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

A. 510(k) Number:
k040703

B. Purpose for Submission:
Premarket Notification 510(k) of intention to manufacture and market the Dirui Industrial Co. Ltd. Uristik H Series Reagent Strips for Urinalysis.

C. Analyte:
Urine Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid.

D. Type of Test:
Qualitative and semi-quantitative urinalysis.

E. Applicant:

Dirui Industrial Co. ltd.
95 Yunhe Street
New & High Technology Development Zone
Changchun, 130012, China

F. Proprietary and Established Names:

URISTK H Series Reagent Strips for Urinalysis.

G. Regulatory Information:

1. Regulation section:

Classification Name	Product Code	Panel Name	Device Class	Regulation Number
Blood occult, colorimetric, in urine	JIO	82 Hematology	II	21 CFR §864.6550
Urinary glucose (non-quantitative) test system	JIL	75 Chemistry	II	21 CFR § 862.1340

Classification Name	Product Code	Panel Name	Device Class	Regulation Number
Urinary urobilinogen (non-quantitative) test system	CDM	75 Chemistry	I	21 CFR §862.1785

Urinary bilirubin and its conjugates (non-quantitative) test system	JJB	75 Chemistry	I	21 CFR §862.1115
Ketones (non-quantitative) test system	JIN	75 Chemistry	I	21 CFR §862.1435
Urinary protein or albumin (non-quantitative) test system	JIR	75 Chemistry	I	21 CFR §862.1645
Nitrite (non-quantitative) test system	JMT	75 Chemistry	I	21 CFR §862.1510
Test, Urine Leukocyte	LJX	82 Hematology	I	21 CFR §864.7675
Urinary pH (non-quantitative	CEN	75 Chemistry	I	21 CFR §862.1550
Ascorbic acid test system	JMA	75 Chemistry	I	21 CFR §862.1095
Refractometer for clinical use	JRE	75 Chemistry	I	21 CFR §862.2800
Automated urinalysis system	KQO	75 Chemistry	I	21 CFR §862.2900

H. Intended Use:

1. Intended use(s):

The URISTIK H Series Urinalysis Reagent Strips for Urinalysis provide qualitative and semi-quantitative test for ascorbic acid, pH, specific gravity, ketones, blood, protein, nitrite, leukocytes, glucose, bilirubin, and urobilinogen in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteria.

2. Indication(s) for use:

The URISTIK H Series Urinalysis Reagent Strips for Urinalysis provide qualitative and semi-quantitative test for ascorbic acid, pH, specific gravity, ketones, blood, protein, nitrite, leukocytes, glucose, bilirubin, and urobilinogen in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteria.

Dirui H Series Reagent Strips are for single use in professional near-patient (point-of-care) and centralized laboratory locations. The strips are intended for use in screening at-risk patients to assist diagnosis in the following areas:

- Kidney function
- Urinary tract infections
- Carbohydrate metabolism (e.g. diabetes mellitus)
- Liver function
- Acid-base balance
- Urine concentration

The results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

3. Special condition for use statement(s):
   For prescription use
4. Special instrument Requirements:

The URISTIK H-8, H-10, and H-11 Reagent Strips are intended for use on the Dirui H-50, H-100 or H-500 Urine Analyzers only.

Summary of Dirui H-50, H-100, and H-500 Urine Analyzers

Type of Strip	For Urine Analyzer	Available Tests
H-8	Dirui H-100	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Glucose, pH
H-10	Dirui H-50, H-100, and H-500	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH
H-11	Dirui H-100 and H-500	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid

I. Device Description:

The URISTIK H Series Reagent Strips for Urinalysis provide qualitative and semi-quantitative test for Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid in urine. The URISTIK H Series Reagent Strips for Urinalysis are firm plastic, dry reagent strips impregnated with chemicals. The reagent areas are dipped into the urine sample and read visually according to a color chart or are read instrumentally with a Dirui H-50, H-100, or H-500 Urine Analyzer. The results are available within one minute. To obtain optimal results, it is necessary to use fresh, well mixed and uncentrifuged urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bayer Corporation MULTISTIX 10 SG Regent Strips
Behring Diagnostics Rapignost Total Screen L Urine Test Strips (k861255)
Boehringer Mannheim Chemstrip 10 with SG Urine Test Strips (k896454)
International Newtech Development Urinalysis Reagent Strips (10 parameters) (k993850)

