

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

**A. 510(k) Number:**

k141289

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Urinary glucose, blood, leukocyte, pH, nitrite, protein, ketones, urobilinogen, bilirubin, and specific gravity

**D. Type of Test:**

Qualitative and semi-quantitative urinalysis

**E. Applicant:**

Teco Diagnostics

**F. Proprietary and Established Names:**

TC-Thunderbolt Automated Urine Analyzer System

**G. Regulatory Information:**

Device / Analyte	Product Code	Device Class	Regulation
Urinary Glucose (non-quantitative) Test System	JIL	II	21 CFR 862.1340
Occult Blood Test	JIO	II	21 CFR 864.6550
Automated Urinalysis System	KQO	I	21 CFR 862.2900
Leukocytes Peroxidase Test	LJX	I	21 CFR 864.7675
Urinary pH (non-quantitative) Test System	CEN	I	21 CFR 862.1550
Nitrite (non-quantitative) Test System	JMT	I	21 CFR 862.1510
Urinary Protein or Albumin (non-quantitative) Test System	JIR	I	21 CFR 862.1645
Ketones (non-quantitative) Test System	JIN	I	21 CFR 862.1435
Urinary Urobilinogen (non-quantitative) Test System	CDM	I	21 CFR 862.1785

Device / Analyte	Product Code	Device Class	Regulation
Urinary Bilirubin and conjugates (non-quantitative) Test System	JJB	I	21 CFR 862.1115
Refractometer for clinical use	JRE	I	21 CFR 862.2800

Panel:

(75) Clinical Chemistry and (81) Hematology

**H. Intended Use:**

1. Intended use(s):

See Indication for use below.

2. Indication(s) for use:

The TC-Thunderbolt Automated Urine Analyzer System is an in vitro diagnostic device used to automate the urine chemistry analysis using TC-Thunderbolt URS-10 strips. It produces semi-quantitative results of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity, and leukocytes in urine. TC-Thunderbolt URS-10 strips are intended for use only with TC-Thunderbolt Automated Urine Analyzer System, they are not intended for manual visual reading. This device is for clinical laboratory use only. This device is not for Point of Care Use. These measurements are used to aid in the diagnosis of metabolic disorders, kidney function abnormalities, urinary tract infection, and liver function.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

TC-Thunderbolt Automated Urine Analyzer

**I. Device Description:**

The TC-Thunderbolt Automated Urine Analyzer System is an automated urine chemistry analyzer design for use with the TC-Thunderbolt Urine Reagent Strips. The system transfers a urine sample via a sample-suction needle and pipe, which extracts and applies the sample to the test strip; the test module then uses the principle of light-reflection to determine the changes in paper color, conduct a digital analysis on the central portion most uniform in color of the paper, and obtain results. When one specimen is finished, the device automatically cleans itself and extracts the next specimen to repeat the testing process, and if required, prints and saves the urine analysis report.

The TC-Thunderbolt Urine Reagent Strips (URS) are firm plastic strips to which ten different reagent pads are affixed. The TC-Thunderbolt URS-10 Reagent Strips are for the semi-quantitative and qualitative detection of glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes in urine. The reagent strips are packaged along with a drying agent in a plastic bottle with a twist-off cap. Each strip is stable and ready to use upon removal from the bottle. The entire strip is disposable.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Teco Diagnostic 720+ Urine Analyzer and Teco Diagnostic URS-10 strips

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

k051526

3. Comparison with predicate:

<b>Similarities / Difference</b>		
<b>Item</b>	<b>Candidate Device TC-Thunderbolt Automated Urine Analyzer System (k141289)</b>	<b>Predicate Device Uritek-720+ Urine Analyzer with Teco Diagnostic URS- 10 strips (k051526)</b>
Intended Use	Analysis of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine of glucose, protein, pH, bilirubin, blood, ketones, urobilinogen, nitrite, specific gravity, and leukocytes in urine.	Same
Analyzer Basic Operating Principle	Reflectance Photometer	Same
Analyzer Calibration method	Calibration strip	Same
Specimen	Urine	Same
Strip physical description	Plastic strips affixed with reagent pads	Same
Urine Application to the Analyzer	Automatic sample suction, strip advance, and sample application technology	Test strip must be dipped in urine. Dry the strip on an absorbent paper and place on the test table manually.

