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

A. 510(k) Number:

k102188

B. Purpose for Submission:

New urine chemistry analyzers to be used with previously cleared CYBOW 11 reagent strips (k052525) for pH, specific gravity, protein, glucose, bilirubin, urobilinogen, ketone, leukocytes, blood, nitrite, and ascorbic acid

C. Measurand:

Urine pH, leukocytes, nitrite, protein, glucose, ketone, urobilinogen, bilirubin, blood, specific gravity, ascorbic acid

D. Type of Test:

Qualitative and semi-quantitative measurements based on reflectance photometry

E. Applicant:

DFI Co., Ltd.

F. Proprietary and Established Names:

CYBOW Reader 300 and CYBOW Reader 700 urine chemistry analyzers

CYBOW 11 Reagent Strip

CYBOW 10 Reagent Strip

G. Regulatory Information:

Name	Regulation	Product Code	Classification
Urinary glucose (non-quantitative) test system.	21 CFR §862.1340	JIL	II
Occult blood test	21 CFR §864.6550	JIO	II
Urinary urobilinogen (non-quantitative) test system	21 CFR §862.1785	CDM	I
Urinary bilirubin and its conjugates (non-quantitative) test system	21 CFR §862.1115	JJB	I

Name	Regulation	Product Code	Classification
Ketones (non-quantitative) test system	21 CFR §862.1435	JIN	I
Urinary protein or albumin (non-quantitative) test system	21 CFR §862.1645	JIR	I
Nitrite (non-quantitative) test system	21 CFR §862.1510	JMT	I
Leukocyte peroxidase test	21 CFR §864.7675	LJX	I
Urinary pH (non-quantitative) test system	21 CFR §862.1550	CEN	I
Specific Gravity	21 CFR§862.2800	JRE	I
Ascorbic acid test system	21 CFR §862.1095	JMA	I
Automated Urinalysis System	21 CFR §862. 2900	KQO	I

Panel:
(75) Clinical Chemistry and (81) Hematology

H. Intended Use:

1. Intended use(s):

   See indication(s) for use below.

2. Indication(s) for use:

   The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers are semi-automated analyzers intended to be used with CYBOW 11 and CYBOW 10 Reagent Strips as a test system to semi-quantitatively or qualitatively measure the specified analytes in urine as follows: glucose, urobilinogen, pH, ketone, occult blood, protein, bilirubin, ascorbic acid, nitrite, leukocyte, and specific gravity. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. The CYBOW Reader 300 and CYBOW Reader 720 urine chemistry test systems are intended for prescription and in vitro diagnostic use only.

3. Special conditions for use statement(s):

   For use only with CYBOW 11 reagent strips and CYBOW 10 reagent strips (does not contain ascorbic acid pad)

   For prescription and in vitro diagnostic use

4. Special instrument requirements:

   CYBOW Reader 300 and CYBOW Reader 720

I. Device Description:

The CYBOW Reader 300 and CYBOW Reader 720 urinalysis systems are intended for use with CYBOW 11 and CYBOW 10 reagent strips for the qualitative and semi-quantitative determination of urine analytes including glucose, urobilinogen, pH, ketone, occult blood, protein, bilirubin, ascorbic acid, nitrite, leukocyte, and specific gravity. The CYBOW 10 reagent strips are identical to the CYBOW 11 reagent strips except they do not include an ascorbic acid test pad. Urine color may be entered manually by the operator, however the test system does not compensate for urine color

The CYBOW Reader 300 has a test throughput of 300 tests per hour versus the CYBOW Reader 720 which has a test throughput of 720 tests per hour. They are technologically very similar and each analyzer includes a built-in printer. An optional barcode reader is available. The CYBOW Reader 720 has a waste box for used reagent strips whereas on the CYBOW 300 the used strips must be dispensed manually by the user.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Bayer Clinitek 200+ with Multistix 10SG reagent strips

2. Predicate 510(k) number(s):
   k926359
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	A semi-automated analyzer which is designed to read test strips for urinalysis for the measurement of bilirubin, blood, glucose, ketones, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.	Same
Analyzer Technology	Reflectance Photometry	Same
Sample Matrix	Urine	Same