2. Predicate K number(s): See J. 1 above

3. Comparison with predicate:

Similarities and Differences between Urinalysis Test Strips

Area of Comparison	Dirui URISTIK H-11	Bayer Multistix 10 SG	Behring Rapignost Total Screen L	Boehringer Mannheim Chemstrip 10 with SG	International Newtech Urinalysis Reagent Strips
Intended Use	Professional use in point-of-care urine testing	Same	Same	Same	Same
Target Population	Patients of physicians, hospitals, and clinics	Same	Same	Same	Same
Test Principles	Established clinical chemistry methods	Same for all tests	Same for all tests	Same for all tests	Same for all tests
Area of Comparison	Dirui URISTIK H-11	Bayer Multistix 10 SG	Behring Rapignost Total Screen L	Boehringer Mannheim Chemstrip 10 with SG	International Newtech Urinalysis Reagent Strips
Test reagents	Ingredients that change color in reaction with analytes	X	Different ingredients or percentages for glucose, protein, ketones, blood, nitrite,	Different ingredients or percentages for glucose, protein, ketones, blood, bilirubin,	Different ingredients or percentages for nitrite, pH, specific gravity tests

			leukocytes, urobilinogen, pH tests	nitrite, urobilinogen, pH, specific gravity tests	
Sensitivity	Trace or clinically low levels of analytes	X	Unspecified for ascorbic acid and leukocytes, different units for all other tests	Not compared	Different units for blood, same units and levels for all other tests
Output values	Negative and 2 to 6 positive values	X	Negative and 1 to 6 positive values	Not compared	Negative an 1 to 6 positive values

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

None Referenced

L. Test Principle:

Protein - The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator attracted by cation on the protein molecule makes the indicator further ionized, which changes its color.

Glucose - The assay for glucose is based on the glucose-specific glucose oxidase/peroxidase method. Oxidation of glucose forms hydrogen peroxide, which in turn oxidizes a chromogen in the peroxidase reaction to generate a green or blue color.

Blood - The assay for blood is based on the peroxidase activity of hemoglobin and myoglobin creating a green color with oxidation of a chromogen. Intact erythrocytes which hemolyze on the test paper will produce a green dot.

Ketones - The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

Leukocytes - Granulocyte leukocytes in urine contain esterase that catalyze the hydrolysis of the pyrrole amino acid ester to liberate 3-hydro-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.

Nitrite - Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change.

Specific Gravity - Electrolyte ($M^+ X^-$) in the form of salt in urine reacts with poly methyl vinyl etherand maleic acid (-COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes a color change.

pH - This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

Bilirubin - The direct bilirubin and dichlorobenzene diazonium produce azo dyes n a strongly acid medium.

Urobilinogen - Urobilinogen and diazonium produce pink azo dyes under the function of strong acid medium.

Ascorbic acid - Ascorbic acid, with 1,2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2, 6-dichloroindophenolate into colorless N-(p-phenol)-2,6-dichloro-p-amine phenol.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility

Bio-Rad Urinalysis Control, Level 1 and Level 2 were used in the precision study. The same lot number of urinalysis control and lot number of reagent strips were used in this study. Two runs per day were performed for 10 days. All three reagent strips (H11, H10, H8) were repeated 10 times. The results of each reagent strip type, for the same read mode (pad) and urinalysis control were the same. The following data for H11 reagent strips read with the H-100 urine analyzer is representative. The results for the same pads on the H10 and H8 reagent strips were the same.

The performance characteristics of the strips are determined by clinical analysis and study. The results for visual readings and instrument readings represent an actual range of analyte concentrations. The following table shows the ± 1 color block % agreement using 1599 samples in laboratory comparison studies between Uristik H Series Reagent Strips and Bayer Multistix 10 SG Reagent Strips.

Analyte	% Agreement	Analyte	% Agreement
Urobilinogen	95.1% 1520/1599	Bilirubin	96.3% 1540/1599
Ketone	96.6% 1544/1599	Blood	96.8% 1548/1599
Protein	95.4% 1526/1599	Nitrite	97.6% 1561/1599
Leukocytes	97.2% 1544/1599	Glucose	97.4% 1558/1599
pH	92.4% 1478/1599	Specific Gravity	92.7% 1482/1599

b. Linearity/assay reportable range:

Uristik H Series Reagent Strips are qualitative and semi-quantitative. The methodology references are NCCLS EP9-A2 and NCCLS EP 10-A. The strips give results over a small range of concentration of each analyte. For a weak positive laboratory assay, the strips may give negative results because of low sensitivity.

The laboratory assay ranges include the output values of Uristik H Series Reagent Strips. The following table is the assay laboratory range for each analyte in the linearity study.

Analyte	Unit	Lab Assay Range	Reportable Range
Urobilinogen	µmol/L	0.2-300	3.3-131
Bilirubin	µmol/L	0-313	0-100
Ketone	mmol/L	0.02-35	0-16
Blood	Ery/µL	0-350	0-200
Protein	g/L	0.003-50	0-200
Nitrite	µmol/L	1.0-400	Neg-Pos
Leukocytes	Leu/µL	0-800	0-500
Glucose	mmol/L	0-300	0-110
Specific Gravity		1.000-1.040	1.000-1.030
pH		0-14.0	5.0-9.0
Ascorbic Acid	mmol/L	0.1-14.0	0-6.0

c. Traceability (controls, calibrators, or method):
Not Provided

d. Detection limit:

Sensitivity was demonstrated to the lowest reporting block. See b. above

e. Analytical specificity:

Twenty five common drug components were tested for interferents. The only components having significant effects that were large enough to affect the test results were a high level of ketones (≥ 1.0 mmol/L) and an abnormally high level of ascorbic acid (≥ 5 mmol/L). These components may cause false negative or lower positive results. High levels of ketones and ascorbic acid are listed as interferences in the labeling.

