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

A. 510(k) Number:

k061419

B. Purpose for Submission:

New device

C. Measurands:

Urine microalbumin and urine creatinine

D. Type of Test:

Semi-quantitative

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Teco Microalbumin 2-1 Combo Strips

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1225 – Creatinine test system

   21 CFR 862.1645 – Urinary protein or albumin (nonquantitative) test system

2. Classification:

   Class II

3. Product code:

   JFY – Enzymatic Method, Creatinine

   JIR – Indicator Method, Protein or Albumin (Urinary, Non-Quant.)

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   Teco Diagnostics Microalbumin 2-1 Combo Strip is designed to give semi-quantitative results for Microalbumin and Creatinine in random urine and also determine the albumin to creatinine ratio in random urine.

2. Indication(s) for use:

   Teco Diagnostics Microalbumin 2-1 Combo Strip is designed to give semi-quantitative results for Microalbumin and Creatinine in random urine and also determine the albumin to creatinine ratio in random urine.

   Microalbuminuria, an abnormal elevation of the urinary albumin excretion rate, is many times one of the first signs of renal diseases and renal damage than can lead to renal failure.

   Creatinine measurements are used in the diagnosis and treatment of renal diseases and in monitoring renal dialysis.

   The Teco Microalbumin 2-1 Combo Strips are read by visual comparing color chart.

   Teco Microalbumin 2-1 Combo Strips are recommended for use in screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage.

3. Special conditions for use statement(s):

   The device is for prescription use (clinical laboratory and point-of-care).

4. Special instrument requirements:

   No instruments are required. This is a visually read test.

I. Device Description:

The Teco Microalbumin 2-1 Combo Strips are plastic strips to which two test pads are affixed for testing microalbumin and creatinine. The microalbumin pad contains sulfonephthalein color, buffer, and nonreactive ingredients. The creatinine pad contains copper sulfate, benzidine, buffer, and nonreactive ingredients. The kit

contains 25 test strips stored in a bottle along with a drying reagent. The strips are ready to use and results are obtained by direct comparison of the test areas to color blocks printed on the bottle label.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Clinitek Microalbumin Reagent Strips

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

   k972706

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Semi-quantitative detection of microalbumin and creatinine in urine	Same
Principle	Indicator method based on reaction between albumin and sulfonephthalein dye	Same

Differences		
Item	Device	Predicate
Sample Type	Random urine	24-hour urine
Principle	Indicator method based on a creatinine-sulfate complex catalyzing the reaction of hydroperoxylcumene and tetramethylbenzidine	Indicator method based on a copper creatinine complex catalyzing the reaction of diisopropylbenzene dihydroperoxide and tetramethylbenzidine
Instrument	None required	Clinitek 50, 100

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

CLSI EP12-P – User Protocol for Evaluation of Qualitative Test Performance
CLSI EP7-A – Interference Testing in Clinical Chemistry

L. Test Principle:

In one pad, albumin binds sulfonephthalein dye to develop a color ranging from pale green to aqua blue. In the other pad, creatinine reacts with an indicator to form a purplish-brown color. The concentration is directly proportional to the color intensity of the test pad. The color produced is compared visually to a color chart provided with the device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The following repeatability studies were determined in-house following CLSI EP12-P. Fresh human microalbumin free urines were spiked with commercial human albumin at five different concentrations: 0, 10, 30, 80, and 150 mg/dL. Each specimen concentration was tested 25 times. The percent agreement of replicate readings for microalbumin was 96% (120/125).

Fresh human urines were spiked with commercial creatinine or diluted at five different concentrations: 0, 100, 500, 1000, 2000, and 3000 mg/L. Each specimen concentration was tested 25 times. The percent agreement of replicate readings for creatinine was 93.3% (140/150).

Reproducibility studies were conducted at three physician office laboratories (POLs) and compared with an in-house professional user. At each site, one POL operator performed the study, testing 125 samples. The POL users had various educational backgrounds and experiences. The average agreement from each site against the professional user are shown in the table below:

	Site 1	**Site 2**	**Site 3**
Microalbumin	95.4%	95.3%	90.8%
Creatinine	96%	94.9%	95%

b. Linearity/assay reportable range:

Not applicable

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

Data was provided to support the claim that the strips are stable up to three months after opening the bottle. The bottle was opened and various concentrations of microalbumin and creatinine were analyzed on the strips at different time points between 5 and 95 days. Acceptable results were obtained.

d. Detection limit:

Sensitivity studies were conducted to evaluate the minimum concentration of albumin and creatinine that has a high probability of being detected with the device. Albumin negative urine samples were spiked with human albumin at four levels of concentrations (5, 10, 20, and 30 mg/l) and tested on the device. The results showed 8 negatives and 12 trace results at 10 mg/L. All results at 5 mg/L were negative and all results at 20 mg/L were positive. The minimum detectable concentration of albumin is 10 mg/L.

Urine samples with creatinine concentrations at 25, 50, 100, and 500 mg/L were tested on the device. The results showed 6 negatives and 14 trace results at 100 mg/L. All results were negative at 25 mg/L and all were positive at 500 mg/L. The minimum detectable concentration of creatinine is 100 mg/L.

e. Analytical specificity:

Interference studies were designed using CLSI EP7-A. Studies were performed to assess common or known substances that could interfere with the Teco Microalbumin 2-1 combo Strip. The following substances were spiked into samples at different concentrations and tested: hemoglobin, bilirubin, vitamin C. The presence of hemoglobin (≥5 mg/dL or visibly bloody urine), bilirubin (≥ 15 mg/dL or visibly dark brown color urine) may cause error results with the albumin and creatinine tests. Vitamin C over 100 mg/dL does not affect the results of the microalbumin and creatinine tests.

f. Assay cut-off:

See detection limit section above.

2. Comparison studies:

a. Method comparison with predicate device:

A total of 86 random urine specimens were collected from outpatients and assayed on a commercially available assay and the Microalbumin 2-1 Combo Strip. In order to cover the assay range, some of the urine specimens were spiked with known concentrations of albumin and creatinine. The study results for the albumin test showed 96.5% agreement between the two devices for the positive results, 98.3% agreement between the two devices for the negative results, and 91.9% overall agreement. For the creatinine test, the percent agreement between the two tests was 86%.

b. Matrix comparison:

Random urines were compared against 24-hour urines. Both urine specimen types were collected from 25 outpatients. Each urine type was run on the Teco Microalbumin 2-1 combo test strips, and the results of albumin/creatinine showed 96% agreement to random urines.

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:

   The expected values provided in the labeling are based on literature.

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.