Similarities / Difference		
Item	Candidate Device TC-Thunderbolt Automated Urine Analyzer System (k141289)	Predicate Device Uritek-720+ Urine Analyzer with Teco Diagnostic URS- 10 strips (k051526)
Analyzer Environment requirement	Ambient temperature: 25°C+5°C; Relative humidity: <75%	Ambient temperature: 0°C to 40°C; Relative humidity: <85%
Strip Dimension	110mm (length) x 5mm (width)	108mm (length) x 5mm (width)

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

None Referenced.

**L. Test Principle:**

**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 potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

**Bilirubin:** This test is based on the coupling of bilirubin with a diazotized dichloroaniline in a strongly acid medium. The colors range from light tan to reddish-brown.

**Ketone:** This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a “Negative” reading to pink and pink-purple for a “Positive” reading.

**Specific Gravity:** This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

**Blood:** This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes, which catalyzes the reaction of 3',3',5',5'-tetramethyl-benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

**pH:** This test is based on the well known double pH indicator method, where bromothymol blue and methyl red give distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

**Protein:** This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a “Negative” reaction to yellow-green and green to blue-green for a “Positive” reaction.

**Urobilinogen:** This test is based on a modified Ehrlich reaction in which *p*-diethylaminobenzaldehyde reacts with urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

**Nitrite:** This test depends on the conversion of nitrate to nitrite by the action of Gram-negative bacteria in the urine. The nitrite reacts with *p*-arsanilic acid to form a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h) quinolin to produce a pink color.

**Leukocytes:** This test is based on the action of esterase present in leukocytes, which catalyzes the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

The repeatability of the TC-Thunderbolt Automated Urine Analyzer System was evaluated using three levels of urine controls. 20 replicates of each level (negative, low positive, and high positive) were analyzed on one TC-Thunderbolt Automated Urine Analyzer with three lots of TC-Thunderbolt URS-10 strips by three operators on one day. The results are summarized below:

Control level 1:

Analyte	Control Level 1	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	500 mg/dL	58/60 (96.67%)	60/60 (100%)
Bilirubin	Moderate	60/60 (100%)	60/60 (100%)
Ketone	40 mg/dL	60/60 (100%)	60/60 (100%)
Specific Gravity	1.015	60/60 (100%)	60/60 (100%)
Blood	Moderate	59/60 (98.34%)	60/60 (100%)
Nitrite	Positive	60/60 (100%)	60/60 (100%)
Protein	300 mg/dL	60/60 (100%)	60/60 (100%)
Urobilinogen	8 EU/dL	60/60 (100%)	60/60 (100%)
Leukocytes	Moderate	60/60 (100%)	60/60 (100%)
pH	7.5	60/60 (100%)	60/60 (100%)

Control level 2:

Analyte	Control Level 2	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	100 mg/dL	58/60 (96.67%)	60/60 (100%)
Bilirubin	Small	60/60 (100%)	60/60 (100%)
Ketone	40 mg/dL	59/60 (98.83%)	60/60 (100%)
Specific Gravity	1.015	57/60 (95%)	60/60 (100%)
Blood	Trace	59/60 (100%)	60/60 (100%)
Nitrite	Positive	60/60 (100%)	60/60 (100%)
Protein	negative	60/60 (100%)	60/60 (100%)
Urobilinogen	0.2 EU/dL	60/60 (100%)	60/60 (100%)
Leukocytes	Small	60/60 (100%)	60/60 (100%)
pH	7.5	60/60 (100%)	60/60 (100%)

Control level 3:

Analyte	Control Level 3	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	Negative	60/60 (100%)	60/60 (100%)
Bilirubin	Negative	60/60 (100%)	60/60 (100%)
Ketone	Negative	60/60 (100%)	60/60 (100%)
Specific Gravity	1.005	58/60 (96.67%)	60/60 (100%)
Blood	Negative	60/60 (100%)	60/60 (100%)
Nitrite	Negative	60/60 (100%)	60/60 (100%)
Protein	Negative	60/60 (100%)	60/60 (100%)
Urobilinogen	0.2EU/dL	60/60 (100%)	60/60 (100%)
Leukocytes	Negative	60/60 (100%)	60/60 (100%)
pH	6.5	60/60 (100%)	60/60 (100%)

A run-to-run precision study was performed testing 2 replicates of each control level (negative, low positive, and high positive) for 2 non-consecutive runs per day over 5 days. The samples were analyzed on one TC-Thunderbolt Automated Urine Analyzer with three lots of TC-Thunderbolt URS-10 strips. Run 1 and Run 2 were separated by 1 hour.

The results are summarized below:

Analyte	Control Level 1	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	500 mg/dL	60/60 (100%)	60/60 (100%)
Bilirubin	Moderate	60/60 (100%)	60/60 (100%)
Ketone	40 mg/dL	60/60 (100%)	60/60 (100%)
Specific Gravity	1.015	59/60 (98.83%)	60/60 (100%)

Analyte	Control Level 1	Exact Block Agreement %	±1 Color Block Agreement %
Blood	Moderate	60/60 (100%)	60/60 (100%)
Nitrite	Positive	60/60 (100%)	60/60 (100%)
Protein	300 mg/dL	60/60 (100%)	60/60 (100%)
Urobilinogen	8 EU/dL	59/60 (98.83%)	60/60 (100%)
Leukocyte	Moderate	60/60 (100%)	60/60 (100%)
pH	7.5	60/60 (100%)	60/60 (100%)

Analyte	Control Level 2	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	100 mg/dL	60/60 (100%)	60/60 (100%)
Bilirubin	Small	60/60 (100%)	60/60 (100%)
Ketone	40 mg/dL	60/60 (100%)	60/60 (100%)
Specific Gravity	1.015	56/60 (95%)	60/60 (100%)
Blood	Trace	60/60 (100%)	60/60 (100%)
Nitrite	Positive	60/60 (100%)	60/60 (100%)
Protein	Negative	60/60 (100%)	60/60 (100%)
Urobilinogen	0.2 EU/dL	60/60 (100%)	60/60 (100%)
Leukocytes	Small	58/60 (96.67%)	60/60 (100%)
pH	7.5	60/60 (100%)	60/60 (100%)

Analyte	Control Level 3	Exact Block Agreement %	±1 Color Block Agreement %
Glucose	Negative	60/60 (100%)	60/60 (100%)
Bilirubin	Negative	60/60 (100%)	60/60 (100%)
Ketone	Negative	60/60 (100%)	60/60 (100%)
Specific Gravity	1.005	60/60 (100%)	60/60 (100%)
Blood	Negative	60/60 (100%)	60/60 (100%)
Nitrite	Negative	60/60 (100%)	60/60 (100%)
Protein	Negative	60/60 (100%)	60/60 (100%)
Urobilinogen	0.2 EU/dL	60/60 (100%)	60/60 (100%)
Leukocytes	Negative	60/60 (100%)	60/60 (100%)
pH	6.5	60/60 (100%)	60/60 (100%)

*b. Linearity/assay reportable range:*

The study to evaluate the reportable range (percent recovery) for each analyte color block on the TC-Thunderbolt URS-10 strip was evaluated by measuring a negative

urine and a negative urine pool spiked with known increasing and decreasing concentrations of analytes relative to each color block on the test strip. Samples were performed in replicates of 7 by three operators on three reagents strip lots for a total of 21 measurements for every sample. A pH meter was used to confirm the pH results. The specific gravity was confirmed by a clinical, handheld refractometer. A specific gravity reading of 1.000 was obtained from distilled water. The reportable range for each pad is defined as the concentration(s) at which there is a >90% exact match for that concentration with one block/result.

