Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

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

I 510(k) Number:

k182038

II Applicant:

YD Diagnostics Corporation

III Proprietary and Established Names:

URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer

IV Regulatory Information:

Product Code(s)	Classification	Regulation Section	Panel
JFY	Class II	21 CFR 862.1225 - Creatinine test System	Clinical Chemistry
JIL	Class II	21 CFR 862.1340 - Urinary glucose (nonquantitative) test system	Clinical Chemistry
JIO	Class II	21 CFR 864.6550 - Occult blood test	Hematology
LJX	Class I	21 CFR 864.7675 - Leukocyte peroxidase test	Hematology
JIR	Class I	21 CFR 862.1645 - Urinary protein or albumin (nonquantitative) test system	Clinical Chemistry
JMT	Class I	21 CFR 862.1510 - Nitrite (nonquantitative) test system	Clinical Chemistry
CEN	Class I	21 CFR 862.1550 - Urinary pH (nonquantitative) test system	Clinical Chemistry
JRE	Class I	21 CFR 862.2800 - Refractometer for clinical use	Clinical Chemistry

Product Code(s)	Classification	Regulation Section	Panel
JIN	Class I	21 CFR 862.1435 - Ketones (nonquantitative) test system	Clinical Chemistry
KQO	Class I	21 CFR 862.2900 Automated urinalysis system	Clinical Chemistry

V Submission/Device Overview:

A Purpose for Submission:
New Device

B Measurand:
Measurement of the following analytes in urine: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine.

C Type of Test:
Qualitative and semi-quantitative urinalysis

VI Intended Use/Indications for Use:

A Intended Use(s):
See indications for use statement below

B Indication(s) for Use:
URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer are intended for the in vitro qualitative and semi-quantitative measurement of the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine and the determination of the ACR (albumin creatinine ratio). These measurements are useful in the evaluation of renal, urinary and metabolic disorders.

The URiSCAN Optima urine analyzer is intended to read the color change on the test pads found on the URiSCAN 10ACR urine strips and to display and print the results.

The URiSCAN 10ACR urine strips include test pads for the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin and creatinine, and can only be read on the URiSCAN Optima urine analyzer.

The URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer are intended for prescription use only, in clinical laboratory and in point-of-care settings.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only
For in vitro diagnostic use only
Strips are not for visual read

D Special Instrument Requirements:
URiSCAN Optima urine analyzer

VII Device Description:

A Device Description:
The URiSCAN 10ACR urine strips are conventional urine dipsticks that must be read on the URiSCAN Optima urine analyzer. The URiSCAN 10ACR urine strip is a plastic strip with ten reagent pads affixed for the determination of blood, ketones, protein, nitrite, glucose, pH, specific gravity, leucocytes, albumin, and creatinine in urine; the ACR (albumin:creatinine ratio) is a calculated value. Once urine is absorbed into each reagent pad of the urine test strip, the subsequent chemical and enzymatic reactions will change the color of the reagent pads accordingly. The degree of color change will be proportional to the concentrations of each element in urine.

The URiSCAN Optima urine analyzer measures and indicates the extent of color change of the reagent pads. The URiSCAN Optima urine analyzer reports qualitative and semi-quantitative results on a liquid crystal display that can be printed on the analyzer's internal printer and transferred to a host computer, if desired.

B Principle of Operation:
Blood: The test is based on the pseudo-peroxidase reaction of hemoglobin. Oxygen is released, oxidizing tetramethylbenzidine, producing a color change from yellow through green to dark blue.

Ketones: This test is based on the reaction of acetoacetic acid with nitroprusside, resulting in a color change from buff-pink to maroon.

Protein: This test is based on the color change of the indicator tetrabromphenol blue type in the presence of protein, producing a color change from yellow/green to blue.

Nitrite: This test is based on the conversion of nitrate to nitrite by the action of Gram negative bacteria in urine. At the acidic pH of the reagent area, nitrite in the urine reacts with sulfanilamide to form a diazonium compound. The diazonium compound couples with an aromatic compound to produce a pink color.

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to product colors ranging from blue through green to brown.

pH: This test is based on a double indicator (methyl red and bromothymol blue) principle that gives a broad range of colors, from orange, yellow, green, and blue.

Specific Gravity: This test is based on the pKa change of pretreated polymeric ion exchange resin in relation to ionic concentration. In the presence of an indicator, colors range from blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.

Leukocytes: This test is based on the color change ranging from beige to pink that occurs when esterase is hydrolyzed then coupled with diazonium salt to form a colored azo dye.

