510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE

A. 510(k) Number:
K031947

B. Analyte:
Urinary Creatinine, Glucose and Blood

C. Type of Test:
Semi-quantitative

D. Applicant:
BAYER HEALTHCARE, LLC

E. Proprietary and Established Names:
BAYER CLINITEK STATUS ANALYZER

F. Regulatory Information:

1. Regulation section:
   21CFR §862.1225 -Creatinine test system.
   21CFR §862.1340 -Urinary glucose (nonquantitative) test system.
   21 CFR §864.6550-Occult blood test.
   21CFR §862.2900 -Automated urinalysis system.

   Class I exempt (not reviewed):
   21 CFR §862.1785-Urinary urobilinogen (nonquantitative) test system.
   21 CFR §862.1550-Urinary pH (nonquantitative) test system.
   21 CFR §862.1435-Ketones (nonquantitative) test system.
   21 CFR §862.1645-Urinary protein or albumin (nonquantitative) test system
   21 CFR §862.1115-Urinary bilirubin and its conjugates (nonquantitative) test system.
   21 CFR §862.1095-Ascorbic acid test system.
   21 CFR §862.1510-Nitrite (nonquantitative) test system.
   25 CFR §864.9320-Copper sulfate solution for specific gravity determinations.
   21 CFR §864.7675-Leukocyte peroxidase test.
2. Classification:
   II and I reserved
3. Product Code:
   JFY, JIL, JIP, KQO
4. Panel:
   Chemistry (75), Hematology (81)

G. Intended Use:

1. Indication(s) for use:

The Clintek Status Urine Chemistry Analyzer is a portable, easy to use instrument which reads Bayer reagent test strips for urinalysis (Multistix brand reagent strips), for testing in the clinical laboratory.
The automated analyzer is intended for the measurement of the following analytes: glucose, bilirubin, ketone, specific cavity, occult blood, pH, protein, uribilinogen, nitrite leukocytes, albumin and creatinine.

2. Special condition for use statement(s):
   Not Applicable
3. Special instrument Requirements:
   BAYER CLINITEK STATUS ANALYZER

H. Device Description

The Clinitek Status Urine Chemistry Analyzer is a portable easy to use instrument which reads Bayer urine reagent test strips (Mutistix) for testing in the clinical laboratory.

The analyzer is a reflectance photometer consisting of six light emitting diodes, a light guide, a mirror, a lens and a detector. Light for the LEDS travels along the guide and is reflected off the calibration bar, strip or cassette onto the mirror. It is then directed through an aperture plate onto the lens, from where it is focused onto the detector. The light intensity detected is converted into electrical impulses, which are processed and converted into results.

When carrying out analysis on a reagent strip the test table positions the strip test pads onto the "read area". The light reflected at specific wavelengths from the test pad is dependent upon the degree of color change in the pad and is directly related to the concentration of the particular constituent in the urine.

The Clinitek Status reports semi-quantitatively assays for 12 urine analytes [albumin, bilirubin, blood (occult), creatinine, glucose, ketone, leukocyte, nitrite, pH, protein, specific gravity, and urobilinogen]. Reagent strip results are automatically displayed on the screen in one minute. A printed hardcopy can also be created either from the results screen or recalled from memory.

The analyzer features a display, internal printer, a serial computer interface and either electrical outlet or battery operation. Communication between the operator and the analyzer is made through the display using the user interface touch screen on the front surface of the instrument.

The instrument performs a "self-test" and calibration each time turned on. Each time a test is run the analyzer re-calibrates using a white plastic calibration bar located at the back of the test strip table.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   CLINITEK 50 URINE CHEMISTRY ANALYZER
2. Predicate K number(s):
   K960546
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Calculated parameters	Alb/Creat Ratio Prot/Creat Ratio	Same
Differences		
Item	**Device**	**Predicate**
Measured parameters	albumin, bilirubin, blood (occult), creatinine, glucose, ketone, leukocyte, nitrite, pH, protein, specific gravity, and urobilinogen	Same except Urine Color
Entered Parameter	Urine Color and Clarity, Patient and Operator ID	Not Applicable
Calibration Method	Dark current, White reflectance strip	Dark current, White reflectance pad
Print out	Fixed Head Printer – Roll or Label Stock	Moving head printer – Roll
Interface ports	Bidirectional RS232 serial port with standard cable for hooking up to the computer	Bidirectional RS232 serial port with customized RJ11 cable for hooking up to the computer
Power	Input 100-240V ± 20% and 45-65 Hz, output + 9V	Input 100-240V ± 20% and 50-60 Hz, 0.5-0.3A output + 9V, 2.78A
Dimensions	Depth 10.7 in Width 6.7 in Height 6.2 in	Depth 9.2 in Width 6.0 in Height 6.1 in
Weight	3.65 lbs	2.8 lbs

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

None used

K. Test Principle:

Previously cleared under Multistix urine test strips, see: K905396, K960546, K992257

Creatinine: Based on enzymatic reactions resulting in color ranges from orange through green to blue.

