Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
www.fda.gov

510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

k191396

B Applicant

Horiba ABX SAS

C Proprietary and Established Names

Yumizen C1200 Calcium AS, Yumizen C1200 Creatinine Jaffe

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CJY	Class II	21 CFR 862.1145 - Calcium Test System	CH - Clinical Chemistry
CGX	Class II	21 CFR 862.1225 - Creatinine test system	CH - Clinical Chemistry

II Submission/Device Overview:

A Purpose for Submission:

New devices

B Measurand:

Calcium (Ca)
Creatinine (Crea)

C Type of Test:

Quantitative, colorimetric methods

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Yumizen C1200 Calcium AS reagent is a diagnostic reagent for quantitative in vitro determination of calcium in human serum, plasma and urine based on colorimetric method, using the clinical chemistry analyzer. Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Yumizen C1200 Creatinine Jaffé reagent is a diagnostic reagent for quantitative in vitro determination of creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Yumizen C1200 Calcium AS:
Do not use EDTA plasma: EDTA anticoagulant is unsuitable for analysis because this compounds chelates calcium, making it unavailable for reaction with the reagent.

D Special Instrument Requirements:

Yumizen C1200

IV Device/System Characteristics:

A Device Description:

The Yumizen C1200 Calcium AS assay consists of the following reagents:

50 mmol/L Phosphate buffer (pH = 7.50)
5 mmol/L 8- Hydroxyquinoline-5-sulfonic acid
120 µmol/L Arsenazo III

The Yumizen C1200 Creatinine Jaffé assay consists of the following reagents:

0.2 mol/L Sodium hydroxide
20 mmol/L Picric acid

B Principle of Operation:

Yumizen C1200 Calcium AS test is a photometric test using Arsenazo III die. Calcium in the sample binds to Arsenazo III at neutral pH yielding a blue colored complex, whose intensity is proportional to the calcium concentration. Interference by magnesium is eliminated by addition of 8-hydroxyquinoline-5-sulfonic acid.

Yumizen C1200 Creatinine Jaffé is a kinetic test without deproteinization according to the Jaffé method. Creatinine from the sample forms a colored orange-red complex in an alkaline picrate solution. The difference in absorbance at fixed times during conversion is proportional to the concentration of creatinine in the sample.

C Instrument Description Information:

Modes of Operation	**Yes**	**No**
Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?	☐	☒
Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?	☐	☒
Software		
FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types.	☐	☒

1. Instrument Name:

   Yumizen C1200

V Substantial Equivalence Information:

A Predicate Device Name(s):

ABX Pentra Calcium AS CP on ABX Pentra 400 / Pentra C400
ABX Pentra Creatinine 120 CP on ABX Pentra 400/ Pentra C400

B Predicate 510(k) Number(s):

k123171
k110530

C Comparison with Predicate(s):

Calcium:

Device & Predicate Device(s):	K191396	K123171
Device Trade Name	Yumizen C1200 Calcium AS	ABX Pentra Calcium AS CP on ABX Pentra 400 / Pentra C400
General Device Characteristic Similarities		
Intended Use/Indications For Use	For quantitative in vitro determination of calcium in human serum, plasma and urine based on colorimetric method, using the clinical chemistry analyzer. Measurement of calcium is used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	Same
Sample type	Serum, plasma, urine	Same
Method	Colorimetry	Same
Measuring Range	Serum, plasma: 4.0-18.5 mg/dL Urine: 0.64-18.05 mg/dL	Same
Automatic post-dilution	Serum, plasma and urine: up to 54.15 mg/dL	Same
General Device Characteristic Differences		
Instrument	Yumizen C1200 Clinical chemistry analyzer	ABX Pentra 400 / Pentra C400
Sample volume	1.0 µL/test	5.0 µL/test
Packaging and number of tests	Serum, plasma: 6 x 290 tests Urine: 6 x 290 tests	Serum, plasma: 285 tests Urine: 285 tests
On board stability	6 weeks	70 days
Calibration stability	24 hours	3 days

Creatinine:

Device & Predicate Device(s):	K191396	K110530
Device Trade Name	Yumizen C1200 Creatinine Jaffé	ABX Pentra Creatinine 120 CP on ABX Pentra 400/ Pentra C400
General Device Characteristic Similarities		
Intended Use/Indications For Use	For quantitative in vitro determination of creatinine in human serum, plasma and urine based on a kinetic method using alkaline picrate (Jaffé method). Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.	Same
Sample type	Serum, plasma, urine	Same
Method	Colorimetry	Same
Automatic post-dilution	Serum, plasma: up to 54.24 mg/dL Urine: up to 847.5 mg/dL	Same
General Device Characteristic Differences		
Instrument	Yumizen C1200 Clinical chemistry analyzer	ABX Pentra 400 / Pentra C400
Sample volume	5.0 µL/test	10.0 µL/test
Measuring Range	Serum, plasma: 0.23-18.08 mg/dL Urine: 3.0-282.5 mg/dL	Serum, plasma: Same Urine: 2.9-282.5 mg/dL
Packaging and number of tests	6 x 315 tests	120 tests
On board stability	7 days	19 days
Calibration stability	24 hours	3 days

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline –Third Edition.

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition.

CLSI C28-A3: Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition.

CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic reagents; Approved Guideline.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were performed in accordance with CLSI EP05-A3 guideline.

Yumizen C1200 Calcium AS:
A study to evaluate repeatability and within-laboratory precision was performed using 2 levels of control materials and 3 levels of serum specimen (or 5 levels of urine specimens). The data was collected using 3 instrument systems and 1 reagent lot, and the samples were tested in duplicate for 20 days, 2 runs per day. The results are given below:

Serum:

Sample	N	Mean (mg/dL)	Within-run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Control N	240	8.91	0.6	0.8	1.0	0.0	1.5
Control P	240	12.21	0.5	0.7	1.1	1.4	1.4
Sample 1	240	6.41	0.8	0.8	1.1	0.4	1.7
Sample 2	240	9.70	0.6	1.2	0.6	0.4	1.6
Sample 3	240	14.68	0.5	1.1	1.0	0.8	1.8

Urine:

Sample	N	Mean (mg/dL)	Within-run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Control 1	240	7.62	0.7	1.4	3.4	0.5	3.8
Control 2	240	11.23	0.5	1.4	3.6	0.0	3.9
Sample 1	240	2.92	1.6	1.0	1.8	0.0	2.6
Sample 2	240	6.12	0.8	1.3	1.4	0.0	2.1
Sample 3	240	8.28	0.7	1.5	1.0	0.0	2.0
Sample 4	240	14.40	0.6	1.0	1.1	0.4	1.7
Sample 5	240	17.07	0.6	0.9	1.2	0.3	1.6

A study to evaluate lot-to-lot imprecision was performed using 2 levels of control materials and 4 levels of serum specimen (or 5 levels of urine specimens). The data was collected using 1 instrument systems and 3 reagent lots, and the samples were tested in triplicate for 5 days, two runs per day. The results are given below:

Serum:

Sample	N	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Control N	90	8.25	1.0	0.8	1.3	0.9	1.5
Control P	90	11.32	1.0	0.8	1.3	0.8	1.5
Sample 1	90	7.19	1.2	0.6	1.4	0.5	1.5
Sample 2	90	9.74	1.2	0.9	1.5	0.7	1.6
Sample 3	90	14.06	0.8	0.0	0.8	0.9	1.2
Sample 4	90	15.86	0.9	0.2	0.9	1.2	1.5

Urine:

Sample	N	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Control 1	90	7.19	1.1	1.0	1.5	1.7	2.2
Control 2	90	10.22	0.7	0.7	1.0	1.2	1.5
Sample 1	90	2.53	2.5	1.4	2.9	4.6	5.5
Sample 2	90	5.80	1.2	1.1	1.6	3.0	3.4
Sample 3	90	10.53	1.0	0.8	1.3	2.4	2.7
Sample 4	90	13.05	1.0	0.5	1.1	2.1	2.4
Sample 5	90	16.11	3.2	2.1	3.8	0.0	3.8

Yumizen C1200 Creatinine Jaffé:
A study to evaluate repeatability and within-laboratory precision was performed using 2 levels of control materials and 5 levels of patient samples (for both serum and urine matrices). The data was collected using 3 instrument systems and 1 reagent lot, and the samples were tested in duplicate for 20 days, 2 runs per day. The results are given below:

Serum:

Sample	N	Mean (mg/dL)	Within-run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Control N	240	1.81	0.6	1.6	1.3	0.0	2.1
Control P	240	5.23	0.5	1.6	1.1	0.1	2.1
Sample 1	240	0.55	1.9	1.8	1.8	0.0	3.1
Sample 2	240	1.56	1.5	1.5	1.9	0.0	2.9
Sample 3	240	6.56	0.5	1.8	0.9	0.0	2.0
Sample 4	240	11.38	0.4	1.5	1.0	0.0	1.9
Sample 5	240	16.56	0.4	2.4	0.5	0.0	2.5