The percent recovery results where a >90% exact match was obtained for each analyte at each concentration block is shown in the table below:

Analyte	TC-Thunderbolt Color Block Output Units (Reportable Range)	Conventional Units corresponding to block	Concentrations Tested resulting in >90% exact match with a block	Percent Exact Match
Glucose	-	0 mg/dL	0 – 50 mg/dL	100%
	±	100 mg/dL	100 – 175 mg/dL	100%
	1+	250 mg/dL	250 – 375 mg/dL	100%
	2+	500 mg/dL	500 – 625 mg/dL	100%
	3+	1000 mg/dL	1000 mg/dL	100%
Bilirubin	-	Negative	0.0 – 0.25 mg/dL	100%
	1+	Small	0.5 – 0.75mg/dL	100%
	2+	Moderate	1.0 – 2.0 mg/dL	100%
	3+	Large	3.0 mg/dL	100%
Ketone	-	Negative	0.0 – 1.25 mg/dL	100%
	±	Trace	5.0 – 7.5 mg/dL	100%
	1+	15 mg/dL	15 mg/dL	100%
	2+	40 mg/dL	33.75 – 40.0 mg/dL	100%
	3+	80 mg/dL	70 – 80 mg/dL	100%
Blood	-	Negative	0.0 mg/dL	100%
	±	Trace	0.03 – 0.043 mg/dL	100%
	1+	Small	0.075 – 0.158mg/dL	100%
	2+	Moderate	0.24 – 0.495 mg/dL	100%
	3+	Large	0.628 – 0.75 mg/dL	90%
Protein	-	Negative	0.0 – 3.75 mg/dL	100%
	±	Trace	15 – 18.75 mg/dL	90%
	1+	30 mg/dL	30 – 47.5 mg/dL	100%
	2+	100 mg/dL	82.5 – 100 mg/dL	95%
	3+	300 mg/dL	250 – 300 mg/dL	95%

Analyte	TC-Thunderbolt Color Block Output Units (Reportable Range)	Conventional Units corresponding to block	Concentrations Tested resulting in >90% exact match with a block	Percent Exact Match
	4+	2000 mg/dL	1575 – 2000 mg/dL	90%
Nitrite	-	Negative	0.025 – 0.075 mg/dL	100%
	+	Positive	> 0.1 mg/dL	100%
Leukocyte	-	Negative	0.0 – 11.25 ca cells/ $\mu$ L	95%
	±	Trace	15 – 28.75 ca cells/ $\mu$ L	95%
	1+	Small	56.25 – 83.75 ca cells/ $\mu$ L	95%
	2+	Moderate	111.25 – 312.5 ca cells/ $\mu$ L	100%
	3+	Large	500 ca cells/ $\mu$ L	100%
Urobilinogen	0.2	0.2 mg/dL	0.2 – 0.6 mg/dL	100%
	1.0	1.0 mg/dL	1.0 - 1.50 mg/dL	90%
	2.0	2.0 mg/dL	2.0 – 3.0 mg/dL	90%
	4.0	4.0 mg/dL	4.0 – 5.0 mg/dL	100%
	8.0	8.0 mg/dL	8.0 mg/dL	100%
pH	5.0	5.0	5.0	95%
	6.0	6.0	6.0	95%
	6.5	6.5	6.5	95%
	7.0	7.0	7.0	95%
	7.5	7.5	7.5	95%
	8.0	8.0	8.0	95%
	8.5	8.5	8.5	95%
SG	1.005	1.005	1.005	100%
	1.010	1.010	1.010	100%
	1.015	1.015	1.015	100%
	1.020	1.020	1.020	100%

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

Calibration is performed using a calibration strip. This ready-to-use calibration strip provided with the TC-Thunderbolt Automated Urinalysis System to evaluate the alignment of the strip.

Shelf-life and open-vial stability protocols and acceptance criteria were reviewed and found to be acceptable for the TC-Thunderbolt URS-10 strips. The stability studies support the following manufacturer’s claim: The strips can be stored between 15°C - 30°C (59°F-86°F) out of direct sunlight for 28 months. The open-vial stability is for 90 days at room temperature (15-30°C).

