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

A. 510(k) Number:

k051526

B. Purpose for Submission:

New submission for the Uritek-720+ Urine Analyzer for the use with Teco Diagnostic's previously cleared urine strips URS-10 k970250.

C. Measurand:

Glucose, Blood, Leukocytes, Specific Gravity, pH, Nitrite, Protein, Ketone, Urobilinogen and Bilirubin in urine

D. Type of Test:

Qualitative /Semi-Quantitative

E. Applicant:

TECO Diagnostics

F. Proprietary and Established Names:

Uritek-720+ Urine Analyzer

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.1340	Urinary glucose (nonquantitative) test system
21 CFR § 864.6550	Occult blood test
21 CFR § 864.7675	Leukocyte peroxidase test
21 CFR § 862.2800	Refractometer for clinical use
21 CFR § 862.1550	Urinary pH (nonquantitative) test system
21 CFR § 862.1510	Nitrite (nonquantitative) test system
21 CFR § 862.1645	Urinary protein or albumin (nonquantitative) test system
21 CFR § 862.1435	Ketones (nonquantitative) test system
21 CFR § 862.1785	Urinary urobilinogen (nonquantitative) test system
21 CFR § 862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system

21 CFR § 862.2900   Automated urinalysis system

2. Classification:

Class II; Urinary glucose (nonquantitative) test system and Occult blood test

Class I; Leukocyte peroxidase test, Refractometer for clinical use, Urinary pH (nonquantitative) test system, Nitrite (nonquantitative) test system, Urinary protein or albumin (nonquantitative) test system, Ketones (nonquantitative) test system, Urinary urobilinogen (nonquantitative) test system and Urinary bilirubin and its conjugates (nonquantitative) test system and Automated urinalysis system

3. Product code:

JIL   Enzymatic Method, Glucose (urinary, non-quant.)
JIO   Blood, Occult, Colorimetric, in urine
LJX   Test, Urine Leukocyte
JRE   Refractometer for clinical use
CEN   Dye-Indicator, pH (urinary, non-Quant.)
JMT   Diazo (colorimetric), Nitrite (urinary, non-quant.)
JIR   Indicator method, Protein or Albumin (urinary, non-quant.)
JIN   Nitroprusside, Ketones (urinary, non-quant.)
CDM   Diazonium Colorimetry, Urobilinogen (urinary, non-quant.)
JJB   Azo-dye, colorimetric, Bilirubin & its conjugates (urinary, non-quant.)
KQO   Automated urinalysis system

4. Panel:

75 Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The Uritek-720+ Urine Analyzer is intended for use with Teco Urine Reagent Strips for Urinalysis such as URS-10, used in the determination of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

    Uritek-720+ Urine Analyzer

I. Device Description:

The Uritek-720+ Urine Analyzer combines a contact Image Sensor (CIS), electronics and computer technology with other technologies. The controlling system processes the reflectance ratios of the lights and converts them into electrical signals for result interpretation.

J. Substantial Equivalence Information:

1. Predicate device name(s):

    Bayer, Clinitek 200+ Urine Chemistry Analyzer

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

    k0926359

3. Comparison with predicate:

Comparison		
Item	Device	Predicate
Intended use	Used in determination of glucose, protein, pH, bilirubin, blood, ketone, urobilinogen, nitrite, specific gravity and leukocytes in urine.	Same
Basic Operating Principle	Reflectance	Same
Testing options	Single-step or continuous testing	Same
Test steps	Dip and place urine strip onto test table	Same
Environment Requirement	0-40 ºC Relative humidity $\leq 85\%$	18-30 ºC Relative humidity 20% - 85%
Dimension	260 x 320 x 178 mm	49.3 x 35.4 x 19.7 cm

Comparison		
Item	Device	Predicate
Weight	2.4 kg	13.6 kg

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

None Referenced

L. Test Principle:

The instrument uses three electric signals of red, green and blue (conversion of reflected light) to scan the difference and depth of color change. The controlling system processes the electrical signal and computes the reflectance ratio of testing color according to the following equation:

$$R\% = \frac{Tm \times Cr}{Tr \times Cm} \times 100\%$$

R -- Reflectance ratio

Tr -- Reflectance intensity of reference light of test sector

Cr --Reflectance intensity of reference light of blank sector

Tm -- Reflectance intensity of test sector of test light

Cm -- Reflectance intensity of blank sector of test light

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

    a. *Precision/Reproducibility:*

    The repeatability study was performed on 20 replicates of three levels of controls using two instruments and two lots. The 2x2 contingency table was applied to evaluate the total agreement, in terms of percentage, on each parameter. Cutoff values were used to determine the difference of positive and negative samples. Results are summarized below:

Control I

Sample	Glucose		Bilirubin		Ketone		SG		Blood	
Cutoff	759.8 mg/dL		4.6 mg/dL		59.4 mg/dL		1.022		129.9 cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	20	0	20	0	19	0	20	0
Negative	0	20	0	20	0	20	1	20	0	20
Agreement %	100%	100%	100%	100%	100%	100%	95%	100%	100%	100%

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Control I

Sample	pH		Protein		Urobilinogen		Nitrite		Leukocyte	
Cutoff	7.7		178.7 mg/dL		4.9 mg/dL		0.8		315.4 cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	20	0	20	0	20	0	20	0
Negative	0	20	0	20	0	20	0	20	0	20
Agreement %	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Control II

Sample	Glucose		Bilirubin		Ketone		SG		Blood	
Cutoff	417.2 mg/dL		1.9 mg/dL		27.9 mg/dL		1.013		39.3 cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	20	1	20	0	20	1	20	1
Negative	0	20	0	19	0	20	0	19	0	19
Agreement %	100%	100%	100%	95%	100%	100%	100%	95%	100%	95%

Control II

Sample	pH		Protein		Urobilinogen		Nitrite		Leukocyte	
Cutoff	7.3		67.4 mg/dL		0.5 mg/dL		0.8		98.6cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	19	0	20	0	20	0	19	0
Negative	0	20	1	20	0	20	0	20	1	20
Agreement %	100%	100%	95%	100%	100%	100%	100%	100%	95%	100%

Control III

Sample	Glucose		Bilirubin		Ketone		SG		Blood	
Cutoff	60 mg/dL		0.6 mg/dL		2.6 mg/dL		1.007		8.8cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	20	0	20	0	20	0	20	0
Negative	0	20	0	20	0	20	0	20	0	20
Agreement %	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Control III

Sample	pH		Protein		Urobilinogen		Nitrite		Leukocyte	
Cutoff	6.2		11 mg/dL		0.5 mg/dL		0.8		9.7cells/µl	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Positive	20	0	20	0	20	0	20	0	20	0
Negative	0	20	0	20	0	20	0	20	0	20
Agreement %	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

b. *Linearity/assay reportable range:*

See k970250

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

See k970250

d. *Detection limit:*

See k970250

e. *Analytical specificity:*

See k970250

f. *Assay cut-off:*

See k970250

2. Comparison studies:

a. *Method comparison with predicate device:*

100 specimens were tested using the Teco strips (Lot 3: 04454 Exp.: 10/07) on Uritek-720+ (S/N: 6015-2184) verses the Bayer Multistix 10SC reagent strips (Lot#: 2K02C Exp.: 04/06) on the Clinitek-200+ (S/N: 1034). The samples included every range measurement for every analyte. The Percent agreement for each analyte was determined by the number of positive and negative results. The comparison data showed substantial equivalence to the predicate device.

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:

See k970250

N. Instrument Name:

URITEK-720+ Urine Analyzer

O. System Descriptions:

1. Modes of Operation:

   Single-step or continuous testing

2. Software:

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

   Yes ___X_____ or No _____

3. Specimen Identification:

   Manual or Barcode patient ID entry

4. Specimen Sampling and Handling:

   Manual Dip and place urine strip onto test table

5. Calibration:

   Uritek-720+ is self-calibrated every time the power is turned on. The calibration is performed twice when the strip bed moves in-out two times. As a preliminary step, the sponsor recommends that users should ensure the position of strip bed and clean the calibration white dot.

6. Quality Control:

The sponsor recommends the following to their users:
1. Positive and negative controls are always recommended for testing purpose.
2. Use commercially available controls: High Abnormal, Abnormal, and Normal.
3. Prepare the controls accordingly to the instruction insert provided.
4. Test the urine strips with the controls. Perform the control testing according to the sample test instructions.
5. Record the results and compare to the ranges provided. *Remark: The control testing is*

only requested on every 100 tests or after turn on the power.

6. Retest the controls with different lot of strips, if test results are in doubt. If the test results are consistently in doubt, please contact TECO technical support for help.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Software documentation provided demonstrates the Uritek-720+ Urine Analyzer was designed and manufactured under well developed software lifecycle processes.

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.