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

A. 510(k) Number:

k063276

B. Purpose for Submission:

New device

C. Measurand:

Urinary Glucose, Blood, Creatinine, Bilirubin, Ketones, Leukocyte, Nitrite, pH, Protein, Specific Gravity and Urobilinogen

D. Type of Test:

Qualitative and semi-Quantitative

E. Applicant:

Bayer HealthCare, LLC

F. Proprietary and Established Names:

Bayer CLINITEK Advantus

G. Regulatory Information:

1. <u>Regulation section:</u>

   21 CFR §862.1340 – Urinary glucose (non-quantitative) test system
   21 CFR §864.6550 – Occult blood test
   21 CFR §862.1225 - Creatinine test system
   21 CFR §862.1115 – Urinary bilirubin and its conjugates (non-quantitative) test system
   21 CFR §862.1435 – Ketones (non-quantitative) test system
   21 CFR §864.7675 – Leukocyte peroxidase test
   21 CFR §862.1510 – Nitrite (non-quantitative) test system
   21 CFR §862.1550 – Urinary pH (non-quantitative) test system
   21 CFR §862.1645 – Urinary protein or albumin (non-quantitative) test system
   21 CFR §862.2800 – Refractometer for clinical use

21 CFR §862.1785 – Urinary urobilinogen (non-quantitative) test system
21 CFR §862.2900 – Automated urinalysis system

2. Classification:

Class II (glucose, blood and creatinine) and the remainder are Class I.

3. Product code:

Class II: JIL, JIO and JFY

Class I: JJB, JIN, LJX, JMT, CEN, JIR, JRE, CDM and KQO

4. Panel:

75 (Chemistry) and 81 (Hematology)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The CLINITEK Advantus Urinalysis analyzer is a semi-automated, benchtop analyzer. It is designed to read Bayer Reagent Strips for Urinalysis, such as, MULTISTIX 10 SG and MULTISTIX PRO Reagent Strips.

This analyzer is intended for the measurement of the following: Bilirubin, Blood (Occult), Creatinine, Glucose, Ketone, Leukocytes, Nitrite, pH, Protein, Protein-to-Creatinine Ratio, Specific Gravity and Urobilinogen. These measurements are used to assist diagnosis in the following areas:

- Kidney Function
- Urinary tract infections
- Metabolic disorders (e.g. diabetes mellitus)
- Liver Function

Tests performed using the CLINITEK Advantus are intended for in vitro diagnostic use.

3. Special conditions for use statement(s):

For Prescription Use.

4. Special instrument requirements:

CLINITEK Advantus

I. Device Description:

The Clinitek Advantus Urinalysis analyzer is a semi-automated, bench top analyzer. It is designed to read Bayer Reagent Strips, such as Multistix 10 SG or Multistix PRO Reagent Strips.

The analyzer is a reflectance spectrophotometer that analyzes the color and intensity of the light reflected from the reagent area and reports the results. The analyzer can determine and report the color of the urine. The user can enter the clarity for each specimen. Calibration is performed automatically each time a reagent strip is run.

The analyzer has a touch screen display, printer, push bar and fixed platform which consist of strip loading station, incubation/read station and waste bin.

During testing a reagent strip is manually dipped into a urine sample then placed on the strip loading station. The push bar moves the strip to the incubation/read station, where it is tested. When testing is complete, the strip is dropped into the waste bin and the results are printed.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Clinitek 200+ and 500+(current generation instrument)

2. Predicate 510(k) number(s):

k926359

3. Comparison with predicate:

Similarities/Differences			
Item	Device	Predicate 1	Predicate 2
Specimen Type	Urine	Same	Same
Reported Output	Bilirubin, blood (occult), creatinine, glucose, ketone, leukocyte, nitrite, pH, protein, specific gravity, urobilinogen and protein-to creatinine ratio	Same	Same

Similarities/Differences			
Intended Use	The analyzer is a semi-automated, bench top instrument designed to read Bayer Reagent strips for Urinalysis, such as Multistix 10 SG and Bayer Multistix PRO reagent strips	Same	Same (with k992257)
Calibration method	Performed automatically at each strip reading using dark current and white reflectance strip	Same	Performed automatically when the analyzer is powered on, using white reflectance strip
Data storage	500 patients results, 200 Quality control	Same	200 patient results
Print Out	Fixed Head Printer – Roll	Same	Moving Head Printer -Roll
Entered Parameter	Urine color, Urine clarity, Patient ID, Operator ID and microscopic results	Urine color, Urine clarity, Patient ID and Operator ID	Patient ID
User interface	Color LCD display	Mono color Graphical user interface	Vacuum fluorescent display

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

IEC 61010-1/2001; Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: General requirements.
IEC 61010-2-081/2001; Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.
EN 61010-2-101/2002; Safety requirements for electrical equipment for measurement, control, and laboratory use. Particular requirements In Vitro diagnostic (IVD) medical equipment.
EN 61326-2-6/2005; Electrical equipment for measurement, control and laboratory use. EMC requirements. Particular requirements. In vitro diagnostic 9IVD) medical equipment.