*d. Detection limit:*

A study was performed to validate the cutoff concentration for each analyte on the TC-Thunderbolt URS-10 strip. Urine samples were prepared by spiking a negative urine pool with a minimum of 4 levels across the measuring range for each analyte concentration. The samples were analyzed in replicates of 7 by three operators on three reagent strip lots, for a total of 21 data points for each level. The low cut-off concentration for each color block was defined as the lowest concentration at which  $\geq 55\%$  of the test results are positive for each color block.

Summary of the performance at each color block for the tested analyte concentrations:

<b>Analyte</b>	<b>Color Block</b>	<b>Low Cut-off Concentration</b>	<b>% Positive Results at the Low Cutoff Concentration</b>
Glucose	100 mg/dL	75 mg/dL	90%
	250 mg/dL	212.5 mg/dL	85%
	500 mg/dL	437.5 mg/dL	85%
	1000 mg/dL	875 mg/dL	85%
Bilirubin	Small	0.375mg/dL	57%
	Moderate	1 mg/dL	100%
	Large	2.5 mg/dL	57%
Ketone	Trace	3.75mg/dL	95%
	15 mg/dL	10 mg/dL	55%
	40 mg/dL	27.5 mg/dL	55%
	80 mg/dL	60 mg/dL	95%
Blood	Trace	0.023 mg/dL	61%
	Small	0.064 mg/dL	76%
	Moderate	0.199 mg/dL	90%
	Large	0.628 mg/dL	90%
Protein	Trace	11.25 mg/dL	75%
	30 mg/dL	26.25 mg/dL	85%
	100 mg/dL	82.5 mg/dL	95%
	300 mg/dL	200 mg/dL	85%
	2000 mg/dL	1150 mg/dL	70%
Nitrite	Positive	0.1 mg/dL	55%

Analyte	Color Block	Low Cut-off Concentration	% Positive Results at the Low Cutoff Concentration
Leukocyte	Trace	15 ca cells/ $\mu$ L	100%
	Small	56.25 ca cells/ $\mu$ L	95%
	Moderate	97.5 ca cells/ $\mu$ L	60%
	Large	406.25 ca cells/ $\mu$ L	55%
Urobilinogen	0.2 mg/dL	0.2 mg/dL	100%
	1.0 mg/dL	0.8 mg/dL	71%
	2.0 mg/dL	2.0 mg/dL	90%
	4.0 mg/dL	3.5 mg/dL	55%
	8.0 mg/dL	6.0 mg/dL	80%
pH	5.0	5.0	95%
	6.0	6.0	95%
	6.5	6.5	95%
	7.0	7.0	95%
	7.5	7.5	95%
	8.0	8.0	100%
	8.5	8.5	100%
SG	1.005	1.005	100%
	1.010	1.010	100%
	1.015	1.015	100%
	1.020	1.020	100%
	1.025	1.025	100%
	1.030	1.030	100%

e. *Analytical specificity:*

Studies were performed to assess the effect of various potential interferences on the test results of the TC-Thunderbolt Automated Urine Analyzer System. Testing was performed using two urine pools with negative and positive concentrations for all analytes. The positive pool was prepared by spiking each analyte into a negative urine sample. Each urine sample was tested in 3 replicates using the TC-Thunderbolt Automated Urine Analyzer System. Possible interference was noted when a difference of one color pad in any of the three replicates for the particular test analyte compared to either the negative (specificity) or analyte-spiked positive sample (interference).

The concentrations of the potential interfering substances that will not have influence on the tests are shown below:

<b>Potential Interfering Substances</b>	<b>Highest Concentration not affecting the test (mg/dL)</b>
Ascorbic Acid	10 mg/dL
Ammonia chloride	400 (mg/dL)
Albumin	300 (mg/dL)
Bilirubin	4 (mg/dL)
Calcium Chloride	80 (mg/dL)
Citric Acid	65 (mg/dL)
Creatinine	600 (mg/dL)
D (+) Glucose	500(mg/dL)
Glycine	900 (mg/dL)
Hemoglobin	0.3 (mg/dL)
Potassium Chloride	1000 (mg/dL)
Sodium Chloride	2000 (mg/dL)
Oxalic Acid	20 (mg/dL)
Sodium Nitrate	10 (mg/dL)
Sodium Nitrite	0.5 (mg/dL)
Sodium Phosphate	1000 (mg/dL)
Urea	3000 (mg/dL)
D(+) Galactose	300 (mg/dL)
Tetracycline	100 (mg/dL)

