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

A. 510(k) Number:
k073370

B. Purpose for Submission:
Clearance of a new device.

C. Measurand:
Alanine amino transferase (ALT/SGPT), Albumin, Urea nitrogen (BUN), Glucose

D. Type of Test:
Photometric

E. Applicant:
TECO Diagnostics

F. Proprietary and Established Names:
TC Matrix Clinical Chemistry Analyzer

G. Regulatory Information:
1. Regulation section:
   21 CFR § 862.1030, Alanine amino transferase (ALT/SGPT) test system
   21 CFR § 862.1035, Albumin test system
   21 CFR § 862.1770, Urea nitrogen test system
   21 CFR § 862.1345, Glucose test system
   21 CFR § 862.1150, Calibrator, multi-analyte mixture
   21 CFR § 862.2160, Discrete photometric chemistry analyzer for clinical use
2. Classification:
   Class I, subject to the limitations of exemption in 862.9(c)(4)
   Class II
   Class II
   Class II
   Class II
   Class I
3. Product code:
   CKA
   CIX
   CDQ
   CGA
   JIX
   JJE
4. Panel:
   75 (Clinical Chemistry)

H. Intended Use:
   1. Intended use(s):
      See indications for use below.
   2. Indication(s) for use:
      The TC Matrix Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by automatically performing various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes of clinical interest in serum, plasma samples.

      TECO MULTI Calibrator is intended for the calibration of quantitative assays.

      Teco Albumin reagent is intended to measure the albumin concentration in serum and plasma. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

      Teco ALT reagent is intended to measure the activity of the enzyme alanine amino transferase (ALT) (also known as a serum glutamic pyruvic transaminase or SGPT) in serum and plasma. Alanine amino transferase measurements are used in the diagnosis and treatment of certain liver diseases (e.g., viral hepatitis and cirrhosis) and heart diseases.

      Teco Glucose reagent is intended for the quantitative determination of total glucose in human serum or plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

      Teco BUN reagent is intended to measure urea nitrogen (an end-product of nitrogen metabolism) in serum, and plasma. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.
   3. Special conditions for use statement(s):
      For prescription use.
   4. Special instrument requirements:
      TC Matrix Clinical Chemistry Analyzer

I. Device Description:
   TC Matrix Clinical Chemistry Analyzer is an automated system intended for the in vitro determination of variety of general chemistries in biological fluid such as serum or plasma. The analyzer operates in conjunction with reagents and calibrators designed for use with the system. The instrument automatically delivers samples to the reaction cuvette along with reagents and reaction constituents. The system analyzes up to 40 samples per run with up to 19 analytes (double reagents) or 38 analytes (single reagent). Major hardware components include a sample/reagent disk, dispenser, mixer, reaction Disk and photometric system.

J. Substantial Equivalence Information:
   1. Predicate device name(s):
      Beckman Coulter Synchron CX Delta Clinical System

2. Predicate 510(k) number(s):
   k950958
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	The TC Matrix Clinical Chemistry Analyzer is a discrete photometric chemistry analyzer for clinical use. The device is intended to duplicate manual analytical procedures by automatically various steps such as pipetting, heating, and measuring color intensity. This device is intended for use in conjunction with certain materials to measure a variety of analytes of clinical interest in serum, plasma.	The Synchron CX Delta Clinical System is a fully automated, computer controlled, clinical chemistry analyzer intended for the *in vitro* quantitative measurement of a variety of analytes of clinical interest in biological fluid, such as, serum, plasma, urine, and cerebral spinal fluid.
User Interface	Keyboard Control	Keyboard Control, Barcode Scanner
Reaction Vessels	Hard plastic cuvettes and plastic reaction vessels	Hard plastic cuvettes and plastic reaction vessels

Differences		
Item	Device	Predicate
Sample Type	Serum, Plasma	Serum, Plasma, Urine, Cerebrospinal Fluid
Detection Technologies	Photometric	Photometric, turbidimetric, multisensor electrodes, ion selective
Throughput	200 tests/Hour	900 tests/Hour