Albumin: This test is based on albumin binding to sulfonephthalein dye, producing a color ranging from pale green to aqua blue.

Creatinine: This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of hydroperoxide and chromogen, producing color change from yellow through green to blue.

C Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☐	☒
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:	☒	☐

1. Instrument Name:
URiSCAN Optima urine analyzer

2. Specimen Identification:
Each sample's identification can be entered prior to testing by way of an alpha-numeric keyboard and optional barcode reader.

3. Specimen Sampling and Handling:
Room temperature urine samples should be measured within 2 hours.

4. Calibration:
The URiSCAN Optima urine analyzer calibrates automatically before each measurement.

5. Quality Control:
The sponsor recommends the use of commercially available controls intended for monitoring urine strip results at two levels (negative/low and positive).

VIII Substantial Equivalence Information:

A Predicate Device Name(s):
URiSCAN urine strips on the URiSCAN Optima II urine analyzer , URiSCAN 2ACR urine strips on the URiSCAN Optima urine analyzer

B Predicate 510(k) Number(s):
k050801, k141874

C Comparison with Predicate:

Device & Predicate Devices:	k182038 URiSCAN 10ACR urine strips on the URiSCAN Optima urine analyzer	k141874 URiSCAN 2ACR urine strips on the URiSCAN Optima urine analyzer	k050801 URiSCAN urine strips on the URiSCAN Optima II urine analyzer
Intended Use	for the in vitro qualitative and semi-quantitative measurement of the following parameters: blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin, creatinine, and ACR (albumin creatinine ratio).	for the in vitro semi-quantitative measurement of the following parameters: Albumin, Creatinine, ACR (Albumin Creatinine Ratio)	for the in vitro qualitative and semi-quantitative measurement of urine parameters, specifically urobilinogen, glucose, ketones (acetoacetic acid), bilirubin, protein, nitrite, pH, blood, specific gravity, and leucocytes.
Analytes measured	blood, ketones (acetoacetic acid), protein, nitrite, glucose, pH, SG (specific gravity), leucocytes, albumin, creatinine.	Albumin, Creatinine	urobilinogen, glucose, ketones (acetoacetic acid), bilirubin, protein, nitrite, pH, blood, specific gravity, and leucocytes.
Specimen	Urine	Same	Same
Result Type	Qualitative and Semi-quantitative	Semi-quantitative	Qualitative and Semi-quantitative

IX Standards/Guidance Documents Referenced:
Clinical and Laboratory Standards Institute (CLSI) EP05-A2, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - 2nd Ed

X Performance Characteristics (if/when applicable):
The URiSCAN 10ACR urine strips' test pads are a new combination of some of the test pads previously cleared in k050801 and k141874. There is no change to the chemistries or basic manufacturing processes of the pads.

A Analytical Performance:

1. Precision/Reproducibility:

Within-run and within-day precision studies were performed at three point-of-care (POC) sites by three representative operators per site. The study included commercially available MAS Urinalysis Controls (Level 1 and Level 2) and 11 spiked urine pools to cover various

concentrations per analyte. Precision testing was done in accordance with the recommendations in the CLSI guideline EP5-A2.

Within-run precision: These studies used three different URiSCAN Optima urine analyzers and three different lots of URiSCAN 10ACR urine strips. Each of the three operators per site tested each control level and each urine pool in ten replicates within a run (N=90, 30 results per analyte x 3 sites).

Within-day precision: These studies used three different URiSCAN Optima urine analyzers and three different lots of URiSCAN 10ACR urine strips. Each of the three operators per site tested each control level and each urine pool once per day for 10 days at each site (N=90, 30 results per analyte x 3 sites).

Level 1 quality control					
	Exact value	Within-run (N=90)		Within-day (N=90)	
		Agreement within same grade	Agreement within ± 1 grade	Agreement within same grade	Agreement within ± 1 grade
Leucocytes	−	100%	100%	100%	100%
Nitrite	−	100%	100%	100%	100%
Blood	−	100%	100%	100%	100%
pH	5.5	100%	100%	100%	100%
Creatinine	±	100%	100%	100%	100%
SG	1.015	100%	100%	100%	100%
Ketones	−	100%	100%	100%	100%
Microalbumin	−	100%	100%	100%	100%
Protein	−	100%	100%	100%	100%
Glucose	−	100%	100%	100%	100%
ACR	<30mg/g	100%	100%	100%	100%

