SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELICAL 2

MAY - 6 2011

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: **K100263**

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Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation Friday, January 22nd 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems ELICAL 2**
Common or Usual Name:	Calibrator, multi-analyte mixture, **"ELICAL 2"**
Device Class	Class II
Classification name	Calibrator (21 CFR 862.1150)
Product code	JIX- Calibrator, multi-analyte mixture

Predicate device Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

Device description ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s.)
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.	For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open one bottle, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : - 8 hours between 15-25 °C. - 2 days between 2-8 °C. - 4 weeks between -25 and -15 °C (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 8 hours at 15-25 °C. - 2 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once) *Exception for bilirubin total & direct as noted in package insert

Conclusion The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary

ELITech Clinical Systems UREA UV SL reagent

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: **K100263**

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Date of Preparation Friday, January 22nd 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems UREA UV SL**
Common or Usual Name:	Urea nitrogen, **"UREA UV SL"**
Device Class	Class II
Classification name	Urea nitrogen test system (Sec.862.1770)
Product code	CDQ – Urease And Glutamic Dehydrogenase, Urea Nitrogen

Predicate device ABX PENTRA UREA CP (K060205, K070146)

Device description

The device for this submission is available as kit only. It consists of 2 reagents:
Reagent 1 contains Tris buffer (pH 7.60), Adenosine diphosphate potassium salt (ADP), α-Ketoglutarate, Urease (jack bean), Glutamate dehydrogenase (GlDH) (bovine liver) and sodium azide.
Reagent 2 contains NADH and sodium azide

Intended Use

ELITech Clinical Systems UREA UV SL is intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative *in vitro* diagnostic determination of urea nitrogen in human serum and plasma.
It is not intended for use in Point of Care settings.

Indication(s) for Use

ELITech Clinical Systems UREA UV SL is intended to measure urea nitrogen in human serum and plasma. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.

Comparison to Predicate device

	ELITech Clinical Systems Device UREA UV SL	Predicate device (ABX PENTRA UREA CP)
Intended Use	Intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative *in vitro* diagnostic determination of urea nitrogen in human serum and plasma. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of urea/urea nitrogen in serum, plasma and urine.
Indication(s) for Use	Intended to measure urea nitrogen in human serum and plasma. Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.	Urea nitrogen measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
Assay protocol	Enzymatic UV method using Urease and Glutamate dehydrogenase	Enzymatic UV method using Urease and Glutamate dehydrogenase
Composition	Reagent R1: Tris buffer, pH 7.60 125 mmol/L ; ADP 1 mmol/L ; α-Ketoglutarate 9 mmol/L ; Urease ≥ 8 100 U/L ; GlDH ≥ 1 350 U/L ; Sodium azide < 0.1%; Reagent R2: NADH 1.5 mmol/L; Sodium azide < 0.1%;	Reagent 1: Tris buffer, pH 7.8 150 mmol/L ; 2-Oxoglutarate 8.75 mmol/L ; ADP 0.75 mmol/L ; Urease ≥ 7 500 U/L ; GlDH ≥ 1 250 U/L ; Sodium azide < 1 g/L; Reagent 2: NADH 1.32 mmol/L ; Sodium azide < 1 g/L;
Appearance of reagent	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin Urine
Reagent storage	Store at 2-8 °C and protected from light. The reagents are stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8 °C and contamination avoided.
Expected values	Serum, plasma: *Urea nitrogen (BUN)* Adults (21-60 years) 6-20 mg/dL Adults (60-90 years) 8-23 mg/dL Adults (> 90 years) 10-31 mg/dL	Serum, plasma: *Urea nitrogen (BUN)* **Adults:** Global : 7.9-20.2 mg/dL Women < 50 years 7.3-18.8 mg/dL Women > 50 years 9.8-20.2 mg/dL Men < 50 years 9.0-20.5 mg/dL Men > 50 years 8.4-25.8 mg/dL **Children:** 1-3 years 5.1-16.8 mg/dL 4-13 years 7.0-16.8 mg/dL

	ELITech Clinical Systems Device UREA UV SL	Predicate device (ABX PENTRA UREA CP)
		14-19 years 8.1-21.1 mg/dL
Instrument	SELECTRA JUNIOR	ABX PENTRA 400
Measuring range*	4.7 to 140.0 mg/dL Extended measuring range : 140.0 to 670.0 mg/dL	1.03 to 140.3 mg/dL Automatic post-dilution: 701.5 mg/dL
Limit of detection (LoD)*	0.3 mg/dL	0.9 mg/dL
Limit of quantification (LoQ)*	2.3 mg/dL	
Precision*	**Within run** Level 7.3 mg/dL CV=2.1% Level 29.2 mg/dL CV=0.8% Level 72.4 mg/dL CV=0.7% **Total** Level 7.3 mg/dL CV=2.8% Level 29.2 mg/dL CV=1.3% Level 72.4 mg/dL CV=1.6%	**Within run** Level 18.7 mg/dL CV=2.27% Level 72.8 mg/dL CV=1.66% Level 6.0 mg/dL CV=2.76% Level 20.9 mg/dL CV=1.58% Level 85.5 mg/dL CV=1.80% **Total** Level 18.5 mg/dL CV=2.14% Level 71.7 mg/dL CV=1.93% Level 19.2 mg/dL CV=2.14% Level 70.1 mg/dL CV=1.97%
Method comparison*	y=0.991 x + 0.6 mg/dL r= 0.999 range: 4.4 to 139.8 mg/dL	y=0.99 x - 0.06 mg/dL r^2= 0.996 range: 1.03 to 138.89 mg/dL
Limitations	**Hemoglobin:** No significant interference up to 500 mg/dL. **Turbidity:** No significant interference up to 614 mg/dL triglyceride equivalent. **Unconjugated bilirubin:** No significant interference up to 30 mg/dL. **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL. **Ascorbic acid:** No significant interference up to 20 mg/dL. **Methyldopa:** No significant interference up to 1 mg/dL.	**Hemoglobin:** No significant influence is observed up to 460 mg/dL. **Triglycerides:** No significant influence is observed up to 612.5 mg/dL. **Total bilirubin:** No significant influence is observed up to 22.23 mg/dL. **Direct bilirubin:** No significant influence is observed up to 23.40 mg/dL.
Calibration Frequency	7 days	8 days
On board stability	refrigerated area : 14 days	refrigerated area: 70 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Elical 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems Elitrol I	Recommended quality control material (not included): ABX Pentra N Control