K. Standard/Guidance Document Referenced (if applicable):
   CLSI EP5-A: Evaluation of Precision Performance of Clinical Chemistry Devices
   CLSI EP6-A: Evaluation of Linearity of Quantitative Analytical Methods
   CLSI EP7-A2: Method Comparison and Bias Estimation Using Patient Samples

L. Test Principle:
   Albumin:
   Bromcresol purple (BCP), an ionic dye, binds tightly to albumin when serum is added. The albumin- BCP complex absorbs light at 600 nm more intensively than BCP alone. The system monitors the change in absorbance at 600 nanometers. This change in absorbance is

directly proportional to the concentration of albumin in the sample and is used by the TC Matrix System to calculate and express albumin concentration.

ALT:
ALT converts L-Alanine and α-ketoglutaric acid to pyruvate and glutamate. Pyruvate, NADH, and H+ are then converted by lactate dehydrogenase to lactate, NAD+, and water. The system monitors the change in NAD+ absorbance at 340 nanometers. This change in absorbance is directly proportional to the activity of alanine aminotransferase in the sample and is used by the TC Matrix System to calculate and express alanine aminotransferase activity.

BUN:
Urea is hydrolyzed by urease to produce ammonia. The ammonia is then coupled with α-ketoglutarate and NADH to produce glutamate and NAD+. The rate of absorbance decrease is directly proportional to the amount of urea present in the sample. The system monitors the change in absorbance at 340 nanometers. This change in absorbance is directly proportional to the concentration of urea in the sample and is used by the TC Matrix System to calculate and express the urea concentration.

Glucose:
β-D-Glucose is oxidized by glucose oxidase to produce D-gluconic acid and hydrogen peroxide. The hydrogen peroxide is then oxidatively coupled with 4-aminoantipyrine and phenol substitute, p¬HBS, in the presence of peroxidase to yield a red quinoneimine dye. The amount of colored complex formed is proportional to glucose concentration and can be photometrically measured.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Within and between-batch precision:
      Three levels of commercial controls were used each repeatedly measured 20 times over 8 hours.

Test Name	Control 1			
	Range	Mean	SD	CV%
Glucose	52-72	62.35	1.14	1.8
ALT	20-30	24.9	0.79	3.2
Albumin	2.2-2.6	2.34	0.06	2.6
BUN	13-19	16.05	0.6	3.8

	Control 2			
	Range	Mean	SD	CV%
Glucose	112-	122.65	1.5	1.2
ALT	74-86	79.4	0.88	1.1
Albumin	2.9-3.5	3.26	0.06	1.8
BUN	35-47	40.25	0.85	2.1
	Control 3			
	Range	Mean	SD	CV%
Glucose	336-	364.1	2.47	0.7
ALT	155-	166.75	1.52	0.9
Albumin	3.7-4.5	4.07	0.07	1.8
BUN	61-81	69.2	0.95	1.4

Run to Run Precision:
Three levels of commercial controls were used each repeatedly measured 5 times per day, continuously for 5 days, for a total of 25 repeats.

Test Name	Control 1			
	Range	Mean	SD	CV%
Glucose	52-72	61.92	1.38	2.2
ALT	20-30	25.24	0.83	3.3
Albumin	2.2-2.6	2.33	0.05	2.2
BUN	13-19	16.36	0.49	3
	Control 2			
	Range	Mean	SD	CV%
Glucose	112-	123.24	2.54	2.1
ALT	74-86	78.88	0.97	1.2
Albumin	2.9-3.5	3.23	0.07	2.3
BUN	35-47	41.44	1.04	2.5
	Control 3			
	Range	Mean	SD	CV%
Glucose	336-	361.36	5.3	1.5
ALT	155-	167.52	1.83	1.1
Albumin	3.7-4.5	4.08	0.06	1.4
BUN	61-81	69.08	2.18	3.2

b. *Linearity/assay reportable range:*
Linearity studies were designed using CLSI EP6. Each analyte was tested with a commercial linearity kit. Each concentration was tested two times to determine the mean concentration. The results of this study demonstrate that the measuring range of Glucose is 25 to 500 mg/dL; Albumin is 1.0 to 7.0mg/dL; BUN is 5.0-80 mg/dl; and