Level 2 quality control					
Analyte	Exact value	Within-run (N=90)		Within-day (N=90)	
		Agreement within same grade	Agreement within ± 1 grade	Agreement within same grade	Agreement within ± 1 grade
Leucocytes	2+	100%	100%	100%	100%
Nitrite	+	100%	100%	100%	100%
Blood	3+	100%	100%	100%	100%
pH	7.0	100%	100%	100%	100%
Creatinine	4+	100%	100%	100%	100%
SG	1.020	100%	100%	100%	100%
Ketones	3+	100%	100%	100%	100%

Level 2 quality control					
Analyte	Exact value	Within-run (N=90)		Within-day (N=90)	
		Agreement within same grade	Agreement within ± 1 grade	Agreement within same grade	Agreement within ± 1 grade
Microalbumin	3+	100%	100%	100%	100%
Protein	4+	100%	100%	100%	100%
Glucose	1+	100%	100%	100%	100%
ACR	>300 mg/g	100%	100%	100%	100%

Sample	Analyte	Exact value	Within-run (N=90)		Within-day (N=90)	
			Agreement within same	Agreement within ± 1 grade	Agreement within same grade	Agreement within ± 1 grade
Pool 1	ALB	−	100%	100%	100%	100%
	CRE	±	100%	100%	100%	100%
	ACR	<30 mg/g	100%	100%	100%	100%
Pool 2	ALB	+	100%	100%	100%	100%
	CRE	+	100%	100%	100%	100%
	ACR	30-300 mg/g	100%	100%	100%	100%
Pool 3	ALB	2+	100%	100%	100%	100%
	CRE	2+	100%	100%	100%	100%
	ACR	30-300 mg/g	100%	100%	100%	100%
Pool 4	ALB	3+	100%	100%	100%	100%
	CRE	3+	100%	100%	100%	100%
	ACR	30-300 mg/g	100%	100%	100%	100%
Pool 5	ALB	−	100%	100%	100%	100%
	CRE	4+	100%	100%	100%	100%
	ACR	<30 mg/g	100%	100%	100%	100%
Pool 6	Leucocyte	−	100%	100%	100%	100%
	Nitrite	−	100%	100%	100%	100%
	Blood	−	100%	100%	100%	100%
	pH	5	100%	100%	100%	100%
	SG	1.000	100%	100%	100%	100%
	Ketones	−	100%	100%	100%	100%
	Protein	−	100%	100%	100%	100%
	Glucose	−	100%	100%	100%	100%
	Leucocyte	±	100%	100%	100%	100%
Pool 7	Nitrite	+	100%	100%	100%	100%
	Blood	±	100%	100%	100%	100%
	pH	6	100%	100%	100%	100%
	SG	1.005	100%	100%	100%	100%
	Ketones	±	100%	100%	100%	100%
	Protein	±	100%	100%	100%	100%

Sample	Analyte	Exact value	Within-run (N=90)		Within-day (N=90)	
			Agreement within same	Agreement within ± 1 grade	Agreement within same grade	Agreement within ± 1 grade
	Glucose	±	96.7%	100%	100%	100%
Pool 8	Leucocyte	+	100%	100%	100%	100%
	Nitrite	−	100%	100%	100%	100%
	Blood	+	100%	100%	100%	100%
	pH	7	100%	100%	100%	100%
	SG	1.010	100%	100%	100%	100%
	Ketones	+	100%	100%	100%	100%
	Protein	+	100%	100%	100%	100%
	Glucose	+	93.3%	100%	96.7%	100%
Pool 9	Leucocyte	2+	100%	100%	100%	100%
	Nitrite	−	100%	100%	100%	100%
	Blood	2+	100%	100%	100%	100%
	pH	8	100%	100%	100%	100%
	SG	1.020	100%	100%	100%	100%
	Ketones	2+	100%	100%	100%	100%
	Protein	2+	100%	100%	100%	100%
	Glucose	2+	96.7%	100%	93.3%	100%
Pool 10	Leucocyte	3+	100%	100%	100%	100%
	Nitrite	−	100%	100%	100%	100%
	Blood	3+	100%	100%	100%	100%
	pH	9	100%	100%	100%	100%
	SG	1.025	100%	100%	100%	100%
	Ketones	3+	100%	100%	100%	100%
	Protein	3+	100%	100%	100%	100%
	Glucose	3+	93.3%	100%	93.3%	100%
Pool 11	Leucocytes	−	100%	100%	100%	100%
	Nitrite	−	100%	100%	100%	100%
	Blood	−	100%	100%	100%	100%
	SG	1.030	100%	100%	100%	100%
	Ketones	−	100%	100%	100%	100%
	Protein	4+	100%	100%	100%	100%
	Glucose	4+	100%	100%	100%	100%

2. Linearity:

The test pads are unchanged. The claims remain the same as those established in k050801 and k141874.