Differences		
Item	Device	Predicate
Test parameters	Includes ascorbic acid test pad on test strip	Does not include ascorbic acid test pad
Measuring sensor	CIS module	Photodiode
Light source	LED	Xenon
Throughput/Tests per hour	CYBOW Reader 300: 300 tests per hour	Clinitek 200+: 360 per hour

Differences		
Item	Device	Predicate
	CYBOW Reader 720: 720 tests per hour	

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

ISO 14971:2007 Medical devices-Application of risk management to medical devices

CLSI EP5-A2 Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline Second Edition

CLSI EP7-A: Interference Testing in Clinical Chemistry, Approved Guideline

CLSI EP9-A: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline

L. Test Principle:

The CYBOW Reader 300 and CYBOW Reader 720 are reflectance photometers that analyze the intensity and color of light reflected from the reagent areas of the urinalysis reagent strip. Using a light emitting diode (LED) as the light source and a contact image sensor (CIS) module, the optical system reads the color change in the urine strips after the sample is applied.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
The sponsor evaluated precision of the test systems using two levels of control materials (MAS Urinalysis Control, Level 1 and Level 2). Precision was performed at three point of care sites by three operators on the CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers.

The within run precision study included three different CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers and three lots of urine test strips. Each operator tested ten test strips from each lot number on each analyzer in one testing day.

The within day precision study included three different CYBOW Reader 300 and CYBOW Reader 720 urine chemistry analyzers and three lots of urine test strips. Each operator tested each lot of test strips on each analyzer, once per day for 10 days. The results for the three testing sites combined are summarized in the following tables:

Level 1 Control –CYBOW Reader 300					
		Within-run (n=90)		Within-day (n=90)	
Analyte	**Expected result**	**Exact Agreement (%)**	**Within +/- 1 block (%)**	**Exact Agreement (%)**	**Within +/- 1 block (%)**
Urobilinogen	Normal	100	100	100	100
Glucose	Negative	100	100	100	100
Bilirubin	Negative	100	100	100	100
Ketones	Negative	100	100	100	100
SG	1.020	100	100	97.8	100
Blood	Negative	100	100	100	100
pH	6	100	100	98.9	100
Protein	Negative	100	100	100	100
Nitrite	Negative	100	100	100	100
Leukocytes	Negative	100	100	100	100
Ascorbic Acid	Negative	100	100	100	100

Level 2 Control –CYBOW Reader 300					
		Within-run (n=90)		Within-day (n=90)	
Analyte	**Expected Result**	**Exact Agreement (%)**	**Within +/- 1 block (%)**	**Exact Agreement (%)**	**Within +/- 1 block (%)**
Urobilinogen	4 mg/dL	98.9	100	98.9	100
Glucose	1000 mg/dL	100	100	100	100
Bilirubin	4 mg/dL	98.9	100	100	100
Ketones	40 mg/dL	98.9	100	98.9	100
SG	1.020	98.9	100	98.9	100
Blood	250 RBC/µl	100	100	98.9	100
pH	7	100	100	97.8	100
Protein	100 mg/dL	100	100	100	100
Nitrite	Pos	100	100	100	100
Leukocytes	75 WBC/µl	98.9	100	98.9	100
Ascorbic Acid	20 mg/dL	100	100	100	100

Level 1 Control –CYBOW Reader 720					
		Within-run (n=90)		Within-day (n=90)	
Item	**Test Results**	**Exact Agreement (%)**	**Within +/- 1 block (%)**	**Exact Agreement (%)**	**Within +/- 1 block (%)**
Urobilinogen	Normal	100	100	100	100
Glucose	Negative	100	100	100	100
Bilirubin	Negative	100	100	100	100
Ketones	Negative	100	100	100	100
SG	1.020	98.9	100	100	100
Blood	Negative	100	100	100	100
pH	6	98.9	100	98.9	100
Protein	Negative	100	100	100	100
Nitrite	Negative	100	100	100	100
Leukocytes	Negative	100	100	100	100
Ascorbic Acid	Negative	100	100	100	100