L. Test Principle:

Previously cleared under Multistix urine test strips k905396 and k992257

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   Fresh urine samples from normal adults were prepared by spiking with various analytes to the desired concentration. The samples were tested using three lots of the Multistix 10SG and three lots of the Multistix Pro 10LS strips on nine Clinitek Advantus and nine Clinitek 500 instruments. Six replicates were performed on each instrument.

Urine analyte	Contrived/Spiked level	Expected result(s) determined by fitness for use requirements	% Agreement with expected results		n
			CLINITEK Advantus	CLINITEK 500	
BIL	0 mg/dL	Negative	100	99.8	486
BIL	0.8 mg/dL	Small & Moderate	99.6	99.6	486
BLO	0 mg/dL	Negative	100	100	486
BLO	0.062 mg/dL	Small	98.6	100	486
CRE	50 mg/dL	50 mg/dL	93.8	98.8	162
CRE	200 mg/dL	200 mg/dL	99.4	93.2	162
GLU	0 mg/dL	Negative	100	100	486
GLU	100 mg/dL	100 mg/dL	100	100	486
GLU	250 mg/dL	100 & 250 mg/dL	100	100	486
GLU	1000 mg/dL	500 & $\geq$1000 mg/dL	99.6	100	486
KET	0 mg/dL	Negative	100	100	486
KET	10 mg/dL	Trace & 15 mg/dL	100	100	486
KET	40 mg/dL	40 & $\geq$80 mg/dL	95.1	98.8	486
LEU	0 cells/µL	Negative	98.1	96.3	486
LEU	42 cells/µL	Small 7 Moderate	97.3	95.3	486
NIT	0 mg/dL	Negative	100	100	486
NIT	0.15 mg/dL	Positive	100	100	486
pH	6	5 ~ 6	100	100	486
pH	7	6 ~ 7	99.6	100	486
pH	8	7 ~ 8	100	100	486
PRO	0 mg/dL	Negative	100	100	486
PRO	30 mg/dL	30 mg/dL	99.8	100	486
PRO	500 mg/dL	$\geq$ 300 mg/dL	100	99.8	486
SG	1.004-1.006	$\leq$1.005 & 1.010	99.3	100	810

Urine analyte	Contrived/Spiked level	Expected result(s) determined by fitness for use requirements	% Agreement with expected results		n
			CLINITEK Advantus	CLINITEK 500	
SG	1.022-1.024	1.020 & 1.025	100	100	810
URO	1 mg/dL	0.2 & 1.0 mg/dL	100	100	486
URO	4 mg/dL	2.0 & 4.0 mg/dL	100	100	486

b. *Linearity/assay reportable range:*

Previously cleared

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

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:*

The comparison was performed by using the MULTISIX 10SG and Bayer MULTISTIX PRO Reagent strips. Patient samples were tested on all analyzers as well as visually read. The data was analyzed in a tabular format and it was divided into two levels of percentage agreement (exact and within one level agreement):

Test	Comparative Method	Product	N	% Exact Agreement	% Within one level Agreement
Bilirubin	Clinitek 200+	10SG	2352	94.2	99.9
	Clinitek 500	10SG	2344	95.7	99.9
	Lab Method	10SG	1612	90.4	94.8

