510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k100024

B. Purpose for Submission:

New assay

C. Measurand:

Nitrite and Leukocyte

D. Type of Test: Qualitative

Colorimetric test strips

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Teco Diagnostics UTI Test Strips

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1510, Nitrite (nonquantitative) test system

   21 CFR §864.7675, Leukocyte peroxidase test

2. Classification:

   Class I, meets the limitations of exemptions in 21 CFR 862.9 (c)(9)

3. Product code: JMT, LJX

4. Panel: Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See Indications for use, below.

2. Indication(s) for use:

   Teco Diagnostics UTI Test Strips are intended for the qualitative detection nitrite and leukocytes in urine as an aid in the screening of urinary tract infection (UTI). It is intended for over-the-counter home use only.

3. Special conditions for use statement(s):

   For over the counter use.

   The manufacturer includes the following among the limitations in the package insert: Reading of UTI Detection Strips results may be affected by several factors.

   - Urine with pH≥8.0 may cause false negative in Leukocyte.

   You may get false results if:

   - You have been taking medicine or dietary supplement that may cause abnormal urine color.
   - You have a UTI caused by bacteria that does not change nitrate to nitrite.
   - When urine has not been held in the bladder for more than 4 hours.
   - You are taking antibiotics

   The package insert also instructs users to consult their physician or health professional if the result is positive or if they have symptoms.

4. Special instrument requirements:

   None

I. Device Description:

The product is a firm plastic strip with affixed, separate, dry reagent pad areas, for use as midstream tests. The UTI Detection Strips are packaged with a desiccant in a sealed, foil pouch. The color chart for reading the strips is on the outside of the foil pouch.

J. Substantial Equivalence Information:

1. Predicate device name(s): Bayer Multistix 10 SG Reagent Strips

2. Predicate 510(k) number(s): k905396

3. Comparison with predicate:

Comparisons are shown in the table below:

	Teco Diagnostics UTI Test Strips	**Bayer Multistix 10 SG Reagent Strips**
Intended Use	For the qualitative detection of multiple analytes in urine	Same
Analytes	Leukocyte and Nitrite	Glucose, Bilirubin, Ketone, pH, Blood (Occult), Specific Gravity, Protein, Urobilinogen, Leukocyte and Nitrite
Intended Users	Lay persons, over-the-counter use	For professional use in point-of-care urine testing
Specimen	Human Urine	Same
Materials Provided	Plastic test strips affixed with reagent pads	Same
Nitrite Parameter Methodology	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 from 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.	Same
Leukocyte Parameter Methodology	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.	Same

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

None were referenced.

L. Test Principle:

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) quinoline 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 precision study on the UTI Detection Strips was performed at two clinical sites with three operators at each site. The evaluation included four replicate assays over five days for a total of twenty assays on each of three levels of control, for a total of forty results from each site. All sample concentrations were masked. Three lots of strips were used with each level of control. The specified controls values are listed in the following table:

Analyte	**Control (Level I)**	**Control (Level II)**	**Control (Level III)**	**Near cutoff (prepared) control)**
Nitrite	Positive	Positive	Negative	Positive
Leukocyte	2+ - 3+	Trace - 2+	Negative	Trace

Summary of Precision Results

Analyte	**Expected Value Control I, II and III**	**Expected Results Determined by Comparator Method**	**UTI Detection Strips Results**	**% Agreement with Expected Results (exact color block match)**	**n**
NIT level I	Positive	Positive	Positive	100	40
NIT level II	Positive	Positive	Positive	100	40
NIT level III	Negative	Negative	Negative	100	40
NIT near cutoff	Positive	Positive	Positive	100	40
LEU level I	Positive	Positive	Positive	100	40
LEU level II	Trace - 2+	1+	1+	100	40
LEU level III	Negative	Negative	Negative	100	40
LEU near cutoff	Trace	Trace	Trace	100	40

Results of evaluations by lay users are shown below in section 2a.

b. Linearity/assay reportable range:

Not applicable. This is a qualitative test.

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

Stability Studies:

Ongoing temperature and humidity stability studies are performed on the test strips to validate the accelerated stability studies which preliminarily support a two year shelf life. Three strip lots are tested at intervals up to two years. Storage conditions are 15-30 ^{o}C (out of sunlight). Criteria are that the product must read all control results as shown below to confirm the shelf life.

The labeling emphasizes that the test should be run immediately after the foil pouch is opened.

Analyte	**Control (Level I)**	**Control (Level II)**	**Control (Level III)**	**Near cutoff (prepared) control)**
Nitrite	Positive	Positive	Negative	Positive
Leukocyte	2+ - 3+	Trace - 2+	Negative	Trace

d. Detection limit:

See Assay cutoff section below

e. Analytical specificity:

Potentially interfering substances were added to negative urine at the concentrations specified below. Each urine sample was tested in replicates of five (5) with Teco Diagnostics' UTI Detection Strips. The following substances at the concentrations shown did not affect assay results. Testing was performed in the presence of leukocytes at the following leukocyte concentrations: 0, 15, 70 and 125 cells/uL and the following nitrite concentrations: 0, .075, .1 and .5 mg/dL.

Substance	Highest Concentration tested that does not affect the test results (mg/dL)

Albumin	1000
Ammonium Chloride	400
Ascorbic Acid	10*
Bilirubin	10
Ciprofloxacin	1
Creatinine	600
Fructose	18
Galactose	15
Glucose	1000
Glycine	900
Hemoglobin	100*
Lactose	29
Oxalic Acid	0.97
Phenazopyridine	5*
Phenolpthalein	4
Potassium Chloride	1200
Riboflavin	10*
Sodium Nitrate	0.3
Sodium Nitrite (tested for affect on leukocyte results)	10
Sodium Phosphate	1000
Sulfamethoxazole	40
Theophylline	4
Urea	4000

*See Tables below for description of interference from these analytes at higher concentrations.

pH	Leukocyte Concentration (cells/uL)			
	0	15	70	125
5.0	-	Trace	+	++
6.5	-	Trace	+	++
8.0	-	2/5 negative	+	++

In addition, the following results were obtained, and are specified where relevant in the package insert.