Level 2 Control –CYBOW Reader 720					
		Within-run (n=90)		Within-day (n=90)	
Item	**Test Results**	**Exact Agreement (%)**	**Within +/- 1 block (%)**	**Exact Agreement (%)**	**Within +/- 1 block (%)**
Urobilinogen	4 mg/dL	100	100	98.9	100
Glucose	1000 mg/dL	100	100	100	100
Bilirubin	4 mg/dL	98.9	100	100	100
Ketones	40 mg/dL	98.9	100	100	100
SG	1.020	100	100	97.8	100
Blood	250 RBC/µl	98.9	100	100	100
pH	7	98.9	100	98.9	100
Protein	100 mg/dL	98.9	100	100	100
Nitrite	Pos	100	100	100	100
Leukocytes	75 WBC/µl	100	100	98.9	100
Ascorbic Acid	20 mg/dL	100	100	100	100

b. *Linearity/assay reportable range:*
The sponsor validated the values assigned to each color pad for each analyte by testing pooled, negative urine spiked with commercially available standards to specific target concentrations. Each concentration of analyte was tested 10 times, across 3 lots of strips for a total of 30 measurements at each concentration. The study

was performed with 3 serial numbers of CYBOW Reader 300 and CYBOW Reader 720 analyzers (n = 90). The results for the three serial numbers combined are summarized in the tables below:

CYBOW Reader 300

Urobilinogen

8 mg/dL				1	89
4 mg/dL			2	89	1
2 mg/dL			88		
1 mg/dL		90			
0.1 mg/dL	90				
	0.1	**1 mg/dL**	**2 mg/dL**	**4 mg/dL**	**8 mg/dL**

Expected Results

Glucose

1000 mg/dL				1	88
500 mg/dL			2	89	2
250 mg/dL			88		
100 mg/dL		90			
Neg	90				
	Neg	**100 mg/dL**	**250 mg/dL**	**500 mg/dL**	**1000 mg/dL**

Expected Results

Bilirubin

4 mg/dL			1	90
2 mg/dL		1	87	
1 mg/dL		89	2	
Neg	90			
	Neg	**1 mg/dL**	**2 mg/dL**	**4 mg/dL**

Expected Results

Ketones

100 mg/dL					90
40 mg/dL			3	89	
15 mg/dL		1	87	1	
5 mg/dL		89			
Neg	90				
	Neg	**5 mg/dL**	**15 mg/dL**	**40 mg/dL**	**100 mg/dL**

Expected Results

Specific Gravity

1.030						2	90
1.025					2	87	
1.020				2	85	1	
1.015				87			
1.010		4	90	1			
1.005		85					
1.000	90	1					
	1.000	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**

Expected Results

Blood

250 RBC/µL			1	89
50 RBC/ µL			89	1
10 RBC/ µL		90		
Neg	90			
	Neg	**10 RBC/ µL**	**50 RBC/ µL**	**250 RBC/ µL**

Expected Results

pH

9					1	90
8					89	
7			1	88		
6.5		1	89	2		
6		89				
5	90					
	5	**6**	**6.5**	**7**	**8**	**9**

Expected Results

Protein

1000 mg/dL					1	90
300 mg/dL				2	88	
100 mg/dL				87	1	
30 mg/dL		1	89	1		
15 mg/dl (Trace)		89	1			
Neg	90					
	Neg	**15 mg/dL**	**30 mg/dL**	**100mg/dL**	**300mg/dL**	**1000mg/dL**

Expected Results

Nitrite

Positive (10 mg/dL)			90
Trace (0.05 mg/dL)		90	
Negative	90		
	Negative	**0.05 mg/dl**	**10 mg/dl**

Expected Results

Leukocytes

500 Leu/µL				90
75 Leu/µL		2	88	
25 Leu/µL		88	2	
Neg	90			
	Neg	**25 Leu/µL**	**75 Leu/µL**	**500 Leu/µL**

Expected Results

Ascorbic Acid

40mg/dL		2	90
20mg/dL		88	
Neg	90		
	Neg	**20 mg/dL**	**40 mg/dL**

Expected Results

CYBOW Reader 720

Urobilinogen

8 mg/dL					90
4 mg/dL			1	89	
2 mg/dL			89	1	
1 mg/dL		90			
0.1 mg/dL	90				
	0.1 mg/dL	**1 mg/dL**	**2 mg/dL**	**4 mg/dL**	**8 mg/dL**