Glucose: Based on enzymatic reactions resulting in color ranges from green to brown.

Blood: Based on the peroxidase-like activity of hemoglobin resulting color ranges from orange through green.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*

    Evaluations of the Clinitek Status® System were conducted at six clinical laboratories (See main report for site details). Each site had four CLINITEK Status analyzers. At each of the six sites, Multistix

PRO® 10LS Reagent Strips (lot 2K04P, expiration date 2004 / 04) were used to assay Bayer control solutions and clinical urine specimens.

The MAS (multiple analyte solutions) and Chek-Stix® positive control (CHKP) were tested in each run. The number of runs at each site varied according to the number of specimen they were able to run each day and their site assigned analyte distributions. All contrived MAS control solutions were kept frozen until used [three (3) day use life after thawing]. The CHKP solution was prepared fresh daily. All controls were run in duplicate.

Analyte Ranges	**CHEK-STIX**	Correct/Total	MAS	Correct/Total
	POSITIVE	% agreement	**MAS6**	% agreement
Creatinine	Negative (10 mg/dl)	250/252 99.21%	50 mg/dL	148/252 58.73%
Glucose	100 - 250 mg/dL	249/252 98.81%	Negative	249/252 98.81%
Blood (occult)	Moderate – Large	249/252 98.81%	Negative	246/252 97.62%

b. Linearity/assay reportable range:
Previously Cleared

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

d. Detection limit:
Previously Cleared

e. Analytical specificity:
Previously Cleared

f. Assay cut-off:
Previously Cleared

2. Comparison studies:

a. Method comparison with predicate device:

Creatinine – Performance of the Clinitek Status system creatinine in comparison to visually read reagent strips- the overall percent agreement within ± one level, was 96.5 (2490 of 2580). Visual reads ranged from 173 -10 mg/dl, 502 - 50 mg/dl, 894 - 100 mg/dl, 895 - 200 mg/dl, 116 -300 mg/dl.

Glucose – Performance of the Clinitek Status system glucose in comparison to visually read reagent strips- the overall percent agreement within ± one level, was 99.7 (2889 of 2899). Visual reads ranged from 2162 - neg., 182 - ±, 157 - 1+, 160 - 2+, 162 - 3+ and 76 - 4+.

Blood – Performance of the Clinitek Status occult blood system in comparison to visually read reagent strips- the overall percent agreement within ± one level, was 99.7 (2890 of 2899). Visual reads ranged from 2001 – neg., 139 trace intact, 219 trace lysed, 202 small, 48 moderate intact, 105 moderate , 185 large.

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):
   Performance of the Cllinitek Status with all urinalysis strip dry reagents, measured by comparing the results obtained by Point of Care (POC) users to the results obtained by laboratory professionals was acceptable, with greater than 98% of the comparative urinalysis reagent pad results within ± one reading level.
4. Clinical cut-off:
   Previously Cleared
5. Expected values/Reference range:
   Previously Cleared

M. Instrument Name:

CLINITEK 50 URINE CHEMISTRY ANALYZER

N. System Descriptions:

1. Modes of Operation:
   Single sample application
2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes ____X____ or No _____

3. Sample Identification:
   Alpha-Numeric Keyboard
4. Specimen Sampling and Handling:
   Test Strip, Test Cassette
5. Assay Types:
   Urinalysis strips and immunoassay cassettes (K032563)
6. Reaction Types:
   End – point colorimetric reflectance photometry
7. Calibration:
   Dark current, White reflectance strip
8. Quality Control:

Periodic Positive and Negative control recommendation per laboratory requirements. No automated QC processing or record keeping.

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Determination Decision Summary.

P. Conclusion:

The information and data provided by BAYER HEALTHCARE, LLC supports a Substantial Equivalence (SE) determination to other AUTOMATED URINALYSIS SYSTEM regulated under 21 CFR §862.2900 - Automated urinalysis system. for the determination of Urinary Creatinine, Glucose and Blood regulated under 21CFR §862.1225, §862.1340 and §864.6550 respectively.