Urine:

Sample	N	Mean (mg/dL)	Within-run (%CV)	Between-Run (%CV)	Between-Day (%CV)	Between-Instrument (%CV)	Total (%CV)
Control 1	240	60.38	0.8	1.7	1.0	0.0	2.1
Control 2	240	150.24	0.5	1.6	1.3	0.0	2.1
Sample 1	240	5.56	3.4	3.5	3.6	1.3	6.2
Sample 2	240	11.52	2.1	2.1	1.9	0.0	3.5
Sample 3	240	92.91	0.8	1.8	0.0	0.3	2.0
Sample 4	240	143.42	0.8	2.9	0.0	0.0	3.0

A study to evaluate lot-to-lot imprecision was performed using 2 levels of control materials and 5 levels of patient samples (for both serum and urine matrices). The data was collected using 1 instrument systems and 3 reagent lots, and the samples were tested in triplicate for 5 days, two runs per day. The results are given below:

Serum:

Sample	N	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Control N	90	1.56	0.9	2.3	2.5	0.0	2.5
Control P	90	5.00	0.9	2.0	2.2	0.0	2.2
Sample 1	90	0.46	1.7	2.5	3.1	0.0	3.1
Sample 2	90	1.65	1.1	4.2	4.4	0.0	4.4
Sample 3	90	6.78	0.8	2.6	2.7	0.0	2.7
Sample 4	90	11.42	0.7	2.1	2.3	0.0	2.3
Sample 5	90	16.67	0.6	1.7	1.8	0.0	1.8

Urine:

Sample	N	Mean (mg/dL)	Within-Day (%CV)	Between-Day (%CV)	Within-Lot (%CV)	Between-Lot (%CV)	Total (%CV)
Control 1	90	68.47	0.9	1.5	1.8	0.0	1.8
Control 2	90	140.31	0.9	1.7	1.9	0.0	1.9
Sample 1	90	5.67	3.4	5.0	6.1	0.0	6.1
Sample 2	90	11.63	2.1	3.1	3.7	0.0	3.7
Sample 3	90	89.03	1.6	2.1	2.6	0.0	2.6
Sample 4	90	132.13	0.8	2.5	2.6	0.0	2.6
Sample 5	90	218.30	0.7	1.7	1.8	0.0	1.8

2. Linearity:

Linearity studies were performed in accordance with CLSI EP06-A guideline.

For each analyte and sample type a series of 10 samples was prepared by combining various volumetric proportions of a low-level analyte sample to a high analyte concentration to produce samples with concentrations spanning the corresponding claimed measuring interval. Each level was measured in 4 replicates using 1 instrument and 1 lot of reagent. Experimentally determined values were compared to expected values using linear regression analysis. The results of the linearity studies supported the claimed measuring ranges, as summarized below:

Analyte	Sample type	Linear regression	Measuring Range	Concentrations tested
Calcium (mg/dL)	Serum	$y = 1.020\ x - 0.065$, $R^2 = 0.9996$	4.0 – 18.05	0.00 – 19.41
	Urine	$y = 1.002\ x + 0.003$, $R^2 = 0.9995$	0.64 – 18.05	0.00 – 20.65
Creatinine (mg/dL)	Serum	$y = 1.021\ x + 0.003$, $R^2 = 0.9995$	0.23 – 18.08	0.00 – 25.16
	Urine	$y = 0.968\ x + 0.112$, $R^2 = 0.9995$	3.0 – 282.5	0.00 -333.70

The sponsor also performed a study to evaluate the auto-dilute feature available for serum and urine calcium and creatinine measurements. The study protocol and acceptance criteria were reviewed and found to be acceptable. The results of the study supported the sponsor's claim that samples with calcium concentrations above 18.05 mg/dL can be diluted onboard the analyzer to obtain results up to 54.15 mg/dL for serum and urine. The results of the study also support the sponsor's claim that samples with creatinine concentrations above 18.08 mg/dL (serum) or 282.5 mg/dL (urine) can be diluted onboard the analyzer to obtain results up to 54.24 mg/dL for serum samples and up to 847.5 mg/dL for urine samples.

3. Analytical Specificity/Interference:

Interference studies were performed in accordance to the CLSI EP07-A2 guideline.