Expected Results

Glucose

1000 mg/dL				3	90
500 mg/dL			2	86	
250 mg/dL			88	1	
100 mg/dL		90			
Neg	90				
	Neg	**100 mg/dL**	**250 mg/dL**	**500 mg/dL**	**1000 mg/dL**

Expected Results

Bilirubin

4mg/dL			1	90
2mg/dL		1	89	
1mg/dL		89		
Neg	90			
	Neg	**1mg/dL**	**2mg/dL**	**4mg/dL**

Expected Results

Ketones

100 mg/dL					90
40 mg/dL			3	90	
15 mg/dL			86		
5 mg/dL		90	1		
Neg	90				
	Neg	**5 mg/dL**	**15 mg/dL**	**40 mg/dL**	**100 mg/dL**

Expected Results

Specific Gravity

1.030						2	90
1.025						87	
1.020				2	89	1	
1.015			1	87	1		
1.010		1	88	1			
1.005		88	1				
1.000	90	1					
	1.000	**1.005**	**1.010**	**1.015**	**1.020**	**1.025**	**1.030**

Expected Results

Blood

250 RBC/ µL				88
50 RBC/ µL			90	
10 RBC/ µL		90		
Neg	90			
	Neg	**10 RBC/ µL**	**50 RBC/ µL**	**250 RBC/ µL**

Expected Results

pH

9						90
8					90	
7			1	88		
6.5		1	89	2		
6		89				
5	90					
	5	**6**	**6.5**	**7**	**8**	**9**

Expected Results

Protein

1000 mg/dL						90
300 mg/dL				2	88	
100 mg/dL				87	1	
30 mg/dL		2	89	1		
15 mg/dL		88	1			
Neg	90					
	Neg	**15 mg/dL**	**30 mg/dL**	**100mg/dL**	**300mg/dL**	**1000mg/dL**

Expected Results

Nitrite

Positive (10 mg/dL)			90
Trace (0.05 mg/dL)		90	
Negative	90		
	Negative	**0.05mg/dL**	**10mg/dL**

Expected Results

Leukocytes

500 Leu/µL			2	89
75 Leu/µL		1	88	1
25 Leu/µL		89		
Neg	90			
	Neg	**25 Leu/µL**	**75 Leu/µL**	**500 Leu/µL**

Expected Results

Ascorbic Acid

40mg/dL		3	89
20mg/dL		87	1
Negative	90		
	Negative	**20 mg/dL**	**40 mg/dL**

The data supports the sponsor's reportable range of color pads stated on the product label:

Test	Reportable Range
Urobilinogen	0.1,1 mg/dL, 2,4, and 8 mg/dL
Glucose	Neg, 100, 250, 500 and 1000mg/dL
Bilirubin	Neg, 1 (+), 2 (++) and 4 (+++) mg/dL
Ketones	Neg, 5, 15, 40, and 100 mg/dL
Specific Gravity	1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030
Blood	Neg, 10, 50, and 250 RBC/ ul
pH	5, 6, 6.5, 7, 8, 9
Protein	Neg, 15, 30, 100, 300 and 1000mg/dL
Nitrite	Neg, 0.05, and 10mg/dL
Leukocytes	Neg, 25, 75, and 500 Leu/µl
Ascorbic acid	Neg, 20, and 40 mg/dL

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

The stability characteristics of the strips was reviewed under k052525

d. *Detection limit:*

The sensitivity of the test strips when read by CYBOW Reader 300 and CYBOW Reader 720 analyzers was determined by spiking positive urine samples with known concentrations for each analyte. Each urine sample was tested with three lots of test strips in 10 replicates, for a total of 30 replicates. Sensitivity was defined as the concentration in which 95% of the contrived pooled measurements were trace or positive. *For urobilinogen, the sensitivity study represents the concentration in which 95% of the measurements were positive at the first above normal color pad.