Nitrite (mg/dL)	Leukocyte Concentration (cells/uL)			
	0	15	70	125
0	-	Trace	+	++
0.1	-	Trace	+	++
10	-	Trace	+	++

pH >8.0 may cause false negative Leukocyte readings

SG	Leukocyte Concentration (cells/uL)			
	0	15	70	125
1.005	-	Trace	+	++
1.015	-	Trace	+	++
1.030	0	3/5 negative	+	++

Specific Gravity >1.030 may cause false negative Leukocyte readings

Glucose (mg/dL)	Leukocyte Concentration (cells/µL) 0	15	70	125
0	-	Trace	+	++
500	-	Trace	+	++
1000	-	-	Trace	+

High Glucose levels (>1000mg/dL) decreases Leukocyte readings.

Albumin (mg/dL)	Leukocyte Concentration (cells/µL) 0	15	70	125
0	-	Trace	+	++
500	-	Trace	+	++
1000	-	Trace	+	++

High riboflavin levels (> 10mg/dL) decrease Leukocyte readings

Ascorbic Acid (mg/dL)	Nitrite Concentration (mg/dL) 0	0.075	0.1	0.5

0	-	+	+	+
10	-	+	+	+
30	-	-	+	+

High Ascorbic Acid (>30mg/dL) decreases the sensitivity of the Nitrite readings

Leukocyte (cell/uL)	Nitrite Concentration (mg/dL)			
	0	0.075	0.1	0.5
0	-	+	+	+
70	-	+	+	+
125	-	+	+	+

There is no effect of Leukocyte on Nitrite

pH	Nitrite Concentration (mg/dL)			
	0	0.075	0.1	0.5
5.0	-	+	+	+
6.5	-	+	+	+
8.0	-	+	+	+

There is no effect of pH on Nitrite

SG	Nitrite Concentration (mg/dL)			
	0	0.075	0.1	0.5
1.005	0	+	+	+
1.015	0	+	+	+
1.030	0	1/5 negative	+	+

Specific Gravity >1.030 may cause false negative Nitrite reading

f. Assay cut-off:

A sensitivity study was performed to evaluate the lower limits of detection for each analyte on the UTI Detection Strips. Urine samples were spiked to known concentrations of each analyte. These samples were then diluted to the lowest positive concentrations that are indicated on the color chart. Each sample was tested ten times total with three lots over three days.

Table of Lowest Detection Limit: Nitrite and Leukocyte

Nitrite (mg/dL)	**Percentage Positive Samples**

0.10	100
0.075	93
0.050	53
Negative	0
Leukocyte (cells/uL)	**Percentage Positive Samples**
15	100
11.25	53
7.5	23
Negative	0

2. Comparison studies:

a. Method comparison with predicate device:

Patient sample testing was performed by lay users at two point of care sites. Each site selected fifty symptomatic lay users to test their own fresh urine using the Teco Diagnostics UTI Detection Strips according to the package insert and to collect samples of the same urine for clinic technicians. The symptoms included at least one of the following: burning or pain during urination, frequent urination or cloudy urine. After the lay user's testing, one clinic (healthcare professional) operator tested the urine sample using the Teco UTI Detection Strips while the other clinic (healthcare professional) operator tested the urine sample using the predicate device (Bayer Multistix 10 SG strips). All previous sample results and sample identity were masked from the operator. In total, one hundred (100) specimens were tested. Each site used a different lot of Urine Reagent Strips Lay users recorded results and the questions listed on the Patient Questionnaire. The clinic personnel recorded the results on the separate Patient Data Forms in order to mask results. Comparative results are shown below:

Nitrite

Teco Lay User Teco Professional	Positive	Negative
Positive	41	0
Negative	0	59
Total	41	59
% Agreement (Exactly Match)	100.0%	
% Agreement (+/- Color Block)	100.0%	

Nitrite

Teco (professional) Bayer (professional)	Positive	Negative
Positive	41	0

Negative	0	59
Total	41	59
% Agreement (Exactly Match)	100.0%	
% Agreement (+/- Color Block)	100.0%	

Leukocyte

Teco/Lay User Teco /Professional	3+	2+	1+	Trace	0 (Neg)
3+	3				
2+		6	2		
1+		1	17	3	
Trace			2	17	
0 (Neg)					49
Total	3	7	21	20	49
% Agreement (Exactly Match)	100.0%	86%	81%	85%	100%
% Agreement (+/- Color Block)	100.0%				

Leukocyte

Teco//Lay User Bayer Professional	3+	2+	1+	Trace	0 (Neg)
3+	3	1			
2+		6	2		
1+			20	2	
Trace				17	
0 (Neg)					49
Total	3	7	22	19	49
% Agreement (Exactly Match)	100%	86%	91%	89%	100%
% Agreement (+/- Color Block)	100.0%				

Survey results included in the 510(k) demonstrated that users included a spectrum across ages and educational levels, and that almost all participants (99%) thought the instructions were not difficult to understand.

b. Matrix comparison: Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. Clinical Sensitivity: Not typically reviewed for this device type.

b. Clinical specificity: Not typically reviewed for this device type.

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:

Not applicable.

N. Proposed Labeling:

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

O. Conclusion:

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