Yumizen C1200 Calcium AS:
Various concentrations of interferents were spiked into pooled human serum or pooled human urine containing calcium at normal and high concentrations. All samples were tested in quadruplicate. Non-significant interference was defined by the sponsor as the highest interferent level tested with bias ≤10% of the control for both serum and urine samples. The results of the interference study are summarized below:

Test Interferent	Highest concentration tested that showed no interference	
	Serum	Urine
Hemoglobin	500 mg/dL	500 mg/dL
Triglycerides	495 mg/dL	454 mg/dL
Total Bilirubin	32.9 mg/dL	N/A
Direct Bilirubin	24.0 mg/dL	19.2 mg/dL
Acetylsalicylic Acid	65.16 mg/dL	N/A
Ascorbic Acid	5.98 mg/dL	5.98 mg/dL
Ibuprofen	50.1 mg/dL	50.1 mg/dL
Acetaminophen	20.0 mg/dL	N/A
Glucose	N/A	1463.4 mg/dL

Yumizen C1200 Creatinine Jaffé:
Various concentrations of interferents were spiked into pooled human serum or pooled human urine containing creatinine at normal and high concentrations. All samples were tested in quadruplicate. Non-significant interference was defined by the sponsor as the highest interferent level tested with bias ≤10% of the control for both serum and urine samples. The results of the interference study are summarized below:

Test Interferent	Highest Concentration tested that showed no interference	
	Serum	Urine
Hemoglobin	500 mg/dL	500 mg/dL
Triglycerides	507.50 mg/dL	393.75 mg/dL
Total Bilirubin	23.24 mg/dL	N/A
Direct Bilirubin	37.15 mg/dL	31.39 mg/dL
Acetylsalicylic Acid	48.87 mg/dL	N/A
Ascorbic Acid	4.49 mg/dL	5.98 mg/dL
Ibuprofen	50.1 mg/dL	N/A
Acetaminophen	20.0 mg/dL	N/A
Glucose	682 mg/dL	N/A
Total Protein	36 to 101 g/L	N/A

4. Assay Reportable Range:

Analyte	Sample type	Reportable Range
Calcium	Serum	4.0 – 18.05 mg/dL
	Urine	0.64 – 18.05 mg/dL
Creatinine	Serum	0.23 – 18.08 mg/dL
	Urine	3.0 – 282.5 mg/dL

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The calibrators are traceable to NIST reference materials for calcium and creatinine. The information on the traceability of the assays is provided below:

Test	Traceability
Calcium	NIST SRM909c
Creatinine	NIST SRM967a

6. Detection Limit:

The limit of blank (LoB), limit of detection (LoD) and limit of quantitation (LoQ) studies were performed according to the CLSI EP17-A2 guideline.

Yumizen C1200 Calcium AS:
Limit of blank (LoB) study was performed by testing 4 individual blank serum samples, using two reagent lots over 5 days on a single instrument (or 5 individual blank urine samples using two reagent lots over 4 days on a single instrument). Each day, for each reagent lot, 4 replicate measurements were recorded (80 results per reagent lot). Data was analyzed using non-parametric analysis.

Limit of detection (LoD) study was performed by testing 4 low level serum samples and 4 low level urine samples using two reagent lots over 4 days on a single instrument. Each day, for each reagent lot, 4 replicate measurements were recorded (64 results per reagent lot). Data was analyzed using non-parametric analysis.

Limit of quantitation (LoQ) study was performed by testing 5 low level serum samples (or 5 low level urine samples) using 2 reagent lots over 4 days on a single instrument. Each day, for each reagent lot, 4 replicate measurements were recorded (80 results per reagent lot). The LoQ for calcium met an imprecision ≤ 20% CV.

Yumizen C1200 Creatinine Jaffé:
Limit of blank (LoB) study was performed by testing 1 blank sample, using two reagent lots over 4 days on 3 instrument systems. Each day, for each reagent lot and each instrument, 5 replicate measurements were recorded (60 results per reagent lot). Data was analyzed using non-parametric analysis.

Limit of detection (LoD) study was performed by testing 4 low level serum samples and 4 low level urine samples using two reagent lots over 4 days on a single instrument. Each day, for each reagent lot, 4 replicate measurements were recorded (64 per reagent lot). Data was analyzed using non-parametric analysis.

Limit of quantitation (LoQ) study was performed by testing 5 low level serum samples and 5 low level urine samples using 2 reagent lots over 4 days on a single instrument. Each day, for each reagent lot, 4 replicate measurements were recorded (80 results per reagent lot). The LoQ for creatinine met an imprecision ≤ 20% CV.