Test	**Claim (Package Insert CYBOW 11)**	**Point at which sensitivity meets criteria of >95% detection**
Urobilinogen	2 mg/dL*	2 mg/dL*
Glucose	100mg/dL	100mg/dL
Bilirubin	1mg/dL	1mg/dL
Ketones	5mg/dL	5mg/dL
Blood	5 RBC/ uL	5 RBC/ uL
Protein	15mg/dL	15mg/dL
Nitrite	0.05mg/dL	0.05mg/dL
Leukocytes	15-25 Leu/µL	15 Leu/µL
Ascorbic Acid	20mg/dL	20mg/dL

The lower limits of detection for pH and Specific Gravity are 5 and 1.000 respectively.

e. *Analytical specificity:*

The effect of potentially interfering substances was evaluated using the CYBOW 300 and CYBOW 720 readers and CYBOW 11 test strips. The sponsor tested medically relevant concentrations of each substance using urine pools spiked with concentrations of analyte corresponding to the claimed assay ranges of the devices. All potential result/color blocks were evaluated. The results are summarized below.

Test	Interfering Analyses	Impact on CYBOW Reader 300 and CYBOW Reader 720 test result
Urobilinogen	p-amino salicylic acid (≥12500mg/L)	False positive
	Azo gantrinsin (Sulfamethoxazol) (≥1000mg/L)	False positive
Glucose	Chlorine Bleach (≥100mg/L)	False positive
	Mecetronium Etilsulfate (≥40mg/L)	False positive
	Ascorbic acid (≥40mg/dL)	False negative
	Ketones (≥40mg/dL)	False negative
Bilirubin	Selenium(≥2000mg/L)	False Positive
	p-amino salicylic acid(≥12500mg/L)	False positive
	Urobilinogen(≥120mg/L)	False positive
	Penicillin(≥7000mg/L)	False positive
	Ascorbic acid (≥40mg/dL)	False negative
Ketones	Formaline(≥1500mg/L)	False positive
	Captopril (≥50mg/L)	False positive
Blood(hemolyzed and non-hemolyzed)	Nitrofurantion(≥200mg/L)	False positive
	Ascorbic acid(≥30mg/dL)	False negative
	Leukocytes(≥500 WBC/μL)	False positive
Specific gravity	Buffered alkaline samples(pH≥9)	Low reported specific gravity
Protein	Sodium acetate(≥2800mg/dL)	False positive
	High pH(>9)	False positive
	Acetaminophen(≥500mg/L)	False positive
Nitrite	Ascorbic acid(≥40mg/dL)	False negative
Leukocytes	Glucose(≥2000mg/dL)	False negative
	Albumin(≥1000mg/dL)	False negative
	Formaldehyde(≥1000mg/L)	False positive
	Captopril(≥100mg/L)	False negative
	Tetracycline(≥400mg/L)	False positive

In addition, the labeling includes a reference for known interference from MESNA. Gyorgy Csako, Mesna and Other Free-Sulfhydryl Compounds Produce False-Positive Results in a Urine Test Strip Method for Ascorbic Acid, Clin Chem 1999 45: 2295-2296.

The labeling clearly states that the test system does not compensate for urine color. However, urine color may be documented by the operator in the test report.

f. *Assay cut-off:*

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Method comparison studies were performed with clinical samples at three point of care sites. The performance of the CYBOW Reader 300 and CYBOW Reader 720 with CYBOW 11 test strips was compared to the predicate device with Multistix® 10SG test strips). For ascorbic acid, performance was compared to the Uriscan S-300 with Uriscan 11SG test strips (k980047). The sponsor states that the operators at the point of care sites had education backgrounds similar to those individuals expected to be the intended users of the device.

Fresh urines were obtained at the different clinical sites. They were evaluated using three lots of test strips and three serial numbers of CYBOW Reader 300 and CYBOW Reader 720 analyzers. The summarized results are found in the tables below.