Interference List

Urine and Common Drug Components	Amount Not Affecting URISTIK H Series Test
Albumin	800 mg/dL
Ascorbic Acid	20 mg/dL
Hemoglobin [1]	50 mg/dL
Citric Acid	50 mg/dL
Bilirubin	3.0 mg/dL
Creatine	8 mg/dL
Acetoacetate Acid	1 mmol/L
Ammonium Chloride	189 mg/dL
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Glucose [2]	2000 mg/dL
Glycine	1000 mg/dL
KCL	550 mg/dL
NaCl	2800 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	1200 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	0.26 mg/dL
Sodium Nitrite	0.3 mg/dL
Sodium Phosphate	16 mg/dL
Urobilinogen	3.0 mg/dL
Urea	3000 mg/dL
Riboflavin	100 mg/L
Theophylline	100 mg/L
Phenolphthalein	1200 mg/L

[1] The affect on only glucose reagent shown.
[2] The affect on only blood reagent shown.

f. Assay cut-off:
Not Applicable

2. Comparison studies:
   a. Method comparison with predicate device:

When the urine samples were tested with the Uristik H 11 Reagent Strips for urinalysis, the samples were also tested with the predicate Bayer 10 SG Reagent Strip for Urinalysis. Results were read by urine analyzers and visually. The results are listed in the table below.

H11 Compared to Bayer 10 SG Reagent Strips For Urinalysis Both Read With Urine Analyzer

Analyte	Agreement Total	% Agreement within ± 1 color block	Analyte	Agreement Total	% Agreement within ± 1 color block
Glucose	1620/1661	97.5	Protein	1620/1661	97.5
Blood	1610/1661	96.9	Ketone	1606/1661	96.7
Leukocytes	1616/1661	97.3	Urobilinogen	1582/1661	95.2
Nitrite	1623/1661	97.7	Bilirubin	1602/1661	96.4
pH	1549/1661	93.3	Specific Gravity	1543/1661	92.9

H11 Compared to Bayer 10 SG Reagent Strips For Urinalysis Both Read Visually

Analyte	Agreement Total	% Agreement within ± 1 color block	Analyte	Agreement Total	% Agreement within ± 1 color block
Glucose	1604/1661	96.6	Protein	1614/1661	97.2
Blood	1604/1661	96.6	Ketone	1610/1661	96.9
Leukocytes	1613/1661	97.1	Urobilinogen	1572/1661	94.7
Nitrite	1605/1661	96.6	Bilirubin	1605/1661	96.6
pH	1536/1661	92.5	Specific Gravity	1530/1661	92.1

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):

4. Clinical cut-off:
   Not Applicable

5. Expected values/Reference range:

   Expected Values are referenced to European Urinalysis Guidelines, The Clinical Analysis Of Urine Recent Period Compendium – Urinalysis With Test Strips [2, 4 , 5].

[2.] "European Urinalysis Guidelines", The Scandinavian Journal of Clinical & Laboratory Investigation, Scand J Clin Lab Invest-Vol. 60-Supplement 231.2000.

[4.] "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editor's; 1998; pp. 37-81, 96-97.

[5.] "Compendium- Urinalysis With Test Strips" Roche Diagnostics, Combur® Reagent Strips.

N. Instrument Name:

Dirui Industrial Co., Ltd	H- 50 Urine Analyzer
Dirui Industrial Co., Ltd	H-100 Urine Analyzer
Dirui Industrial Co., Ltd	H-500 Urine Analyzer

O. System Descriptions:

1. Modes of Operation:

Semi-automatic – must manually place reagent strips on strip table.

2. Software:

RS-232 Port communication connection

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

3. Sample Identification:

Data Memory - will store 1,000 patient results

4. Specimen Sampling and Handling:

Test Speed - fast mode 120 specimens per hour
- slow mode 60 specimens per hour

5. Assay Types:

Qualitative and semi-quantitative

6. Reaction Types:

Spectrophotometric readings at 525nm 620nm and 660nm

7. Calibration:

   Calibration Strip – The calibration strip that comes with the analyzer has the function of calibrating the urine analyzer, so that you get the correct test results. When the calibration results are the same after comparison, the urine analyzer has passed the calibration, it can be used normally. When the calibration results are not the same, the calibration has failed, and you must contact the supplier.

8. Quality Control:

   Quality control monitoring is recommended and should be conducted under the following conditions:

   before daily use
   whenever new test strips are opened
   when there is a different operator
   whenever you suspect erroneous results

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

Q. Conclusion:

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