ALT is 5 to 400 IU/L. Linear regression statistics and data is summarized below:

Albumin

Level	Concentration g/dL	Rep(1) g/dL	Rep.(2) g/dL
A	1.0	1.0	1.0
B	2.0	1.9	2.0
C	3.0	3.1	3.0
D	4.5	4.4	4.6
E	5.0	5.2	5.2
F	6.0	5.9	6.0
G	7.0	6.8	6.9

Level	Mean g/L	Difference g/L	Difference%
A	1.0	0.0	0.0
B	1.95	-0.05	-2.5
C	3.05	0.05	1.6
D	4.5	0.0	0.0
E	5.2	0.2	0.4
F	5.95	-0.05	-0.8
G	6.85	-0.15	-2.1

Linear Regression Analysis: y = 1.0x + 0.027
R Square: 1.00

BUN

Level	Concentration mg/dL	Rep.(1) mg/dL	Rep.(2) mg/dL
A	5.0	5.2	5.1
B	12.5	13.1	12.9
C	25.0	23.8	23.1
D	50.0	48.5	48.1
E	80.0	78.5	78.1

Level	Mean mg/dL	Difference mg/dL	Difference%
A	5.15	0.15	3.0
B	13.0	0.5	4.0
C	23.45	-1.55	-6.2
D	48.3	-1.7	-3.4
E	78.3	-1.7	-2.1

Linear Regression Analysis: y = 0.95x + 0.42
R Square: 0.99

Glucose

Level	Concentration mg/dL	Rep.(1) mg/dL	Rep.(2) mg/dL
A	25	26	26
B	50	51	52
C	100	98	98
D	200	201	204
E	300	294	295
F	400	391	389
G	500	495	497

Level	Mean mg/dL	Difference mg/dL	Difference %
A	26.0	1.0	4.0
B	51.5	1.5	3.0
C	98.0	-2.0	-2.0
D	202.5	2.5	1.25
E	294.5	-5.5	-1.8
F	390.0	-10	-2.5
G	496.0	-4.0	-0.8

Linear Regression Analysis: $y = 0.98x + 2.15$
R Square: 1.00

ALT

Level	Concentration IU/L	Rep(1) IU/L	Rep(2) IU/L
A	5	5	6
B	25	24	25
C	75	74	76
D	200	198	195
E	300	295	291
F	400	391	394

Level	Mean IU/L	Difference IU/L	Difference %
A	5.5	0.5	10.0
B	24.5	-0.5	-2.0
C	75.0	0.0	0.0
D	196.5	-3.5	-1.75
E	293.0	-7.0	-2.3
F	392.5	-7.5	-1.9

Linear Regression Analysis: $y = 0.98x + 0.66$
R Square: 1.00

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The calibrators for the assays are traceable to an in house solution using commercial components. The calibrator target values are glucose: 200mg/dL, urea: 45mg/dL, and albumin: 3.0g/dL. The glucose, BUN, and albumin solutions are run 20 times to get the mean as TC Multi-Cal target value. Stability studies showed the shelf-life of TC Multi-Calibrator is 24 months. For ALT, there is no calibration required as the analyzer calculates the activity by using a constant factor times the change in absorbance per minute after adding sample.