CYBOW Reader 300

Urobilinogen		Predicate device (mg/dL)				
		Norm	1	2	4	8
New device (mg/dL)	8				4	36
	4			3	40	1
	2		2	43	1	
	1		47	2		
	0.1	688				
Total		688	49	48	45	37
Exact agreement		100%	96%	90%	89%	97%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Glucose		Predicate device (mg/dL)					
		NEG	100	250	500	1000	2000
New device (mg/dL)	1000				3	31	38
	500			6	54	1	1
	250		5	58	5		
	100		59				
	NEG	606					
Total		606	64	64	62	32	39
Exact agreement		100%	92%	91%	87%	97%	97%
Within ± 1 Color Block		100%	100%	100%	100%	100%	97%

Bilirubin		Predicate device (mg/dL)			
		NEG	1	2	4
New device (mg/dL)	4				18
	2		4	33	
	1		51	5	
	NEG	756			
Total		756	55	38	18
Exact agreement		100%	93%	87%	100%
Within ± 1 Color Block		100%	100%	100%	100%

Ketones		Predicate device (mg/dL)					
		NEG	5	15	40	80	160
New device (mg/dL)	100				6	36	8
	40				44		
	15		2	57			
	5		48	5			
	NEG	661					
Total		661	50	62	50	36	8
Exact agreement		100%	96%	92%	88%	100%	100%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%

Leukocytes		Predicate device(WBC/µL)				
		NEG	15	70	125	500
New device (WBC/µL)	500			2	10	120
	75		1	125	113	3
	25		99	3		
	NEG	391				
Total		391	100	130	123	123
Exact agreement		100%	99%	96%	92%	98%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Blood		Predicate device (RBC/ µL)				
		NEG	10	25	80	250
New device (RBC/ µL)	250				3	58
	50		1	6	57	1
	10		32	62		
	NEG	80				
Total		80	33	68	60	59
Exact agreement		100%	97%	91%	95%	98%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Protein		Predicate device (mg/dL)					
		NEG	15	30	100	300	1000
New device (mg/dL)	1000					2	16
	300				2	39	1
	100			4	62		
	30		6	93	2		
	15		113	2			
	NEG	525					
Total		525	119	99	66	41	17
Exact agreement		100%	95%	94%	94%	95%	94%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%

Nitrites		Predicate device	
		NEG	Pos
New device	Pos		310
	Trace		95
	NEG	460	
Total		462	405
Exact agreement		100%	100%
Within ± 1 Color Block		100%	100%

Specific Gravity		Predicate device						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
New device	1.030						5	88
	1.025					6	89	2
	1.020				8	166	3	
	1.015			6	132	8		
	1.010		8	151	8			
	1.005	1	114	8				
	1.000	63	1					
Total		64	123	165	148	180	97	90
Exact agreement		98%	93%	92%	89%	92%	92%	98%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%	100%

pH		Predicate device								
		5	5.5	6	6.5	7	7.5	8	8.5	9
New device	9								13	10
	8						18	35	14	
	7				6	48	19			
	6.5			5	39	6				
	6		33	48	1					
	5	51	14							
Total		51	47	53	46	54	37	35	27	10
Exact agreement		100%	100%	91%	85%	89%	100%	100%	100%	100%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%	100%	100%	100%

Ascorbic acid		Predicate device		
		NEG	20	40
New device (mg/dL)	40		2	38
	20		67	3
	NEG	170		
Total		170	69	41
Exact agreement		100%	97%	93%
Within ± 1 Color Block		100%	100%	100%

CYBOW Reader 720

Urobilinogen		Predicate device (mg/dL)				
		Norm	1	2	4	8
New device (mg/dL)	8				5	35
	4			4	39	2
	2		4	43	1	
	1		45	1		
	0.1	688				
Total		688	49	48	45	37
Exact agreement		100%	92%	90%	87%	95%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Glucose		Predicate device (mg/dL)					
		NEG	100	250	500	1000	2000
New device (mg/dL)	1000				6	29	38
	500			6	51	3	1
	250		3	56	5		
	100		61	2			
	NEG	606					
Total		606	64	64	62	32	39
Exact agreement		100%	95%	88%	82%	91%	97%
Within ± 1 Color Block		100%	100%	100%	100%	100%	97%