Below is a summary of the results:

Analyte	LoB		LoD		LoQ	
	Serum	Urine	Serum	Urine	Serum	Urine
Calcium (mg/dL)	0.16	0.12	0.48	0.24	0.57	0.64
Creatinine (mg/dL)	0.00	0.35	0.04	0.93	0.23	2.66

The upper and lower limits of the measuring range for the calcium and creatinine assays are supported by the LoQ studies and the linearity studies.

7. Assay Cut-Off:

Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Devices:

Performance of the Yumizen C1200 Calcium AS reagent for serum and urine was compared with the predicate device, ABX Pentra Calcium AS CP reagent (k123171). A total of 166 native serum samples and a total of 105 native urine samples were assayed in duplicate over 5 days. Only the first replicate was used for data analysis, which was conducted using Passing-Bablok regression.

Performance of the Yumizen C1200 Creatinine Jaffé reagent for serum and urine was compared with the predicate device, ABX Pentra Creatinine 120 CP reagent (k110530). A total of 131 native serum samples and a total of 148 native urine samples with creatinine concentrations were assayed in duplicate over 5 days. Only the first replicate was used for data analysis, which was conducted using Passing-Bablok regression.

The correlations between the predicate device and the candidate are summarized below.

Analyte	Specimen Type	N	Slope	Intercept	R^2	Test Range
Calcium (mg/dL)	Serum	166	1.0000	0.2406	0.976	6.26 - 17.92
	Urine	105	0.9436	0.5537	0.995	1.08 - 17.24
Creatinine (mg/dL)	Serum	131	0.9633	0.1035	0.995	0.32 – 13.94
	Urine	148	0.9483	-0.4678	0.997	4.93 – 258.30

The sponsor also performed a second method comparison study to evaluate the performance of the candidate device when using lithium heparin plasma samples. For calcium, 108 plasma samples were evaluated on Yumizen C1200 analyzer using Yumizen C1200 Calcium AS reagent and on the Horiba Pentra C400 analyzer using Horiba Pentra reagent (Predicate device). For creatinine, 69 plasma samples were evaluated on Yumizen C1200 analyzer using Yumizen C1200 Creatinine Jaffé reagent and on the Horiba Pentra C400 analyzer using Horiba Pentra reagent. Each sample was measured by the candidate device in duplicate. Only the first replicate was used for data analysis.

Analyte	Specimen Type	N	Slope	Intercept	R^2	Test Range
Calcium	Plasma	108	0.9423	0.4646	0.997	4.33 – 16.8 mg/dL
Creatinine	Plasma	69	1.087	-0.0825	0.999	0.58 – 18.29 mg/dL

2. Matrix Comparison:

The performance of the device with serum and lithium heparin plasma samples was evaluated in the method comparison section above. The study results support the sponsor's claims that serum and heparin-lithium plasma specimens are acceptable sample types to be used with the Yumizen C1200 Calcium AS and Yumizen 1200 Creatinine Jaffe assays.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

A reference range study for the Calcium AS and Creatinine Jaffé assays was conducted according to CLSI EP28-A3 to verify serum values cited from the literature. Serum samples were collected from healthy adults (n=40 for Calcium AS and 35 (men) + 25 (women) for Creatinine Jaffé). Each sample was assayed in duplicate. Results of the verification study support the serum reference ranges which were established through literature. Reference ranges for urine samples are cited from the literature.

Calcium:

Serum/Plasma[1]:
Adults: 8.6 – 10.2 mg/dL.
Urine[2]:
Women < 250 mg/24 h
Men < 300 mg/24 h

Creatinine Jaffé:

Serum/Plasma[3]:
Women: 5-9 mg/dL
Men: 7-12 mg/dL
Urine[1]:
Women: 10-20 mg/kg/day
Men: 14-26 mg/kg/day

References:

1. Roberts WL, McMillin GA, Burtis CA, Bruns DE. Reference Information for the Clinical Laboratory, TIETZ Textbook of Clinical Chemistry and Molecular Diagnostics. 4th Ed; Burtis CA, Ashwood ER, Bruns DE, (Elsevier Saunders eds. St Louis, USA), (2006): 2258.
2. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 231–241.
3. Mazzachi BC, Peake MJ, Ehrhard V. Reference range and method comparison studies for enzymatic and Jaffe creatinine assays in plasma and serum and early morning urine. Clin. Lab. (2000) 46: 53-55.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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