The following table shows the substances that did interfere with one or more of the analytes tested with the TC-Thunderbolt Automated Urine Analyzer System. Results are expressed as the lowest concentration of interfering substances that exhibit interference and the resulting change in output of color block:

<b>Analyte</b>	<b>Concentration of Substance at which Interference was observed</b>	<b>Change in Color Block Output</b>
Glucose	Ascorbic Acid	-1
Protein	Hemoglobin $\geq$ 50 mg/dL, D(+) Glucose $\geq$ 2000 mg/dL	+1, -1
Bilirubin	Ascorbic Acid $\geq$ 30 mg/dL, MESNA $\geq$ 50 mg/dL, Sodium Nitrite $\geq$ 2 mg/dL, Sodium Nitrate $\geq$ 10 mg/dL, D(+) Glucose $\geq$ 2000 mg/dL	-1
Urobilinogen	-	-
Blood	Albumin $\geq$ 1000 mg/dL, Ascorbic Acid $\geq$ 30 mg/dL	+1
Nitrite	D(+) Glucose $\geq$ 2000 mg/dL	-1
Leukocytes	D(+) Glucose $\geq$ 2000 mg/dL, Ascorbic Acid $\geq$ 30 mg/dL	-1



Bilirubin							
<b>Thunderbolt</b>	<b>Uritek 720+</b>	3+	2+	1+	Neg	Overall	
	3+	6					
	2+		7				
	1+			40			
	Neg			2	432		
	Total	6	7	42	432	487	
% Agreement (Exact Match)		100.0	100.0	95.24	100.0	99.59	
% Agreement (+/- Color Block)		100.0	100.0	100.0	100.00	100.0	

Ketones							
<b>Thunderbolt</b>	<b>Uritek 720+</b>	80	40	15	TRACE	Neg	Overall
	80	6					
	40		10	3			
	15		3	25	2		
	TRACE			2	14	1	
	Neg					421	
	Total	6	13	30	16	422	487
% Agreement (Exact Match)		100.0	76.92	83.33	87.50	99.76	97.74
% Agreement (+/- Color Block)		100.0	100.0	100.0	100.00	100.00	100.0

Specific Gravity								
<b>Thunderbolt</b>	<b>Uritek 720+</b>	>1.030	1.025	1.020	1.015	1.010	<1.005	Overall
	>1.030	9	1					
	1.025	3	118	12				
	1.020		5	44	4			
	1.015			7	101	3	2	
	1.010				30	68	5	
	<1.005				2	24	49	
	Total	12	124	63	137	95	56	487
% Agreement (Exact Match)		75.0	95.16	69.84	73.72	71.58	87.50	79.88
% Agreement (+/- Color Block)		100.0	100.0	100.0	98.54	100.00	96.43	99.18



pH									
<b>Thunderbolt</b>	<b>Uritek 720+</b>	8.5	8.0	7.5	7.0	6.5	6.0	5.0	Overall
	8.5	10							
	8.0		12						
	7.5			111	4	1			
	7.0			3	59	2	1		
	6.5				3	94	33		
	6.0						64	18	
	5.0						1	71	
	Total	10	12	114	66	97	99	89	487
	% Agreement (Exact Match)	100	100	97.37	89.39	96.91	64.65	79.78	86.45
	% Agreement (+/- Color Block)	100	100	100.0	100	98.97	98.99	100	99.59

Nitrite				
<b>Thunderbolt</b>	<b>Uritek 720+</b>	+	-	Overall
	+	70		
	-	1	416	
	Total	71	416	373
	% Agreement (Exact Match)	98.59	100	99.79
	% Agreement (+/- Color Block)	100.0	100	100.0

Leukocyte							
<b>Thunderbolt</b>	<b>Uritek 720+</b>	3+	2+	1+	TRACE	Neg	Overall
	3+	12					
	2+	1	17	4			
	1+		5	27	5		
	Trace			1	15		
	Neg					400	
	Total	13	22	32	20	400	487
	% Agreement (Exact Match)	92.31	77.27	84.38	75.0	100.0	96.71
	% Agreement (+/- Color Block)	100.0	100.0	96.88	100.0	100.0	100.0

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:

Not applicable.