Bilirubin		Predicate device (mg/dL)			
		NEG	1	2	4
New device (mg/dL)	4				16
	2		6	33	2
	1		49	5	
	NEG	756			
Total		756	55	38	18
Exact agreement		100%	89%	87%	89%
Within ± 1 Color Block		100%	100%	100%	100%

Ketones		Predicate device (mg/dL)					
		NEG	5	15	40	80	160
New device (mg/dL)	100				9	34	8
	40				41	2	
	15		2	53			
	5		48	9			
	NEG	661					
Total		661	50	62	50	36	8
Exact agreement		100%	96%	85%	82%	94%	100%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%

Leukocytes		Predicate device (WBC/µL)				
		NEG	15	70	125	500
New device (WBC/ µL)	500			2	10	113
	75			123	113	10
	25		100	5	0	
	NEG	391				
Total		391	100	130	123	123
Exact agreement		100%	100%	95%	92%	92%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Blood		Predicate device (RBC/ µL)				
		NEG	10	25	80	250
New device (RBC/ µL)	250				3	58
	50		1	7	57	1
	10		32	61		
	NEG	80				
Total		80	33	68	60	59
Exact agreement		100%	97%	90%	95%	98%
Within ± 1 Color Block		100%	100%	100%	100%	100%

Protein		Predicate device (mg/dL)					
		NEG	15	30	100	300	1000
New device (mg/dL)	1000					2	16
	300				4	38	1
	100			4	61	1	
	30		12	93	2		
	15		106	2			
	NEG	525					
Total		525	118	99	67	41	17
Exact agreement		100%	90%	94%	91%	93%	94%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%

Nitrites		Predicate device	
		NEG	Pos
New device	Pos		306
	Trace	2	99
	NEG	460	1
Total		462	405
Exact agreement		100%	100%
Within ± 1 Color Block		100%	100%

Specific gravity		Predicate device						
		1.000	1.005	1.010	1.015	1.020	1.025	1.030
New device	1.030						4	85
	1.025					5	89	5
	1.020				9	169	4	
	1.015			11	131	6		
	1.010		10	138	8			
	1.005	6	109	16				
	1.000	58	4					
Total		64	123	165	148	180	97	90
Exact agreement		91%	89%	84%	89%	94%	92%	94%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%	100%

pH		Predicate device								
		5	5.5	6	6.5	7	7.5	8	8.5	9
New device	9							2	16	10
	8						15	33	11	
	7				4	49	22			
	6.5			5	41	5				
	6		29	48	1					
	5	51	18							
Total		51	47	53	46	54	37	35	27	10
Exact agreement		100%	100%	91%	89%	91%	100%	94%	100%	100%
Within ± 1 Color Block		100%	100%	100%	100%	100%	100%	100%	100%	100%

Ascorbic acid		Predicate device		
		NEG	20	40
New device (mg/dL)	40			38
	20		69	3
	NEG	170		
Total		170	69	41
Exact agreement		100%	100%	93%
Within One Block		100%	100%	100%

b. Matrix comparison:

Not applicable, the device is only intended for urine specimens.

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:

Not applicable

5. Expected values/Reference range:

References for the analyte expected values are stated in the labeling based on literature.

N. Instrument Name:

CYBOW Reader 300 and CYBOW Reader 720

O. System Descriptions:

1. Modes of Operation:

Semi-automated. User performs test strip procedure then loads the test strip onto analyzer.

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:

   Manual or by barcode reader

4. Specimen Sampling and Handling:

   The instructions state that users should collect urine in clean, dry container and test as soon as possible.

5. Calibration:

   Calibration strips are used for calibration. They are plastic white strips with defined reflectance characteristics. Calibration should be performed prior to first use of the analyzer and then every 4 weeks using the calibration strip provided with the analyzer. Each strip should only be used once. Users should contact Customer Service for information on obtaining additional strips.

6. Quality Control:

   Recommendations for quality control are described in the labeling. Additionally, users should follow local, state and federal regulations.

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

None

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.