3. Analytical Specificity/Interference:

The test pads are unchanged. The claims remain the same as those established in k050801 and k141874.

4. Assay Reportable Range:
The test pads are unchanged. The claims remain the same as those established in k050801 and k141874.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
The test pads are unchanged. The claims remain the same as those established in k050801 and k141874.

6. Detection Limit:
The test pads are unchanged. The claims remain the same as those established in k050801 and k141874.

7. Assay Cut-Off:
Not applicable.

8. Carry over study:
Studies were performed to evaluate the effect of run-over from adjacent pads using 43 urine samples covering up to six concentrations for each analyte. The strips were dipped into a urine sample, and then upon removal, held vertically in either upwards or downward directions for 5, 10, 15, and 20 seconds to allow the sample to run over adjacent pads. Testing was performed with three lots of strips on three analyzers, in replicates of three.

The results support the claim that if the test strip is handled appropriately according to the package insert (dip into the urine for 1 second, blot strip immediately after removing strip from urine cup and place on the instrument's strip holder without delay), the results are not impacted. If excessive urine remains on the strip because of improper test procedure, then pH result may be higher than the actual value due to run over effect. The sponsor includes this information in the labeling.

B Comparison Studies:

1. Method Comparison with Predicate Device:
Method comparison studies were performed by nine representative POC operators (three operators per site) at three POC sites. A total of 407 natural patient samples were tested across the three sites: 135 samples at Site 1, 143 samples at Site 2, and 129 samples at Site 3. The operators tested fresh urine specimens with the URiSCAN 10ACR urine strips (candidate device) and the URiSCAN 2ACR urine strips (k141874) and URiSCAN urine strips (k050801), all on the URiSCAN Optima urine analyzer, in a blinded fashion. The comparisons between the candidate and predicate results are shown below:

Albumin (N=407)		Predicate device (mg/L)			
		10	30	80	150
URiSCAN 10 ACR strip (mg/L)	3+			6	79
	2+		4	105	2
	1+		108	1	
	Neg.	102			
Total		102	112	112	81
Exact agreement (%)		100	96	94	98
Within One Block (%)		100	100	100	100

Creatinine (N=407)		Predicate device (mg/dL)				
		10	50	100	200	300
URiSCAN 10 ACR strip (mg/dL)	4+				3	42
	3+			2	75	2
	2+		1	98	1	
	1+	3	109	3		
	+ -	68				
Total		71	110	103	79	44
Exact agreement (%)		96	99	95	95	95
Within One Block (%)		100	100	100	100	100

ACR (N=407)		Predicate device (mg/g)		
		<30	30-300	>300
URiSCAN 10 ACR strip (mg/g)	>300		2	61
	30-300	2	199	2
	<30	137	4	
Total		139	205	63
Exact agreement (%)		99	97	97
Within One Block (%)		100	100	100

Blood (N=407)		Predicate device (RBC/uL)				
		Neg.	+-	1+	2+	3+
URiSCAN 10 ACR strip (RBC/uL)	3+				1	43
	2+				34	1
	1+		2	40	1	
	+-	4	46	2		
	Neg.	232	1			
Total		236	49	42	36	44
Exact agreement (%)		98	94	95	94	98
Within One Block (%)		100	100	100	100	100

Ketones (N=407)		Predicate device (mg/dL)				
		Neg.	+-	1+	2+	3+
URiSCAN 10 ACR strip (mg/dL)	3+				1	16
	2+				29	
	1+		1	23	2	
	+-	4	32			
	Neg.	297	2			
Total		301	35	23	32	16
Exact agreement (%)		99	91	100	91	100
Within One Block (%)		100	100	100	100	100

Protein (N=407)		Predicate device (mg/dL)					
		Neg	+-	1+	2+	3+	4+
URiSCAN 10 ACR strip (mg/dL)	4+						10
	3+				2	25	
	2+			1	44	1	
	1+			46	1		
	+-	2	45	2			
	Neg.	225	3				
Total		227	48	49	47	26	10
Exact agreement (%)		99	94	94	94	96	100
Within One Block (%)		100	100	100	100	100	100