5. Expected values/Reference range:

**Glucose:** Small amounts of glucose are normally excreted by the kidney.<sup>3</sup> Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently.

**Bilirubin:** Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

**Ketone:** Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy, and frequent strenuous exercise.<sup>4-6</sup> In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.<sup>7</sup>

**Specific Gravity:** Random urine may vary in specific gravity from 1.003-1.040+. Twenty-four hour urine from normal adults with normal diets and normal fluid intake will have a specific gravity of 1.016-1.022.<sup>8</sup> In severe renal damage, the specific gravity is fixed at 1.010, the value of the glomerular filtrate.

**Blood:** Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently, but not invariably found in the urine of menstruating females.

**pH:** 4.5-8.0 average: 6.0.<sup>1</sup>

**Protein:** In 24-hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney.<sup>2</sup> A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of trace results.

**Urobilinogen:** In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dl. A result of 2.0 EU/dl may be of clinical significance and the same patient sample should be evaluated further.

**Nitrite:** Normally no detectable amount of nitrite is present in urine.<sup>1</sup> The nitrite area will be positive in a proportion of cases of significant infection, depending on how long the urine specimens were retained in the bladder prior to collection. Retrieval of positive cases with the nitrite test range from as low as 40%, in instances where little bladder incubation occurred, to as high as 80% in instances where a minimum of 4 hours incubation occurred.

**Leukocytes:** Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

1. Tietz, N.W.: Clinical Guide to Laboratory Tests; W.B. Saunders Company, (1976).
2. Burtis, C.A. and Ashwood, E.R.: Tietz Textbook of Clinical Chemistry 2nd Ed. 2205; (1994).
3. Schersten, B. and Fritz, H.: Subnormal Levels of Glucose in Urine. JAMA 201:129-132; (1967).
4. McGarry, J.D.: Lilly Lecture, 1978: New Perspectives in the Regulation of Ketogenesis. Diabetes 28: 517-523 May, (1978).
5. Williamson, D.H.: Physiological ketoses, or Why Ketone Bodies? Postgrad. Med. J. (June Suppl.): 371-375: (1971).
6. Paterson, P. et al.: Maternal and Fetal Ketone Concentrations in Plasma and Urine. Lancet: 862-865; April 22, (1967).
7. Fraser, J. et al.: Studies with a Simplified Nitroprusside Test for Ketone Bodies in Urine, Serum, Plasma and Milk. Clin. Chem. Acta II: 372-378; (1965).
8. Henry, J.B. et al.: Clinical Diagnosis and Management by Laboratory Methods, 16th Ed. Philadelphia: Saunders; (1979).

## **N. Instrument Name:**

TC-Thunderbolt Automated Urine Analyzer

## O. System Descriptions:

### 1. Modes of Operation:

Automatic sample-suction, strip advance, and sample application.

### 2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  or No

The following sections are presented in the submission and they appear adequate based on the level of concern and information provided in the *Guidance for Content of Premarket Submissions for Software Contained in Medical Devices*, May 11, 2005.

Level of Concern – The sponsor has classified their device as a Moderate Level of Concern.

### 3. Specimen Identification:

Bar-code scanner.

### 4. Specimen Sampling and Handling:

The TC-Thunderbolt Automated Urine Analyzer uses automatic sample-suction, strip advance, and sample-application technologies.

### 5. Calibration:

The TC-Thunderbolt Automated Urine Analyzer System uses a plastic calibration strip to perform a calibration reflectance check and test module alignment. The calibration strip is included with the system. There are two different kinds of calibration. One is to ensure the stability of the light source; it is performed every time the instrument is switched on. The other is to align the test module and should be performed every 4 to 6 months.

### 6. Quality Control:

The labeling states:

For best results, performance of TC-Thunderbolt Urine Reagent Strips should be confirmed by controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

**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.