations.

2. Special condition for use statement(s):

   For professional use only. The assay is intended for use in point-of-care and centralized laboratory settings.

3. Special instrument Requirements:
   Clinitek Status Analyzer

H. Device Description:

The Clinitest hCG pregnancy Test is a qualitative sandwich-type immunoassay. The test contains monoclonal anti-alpha hCG antibodies in the test line and goat anti-mouse IgG antibodies on the control line. Colliodal gold particles are coated with anti-beta hCG antibodies. The test strip was previously cleared under K023944. This submission is for clearance of the strip to be automatically read on the Clinitek Status analyzer.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Clinitest® hCG Pregnancy Test and
   Quidel QuickVue® One-Step hCG-Combo
2. Predicate K number(s):
   k023944
   k020801
3. Comparison with predicate:

The device and its predicates share the same intended use and basic assay principle. Other similarities and differences are outlined below.

Similarities			
Item	**Clinitest® hCG Pregnancy Test (read on analyzer)**	**Clinitest® hCG Pregnancy Test**	**Quidel QuickVue® One-Step**
Sample type	Urine	Urine	Urine or Serum
Sample volume	~200 µL	~200 µL	~125 µL
Positive Cut-off	25 mIU/mL	25 mIU/mL	25 mIU/mL
Differences			
Item	**Clinitest® hCG Pregnancy Test (new use)**	**Clinitest® hCG Pregnancy Test**	**Quidel QuickVue® One-Step**
Result reading	Read by Clinitek Status analyzer	Visually read	Visually read
Reagent calibration	WHO 3rd IRP	WHO 3rd IRP	WHO 4th IS (75/589)
Time to result	5 minutes for confirmation of negative	5 minutes for confirmation of negative	3 minutes for confirmation of negative

J. Standard/Guidance Document Referenced (if applicable):
The following standards and guidance documents are referenced in the submission:

- ISO 14971:2000 Medical Devices – Application of Risk Management to Medical Devices

- ISO 13485:1996 – Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001
- IEEE 1012:1998 – Standard for Software Verification and Validation. (Software)
- ISO/IEC 12207:1995 – Information technology – Software Life Cycle Processes
- AAMI/ANSI SW68:2001 – Medical device software – Software Life Cycle Processes Capability - Maturity Model version 1.3
- IEC (EN) 60601-1-2:1993 (Second edition, 2001), Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests
- Recognition and Use of Consensus Standards, Final Guidance for Industry and FDA Staff
- The Least Burdensome Provision of the FDA Modernization Act of 1997: Concepts and Principles; Final guidance for Industry and FDA
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs)

K. Test Principle:

The Clinitest hCG test strips were cleared under k023944. Sample introduced into the sample well reacts with anti-beta hCG antibodies coupled to colloidal gold particles. This mixture moves chromatographically up the test strip. If there is hCG in the sample, the hCG/colloidal gold will bind the anti-alpha hCG antibodies on the test line thus forming a pink colored line. There is also a control line of goat anti-mouse antibodies to control for chromatographic flow in the cassette.

For automatic reading on the Clinitek analyzer, the cassette is placed in the analyzer immediately following sample application. The instrument reads the reflectance and compares the intensity to that of a reference line that has been adjusted to reflect a level of approximately 25 mIU/mL hCG.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

Evaluations of intra- and inter-instrument precision were made using immuno hard standards, which consist of 5 printed lines whose width and reflectance spectra are similar to that of the Clinitest strips. Ten (10) different standards were randomly read on 52 instruments with and 10 measurements of a single cassette on two single instruments. Data was generated for lines designated as blank, weak, moderately intense, or strong. The intra-instrument % CV was reported as <10 % for weak lines, and <4% for moderate and strong lines. Inter-instrument % CV was reported as <11 % for weak lines, and <4.4 % for moderate lines, and < 4.6 % for strong lines. Day-to-day precision was evaluated in a similar manner over a 27-week period. The resulting % CVs were consistent with intra- and inter-instrument precision results.

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

The instrument is designed to self-calibrate prior to every cassette measurement. Reflectance readings are taken at the white plastic calibration bar, at the reference line (designed to represent approximately 25 mIU/mL hCG concentration), at the test line, and at the control line. From those readings, the machine can compare the test line to the reference line (as corrected by the dark current reading and the calibration bar) to determine whether the hCG level is ≥ the intensity of a line with 25 mIU/mL.

The device has an internal process control.

d. Detection limit:

See assay cut-off below for qualitative cut-off levels. The positive cutoff was validated with the clearance of the cassette.

Negative urine samples spiked with hCG were tested on the Clinitek analyzer using the Clinitest strips. The following instrument results were obtained (n=36 at each concentartion of hCG):

hCG (mIU/mL)	Percent Positive
0	0
2	0
5	0
10	0
15	16.6
20	72.2
25	100
50	100
100	100

e. Analytical specificity:

The test strips read by the Clinitek analyzer in this submission were previously cleared under 510(k) K023944. All cross-reactivity and interference studies were done at that time. Please refer to the prior submission for specific information.

Urine samples up to 600,000 mIU/mL hCG cause no high-does hook effect. The sponsor provides references stating that this concentration of hCG is two to three times higher than levels found in pregnant individuals.

f. Assay cut-off:

Hormone levels greater than 25 mIU/mL are reported as positive. Hormone levels less than 25 mIU/mL are negative. Indeterminate results are reported as borderline and the user is prompted to retest in 48-72 hours.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 3120 urine results were obtained at 4 sites using the Clinitek Status and Clinitest test strips. The same samples were read visually using a commercially available test kit (predicate device). The following results were obtained (38 samples were taken out of the analysis because visual readers were unwilling to say whether the tests were positive or negative using the predicate device):

	Predicate test		
Clinitest hCG	**Negative**	**Positive**	**Total**
Negative	1996 98.2 %	10 0.9 %	2006
Borderline	27 1.3 %	2 0.2 %	29
Positive	9 0.5 %	1038 98.9 %	1047
Total	2032	1050	3082

The sponsor then assayed the discrepant results using a commercially available RIA kit to come up with the following agreements (note: the RIA kit is not cleared for quantitative measurement of hCG in urine):

	Predicate test/RIA		
Clinitest hCG	**Negative**	**Positive**	**Total**
Negative	1999 99.7 %	3 0.3 %	2002
Borderline	7 0.3 %	7 0.6 %	14
Positive		1051 99.1 %	1051
Total	2006	1061	3067

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical sensitivity:

Not applicable. Patient samples were not clinically verified.

b. Clinical specificity:

Not applicable. Patient samples were not clinically verified.

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

M. Conclusion:

I recommend that the Bayer Healthcare Clinitest hCG Pregnancy Test for automatic reading on the Clinitek analyzer is substantially equivalent to the legally marketed predicate device.