Test	Comparative Method	Product	N	% Exact Agreement	% Within one level Agreement
	Visual	10SG	2297	89.2	99.2
Blood	Clinitek 200+	Both	4710	84.5	99.6
	Clinitek 500	Both	4692	86.3	99.9
	Lab Method	Both	2966	41.9	64.5
	Visual	Both	4695	71.8	97.7
Creatinine	Clinitek 200+	PRO10LS	2358	81.0	99.8
	Clinitek 500	PRO10LS	2348	83.1	100
	Lab Method	PRO10LS	2358	72.9	99.5
	Visual	PRO10LS	2332	43.5	95.6
Glucose	Clinitek 200+	Both	4710	91.7	99.9
	Clinitek 500	Both	4692	94.0	99.8
	Lab Method	Both	4712	91.3	99.8
	Visual	Both	4706	90.2	99.6
Ketone	Clinitek 200+	Both	4710	88.7	99.9
	Clinitek 500	Both	4692	93.8	100
	Visual	Both	4699	85.6	99.6
Leukocyte	Clinitek 200+	Both	4710	82.5	99.6
	Clinitek 500	Both	4692	87.5	99.9
	Lab Method	Both	2950	58.8	82.4
	Visual	Both	4675	79.8	98.8
Nitrite	Clinitek 200+	Both	4710	94.3	100
	Clinitek 500	Both	4692	93.7	100
	Visual	Both	4684	93.4	99.9
pH	Clinitek 200+	Both	4710	46.7	90.1
	Clinitek 500	Both	4692	73.7	97.0
	Lab Method	Both	4712	62.2	97.2
	Visual	Both	4680	61.8	90.2
Protein	Clinitek 200+	10SG	2352	88.1	100
	Clinitek 200+	PRO10LS	2358	90.5	99.3
	Clinitek 500	10SG	234	91.8	100
	Clinitek 500	PRO10LS	2348	93.1	99.6
	Lab Method Albumin	10SG	2346	72.3	96.4
	Lab Method Total Protein & Alb	PRO10LS	2350	82.0	97.0
	Lab Method Total Protein	10SG	2354	75.6	98.7
	Visual	10SG	2350	76.5	99.2
	Visual	PRO10LS	2353	72.2	93.5
P:C	Clinitek 200+	PRO10LS	2205	83.0	96.6
	Clinitek 500	PRO10LS	2224	89.8	97.0
	Lab Method	PRO10LS	2219	79.9	94.0

Test	Comparative Method	Product	N	% Exact Agreement	% Within one level Agreement
SG	Visual	PRO10LS	2077	72.9	92.2
	Clinitek 200+	Both	4710	43.5	94.1
	Clinitek 500	Both	4692	80.9	99.7
	Lab Method	Both	4708	32.1	77.6
	Visual	Both	4647	52.3	94.7
Urobilinogen	Clinitek 200+	10SG	2352	84.9	99.1
	Clinitek 500	10SG	2344	93.2	100
	Visual	10SG	2345	81.2	98.1

The urine color was also compared. Patient samples were tested on the analyzers and read visually. The results are presented in the tables below. Shaded boxes indicate exact agreement.

		Comparative Method - Visual							
		Color-less	YLW	Orange	Red	GRN	BRN	Other	Total
Clinitek Advantus									
YLW	n	454	3156	672	17	8	25	3	4335
	%	99.3	93.3	87.3	42.5	100	58.1	75.0	92.2
Orange	n		136	81	3		6		226
	%		4.0	10.5	7.5		14.0		4.8
RED	n		10	2	12		7		31
	%		0.3	0.3	30.0		16.3		0.7
GRN	n	3	20	4					27
	%	0.7	0.6	0.5					0.6
BRN	n		60	11	8		5	1	85
	%		1.8	1.4	20.0		11.6	25.0	1.8
Total		457	3382	770	40	8	43	4	4704

		Comparative Method – Clinitek 500					Total
		YLW	Orange	Red	GRN	BRN	
Clinitek Advantus							
YLW	n	4111	57	18	8	75	4269
	%	96.6	25.9	40.9	80.0	70.8	92.1
ORANGE	n	59	160			5	224
	%	1.4	72.7			4.7	4.8
RED	n	7		21		3	31
	%	0.2		47.7		2.8	0.7
GRN	n	25			2		27
	%	0.6			20.0		0.6

BRN	n	52	3	5		23	83
	%	1.2	1.4	11.4		21.7	1.8
Total		4254	220	44	10	106	4634

    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):*

Not applicable

4. Clinical cut-off**:**

Previously cleared

5. Expected values/Reference range:

Previously cleared

N. Instrument Name:

CLINITEK Advantus Urinalysis Analyzer

O. 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. Specimen Identification:

   Alpha-Numeric keyboard, barcode reader or the operator and create a worklist.

4. Specimen Sampling and Handling:

   The Bayer reagent strip is manually dipped into a urine sample then placed on the fixed platform for testing. All steps that follow are automatically controlled by the instrument's software.

5. Calibration:

   Dark current, White reflectance strip

6. Quality Control:

   Periodic Positive and Negative control recommendation per laboratory requirements. Up to 200 QC results are stored in the instrument.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.