d. Detection limit:
Analytical minimal detectable concentration is defined by the sponsor as replicates of a concentration that falls within a calculated range (the mean of the samples run plus and minus two standard deviations). The minimal detectable limit of Teco BUN, Albumin, ALT and Glucose reagents were investigated by reading the change for Distilled Water as the zero sample and a known concentration (diluted the lowest level of a commercial linearity set) on TC Matrix Chemistry Analyzer. Teco BUN, Albumin, ALT and Glucose Reagents on TC Matix showed little or no reagent drift on the zero samples. Teco BUN, Albumin, ALT and Glucose Reagents showed known concentration of BUN 5.0 mg/dL; Albumin 1.0 g/dL; ALT 5.0 U/L and Glucose 25 mg/dL as the minimal detectable limit.

e. Analytical specificity:
Interference Studies were designed using CLSI EP7-A. Studies were performed to assess common or known substances that could interfere with Teco BUN, Albumin, ALT and Glucose Reagent Sets on TC Matrix. The following substances were tested for interference and Limitations. Interference study was demonstrated in a study using serum samples spiked with interferants.

BUN	Sample 1	Sample 2	Sample 3
Without interferants			
Replicate 1	10	37	68
Replicate 2	9	36	67
Replicate 3	10	37	68
Mean	9.7	36.7	67.7
Hemoglobin 150mg/dl			
Replicate 1	10	36	65
Replicate 2	11	36	66
Replicate 3	10	35	67
Mean	10.3	35.7	66
Conclusion	NSI	NSI	NSI

Bilirubin 30mg/dl			
Replicate 1	10	37	66
Replicate 2	9	36	67
Replicate 3	10	36	65
Mean	9.7	36.3	66
Conclusion	NSI	NSI	NSI
Triglyceride 1800mg/dl			
Replicate 1	10	37	68
Replicate 2	10	36	66
Replicate 3	9	36	67
Mean	9.67	36.33	67
Conclusion	NSI	NSI	NSI

NSI= No Significant Interference (within ±10%)

Albumin	Sample 1	Sample 2	Sample 3
Without interferants			
Replicate 1	1.7	3.4	6.4
Replicate 2	1.6	3.3	6.6
Replicate 3	1.7	3.4	6.5
Mean	1.7	3.37	6.5
Hemoglobin 100mg/dl			
Replicate 1	1.5	3.3	6.5
Replicate 2	1.6	3.4	6.6
Replicate 3	1.6	3.3	6.5
Mean	1.6	3.3	6.5
Conclusion	NSI	NSI	NSI
Bilirubin 30mg/dl			
Replicate 1	1.6	3.4	6.4
Replicate 2	1.7	3.5	6.6
Replicate 3	1.6	3.4	6.7
Mean	1.6	3.4	6.6
Conclusion	NSI	NSI	NSI
Triglyceride 1800mg/dl			
Replicate 1	1.6	3.4	6.5
Replicate 2	1.6	3.5	6.5
Replicate 3	1.5	3.3	6.6
Mean	1.6	3.4	6.5
Conclusion	NSI	NSI	NSI

NSI= No Significant Interference (within ± 10%)

ALT	Sample 1	Sample 2	Sample 3
Without interferants			
Replicate 1	15	39	367
Replicate 2	14	36	345
Replicate 3	14	37	356
Mean	14.3	37.3	356
Hemoglobin 150mg/dl			
Replicate 1	15	38	347
Replicate 2	14	39	338
Replicate 3	15	37	345
Mean	14.7	38	343.3
Conclusion	NSI	NSI	NSI
Bilirubin 30mg/dl			
Replicate 1	16	39	365
Replicate 2	15	35	367
Replicate 3	15	36	378
Mean	15.3	36.7	370
Conclusion	NSI	NSI	NSI
Triglyceride 1800mg/dl			
Replicate 1	16	38	375
Replicate 2	15	36	371
Replicate 3	15	38	369
Mean	15.3	37.3	371.7
Conclusion	NSI	NSI	NSI

NSI= No Significant Interference (within ± 20%)