Nitrite (N=407)		Predicate device (mg/dL)	
		Neg.	Pos.
URiSCAN 10 ACR strip (mg/dL)	Pos.	1	91
	Neg.	315	
Total		316	91
Exact agreement (%)		99.7	100
Within One Block (%)		100	100

Glucose (N=407)		Predicate device (mg/dL)					
		Neg	+-	1+	2+	3+	4+
URiSCAN 10 ACR strip (mg/dL)	4+						12
	3+				1	23	
	2+			1	27	1	
	1+		1	37	1		
	+-	4	30	3			
	Neg.	265	1				
Total		269	32	41	29	24	12
Exact agreement (%)		99	94	90	93	96	100
Within One Block (%)		100	100	100	100	100	100

pH (N=407)		Predicate device								
		5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	9.0
URiSCAN 10 ACR strip	9.0									8
	8.5								12	
	8.0							24		
	7.5					2	30	1		
	7.0				1	41	2			
	6.5			3	57	1				
	6.0		1	60	1					
	5.5	3	92	1						
	5.0	64	3							
Total		67	96	64	59	44	32	25	12	8
Exact agreement (%)		96	96	94	97	93	94	96	100	100
Within One Block (%)		100	100	100	100	100	100	100	100	100

SG (N=407)		Predicate device					
		<=1.005	1.010	1.015	1.020	1.025	1.030=<
URiSCAN 10 ACR strip	1.030=<					1	42
	1.025				2	66	
	1.020			3	84	3	
	1.015		3	88	3		
	1.010	1	74	2			
	<=1.005	33	2				
Total		34	79	93	89	70	42
Exact agreement (%)		97	94	95	94	94	100
Within One Block (%)		100	100	100	100	100	100

Leucocytes (N=407)		Predicate device (WBC/uL)				
		Neg.	+-	1+	2+	3+
URiSCAN 10 ACR strip (WBC/uL)	3+				1	30
	2+				32	
	1+		2	41	1	
	+-	4	39	3		
	Neg.	253	1			
Total		257	42	44	34	30
Exact agreement (%)		98	93	93	94	100
Within One Block (%)		100	100	100	100	100

2. Matrix Comparison:

Not applicable. Urine is the only sample matrix.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:
Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):
Not applicable

D Clinical Cut-Off:
Not applicable

E Expected Values/Reference Range:

- Blood: Normally, no hemoglobin is detectable in urine.
- Ketones: Ketones should not be detected in normal urine.
- Protein: Normally less than 10-20mg/dL (150 mg/day) of protein in the urine is not considered pathological.
- Nitrite: Negative.
- Glucose: Glucose is typically not found in urine unless the serum glucose exceeds a certain level (e.g. 180 mg/dL) or at times during pregnancy.
- pH: 5~8, normal kidneys can produce urine with pH from 4.5~8.2, but with ordinary diet, urine pH is about 6.0.
- S.G. (specific Gravity): 1.003~1.029, Adult on normal fluid intake. S.G. may decrease with increasing age.
- Leucocytes: Normal urine ordinarily yield negative results.
- Albumin: Albumin is normally present in urine at concentrations of less than 20 mg/L. Moderately increased albuminuria is defined as an albumin excretion rate of 30 ~ 299 mg/24 hours. Urinary albumin excretions can be temporarily elevated by exercise, urinary tract infections, and acute illness with fever.
- Creatinine: Creatinine is normally present in urine. There are no established reference values for creatinine in the urine however can be used to normalize other analytes found in a random urine sample at concentrations of 10 to 300 mg/dL (0.9 ~ 26.5 mmol/L).
- Albumin to Creatinine Ratio: Albumin to Creatinine Ratio is normally at less than 30 mg albumin/g creatinine (3.4 mg albumin /mmol creatinine). Moderately increased albuminuria is indicated at a ratio result of 30 ~ 300 mg/g (3.4 ~ 33.9 mg/mmol) and severely increased albuminuria at a ratio result of > 300 mg/g (> 33.9 mg/mmol).

Based on the following references:

- Position Statement: Diabetic Nephropathy. Diabetes Care 20: S24-S27; 1997.
- Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: Saunders; 1999; pp. 483-484.
- Mangili, R. et al.: Prevalence of Hypertension and Microalbuminuria in Adult Type 1 (Insulin Dependent) Diabetic Patients without Penal Failure in Italy – Validation of Screening techniques to detect microalbuminuria Acta Diabetol. 29: 156-166; 1992.
- American Diabetes Association, Clinical Practice Recommendations, Diabetes Care, Vol. 31, Suppl. 1, January 2008.

XI Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

XII Conclusion:

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