Glucose	Sample 1	Sample 2	Sample 3
Without interferants			
Replicate 1	34	98	425
Replicate 2	33	95	416
Replicate 3	35	94	421
Mean	34	95.7	420.7
Hemoglobin 150mg/dl			
Replicate 1	36	96	420
Replicate 2	35	94	429
Replicate 3	34	95	418
Mean	35	95	422.3
Conclusion	NSI	NSI	NSI
Bilirubin 30mg/dl			
Replicate 1	33	97	424
Replicate 2	35	96	421
Replicate 3	34	95	422
Mean	34	96	422.3
Conclusion	NSI	NSI	NSI
Triglyceride 1800mg/dl			
Replicate 1	35	94	432
Replicate 2	34	96	435
Replicate 3	36	95	419
Mean	35	95	428.7
Conclusion	NSI	NSI	NSI

NSI= No Significant Interference (within ± 10%)

  f. Assay cut-off:
   Not Applicable

 2. Comparison studies:
   a. Method comparison with predicate device:
    Seventy serum samples covering the assay ranges were used in a method comparison study using CLSI EP9-A2 with the TC Matrix Clinical Chemistry Analyzer compared to a reference method. In order to ensure the claimed ranges were covered for ALT, albumin, glucose and BUN, 4 samples were spike and 2 were diluted. The linear regression information is summarized in the table below.

Test Name	Correlation Coefficient (R2)	Regression
ALT	0.99	y = 1.01x - 0.19
Albumin	0.95	y = 1.05x - 0.17
Glucose	0.99	y = 0.99x + 2.6
BUN	0.98	y = 1.02x - 0.06

b. *Matrix comparison:*
   Twenty matched serum samples covering the assay ranges were used in a matrix comparison study with the serum samples compared to EDTA plasma samples. In order to ensure the claimed ranges were covered for ALT, albumin, glucose and BUN, 2 samples were spike and 1 was diluted. The linear regression is summarized in the table below.

Test Name	Correlation Coefficient (R2)	Regression
ALT	0.99	y = 1.0x - 0.69
Albumin	0.96	y = 1.01x - 0.06
Glucose	0.99	y = 1.02x - 2.6
BUN	0.98	y = 0.98x + 1.01

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:
   ALT:
   10 - 40 IU/L
   Tietz, N.W., Fundamentals of Clin. Chem., Philadelphia, W.B. Saunders (1970).

   Glucose:
   70 - 105 mg/dl
   The sponsor strongly recommends each laboratory establish its own normal range.
   Tietz, N.W., Fundamentals of Clin. Chem., Philadelphia, W.B. Saunders (1970).

ALB:
3.5-5.0g/dL or 35~50 g/L
Tietz, N.W., Fundamentals of Clin. Chem., Philadelphia, W.B. Saunders (1970).

BUN:
15 - 38 mg/dL or 2.5 to 6.4 mmol/L
Wildmann, F.K.: Coodales Clinical Interpretation Laboratory Tests. F.A. Davis Co., Philadelphia (1969).

N. Instrument Name:
TC Matrix Clinical Chemistry Analyzer

O. System Descriptions:
1. <u>Modes of Operation</u>:
The instrument has a single mode of operation.
2. <u>Software</u>:
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes ___X___ or No _____
3. <u>Specimen Identification</u>:
Sample identification is performed through an interface which instructs the device which sample types are present and where on the carousel they are placed.
4. <u>Specimen Sampling and Handling</u>:
This device is intended to be used with serum or plasma. The sponsor recommends sample handling procedures in the package inserts of the assays.
5. <u>Calibration</u>:
Calibration on the analyzer used the TECO MULTI Calibrator. The system must have a valid calibration in memory before controls or patient samples can be run, and the system will automatically perform checks on the calibration and produce data at the end of calibration.
6. <u>Quality Control</u>:
The sponsor recommends that each laboratory establish their frequency of control determination and that quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

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.