	ELITech Clinical Systems Device UREA UV SL	Predicate device (ABX PENTRA UREA CP)
	(Normal control) ELITech Clinical Systems Elitrol II (Pathologic control)	(Normal control) ABX Pentra P Control (Pathologic control)

* : values expressed in BUN

Conclusion The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary

ELITech Clinical Systems PHOSPHORUS reagent

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: **K100263**

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Date of Preparation Friday, January 22nd 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems PHOSPHORUS**
Common or Usual Name:	Inorganic phosphorus, **"PHOSPHORUS"**
Device Class	Class I
Classification name	Phosphorus (inorganic) test system (Sec.862.1580)
Product code	CEO – Phosphomolybdate (colorimetric), inorganic phosphorus

Predicate device ABX PENTRA PHOSPHORUS CP (K060205, K070249)

Device description The device for this submission is available as kit only. It consists of 1 reagent R. Reagent R consists of sulfuric acid and ammonium molybdate.

Intended Use ELITech Clinical Systems PHOSPHORUS is intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative *in vitro* diagnostic determination of inorganic phosphorus in human serum and plasma. It is not intended for use in Point of Care settings.

Indication(s) for Use ELITech Clinical Systems PHOSPHORUS is intended to measure inorganic phosphorus in human serum and plasma. (Inorganic) phosphorus measurements are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Comparison to Predicate device

	ELITech Clinical Systems Device PHOSPHORUS	Predicate device (ABX PENTRA PHOSPHORUS CP)
Intended use	Intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative *in vitro* diagnostic determination of inorganic phosphorus in human serum and plasma. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of phosphorus in serum, plasma and urine.
Indication for Use	Intended to measure inorganic phosphorus in human serum and plasma. (Inorganic) phosphorus measurements are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.	Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.
Assay protocol	UV method using phosphomolybdate	UV method using phosphomolybdate
Composition	Reagent R: Sulfuric acid 210 mmol/L ; Ammonium molybdate 650 µmol/L ;	Reagent: Sulfuric acid 210 mmol/L ; Ammonium molybdate 650 µmol/L ;
Appearance of reagent	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin Urine
Reagent storage	Store at 2-25 °C and protected from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8 °C.
Expected values	Serum, plasma : 2.7 – 4.5 mg/dL	Serum, plasma : 2.7 – 4.5 mg/dL
Instrument	SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	2.0 to 20.0 mg/dL	0.30 to 24.18 mg/dL Automatic post-dilution: 96.72 mg/dL
Limit of detection (LoD)	0.02 mg/dL	0.28 mg/dL
Limit of quantification (LoQ)	1.00 mg/dL	
Precision	**Within run** Level 2.37 mg/dL CV=1.1% Level 4.80 mg/dL CV=1.5% Level 9.55 mg/dL CV=1.7%	**Within run** Level 4.08 mg/dL CV=1.25% Level 6.34 mg/dL CV=0.77% Level 2.39 mg/dL CV=2.48% Level 3.48 mg/dL CV=1.61% Level 9.19 mg/dL CV=1.38%

	ELITech Clinical Systems Device PHOSPHORUS	Predicate device (ABX PENTRA PHOSPHORUS CP)
	Total Level 2.37 mg/dL CV=1.9% Level 4.80 mg/dL CV=1.7% Level 9.55 mg/dL CV=2.2%	**Total** Level 4.01 mg/dL CV=2.50% Level 6.35 mg/dL CV=1.82% Level 2.50 mg/dL CV=3.56% Level 11.44 mg/dL CV=1.38%
Method comparison	y=0.999 - 0.09 mg/dL r= 0.999 range: 2.02 to 20.08 mg/dL	y=1.04x + 0.15 mg/dL r^2= 0.998 range: 0.30 to 24.08 mg/dL
Limitations	**Hemoglobin:** No significant interference is observed up to 50 mg/dL **Unconjugated bilirubin:** No significant interference is observed up to 15 mg/dL **Conjugated bilirubin:** No significant interference is observed up to 1.5 mg/dL. **Glucose:** No significant interference is observed up to 500 mg/dL. **Triglycerides:** No significant interference is observed up to 732 mg/dL.	**Hemoglobin:** No significant influence is observed up to 125 mg/dL. **Triglycerides:** No significant influence is observed up to 262.5 mg/dL. **Total bilirubin:** No significant influence is observed up to 6 mg/dL. **Direct bilirubin:** No significant influence is observed up to 25 mg/dL.
Calibration Frequency	28 days	34 days
On board stability	refrigerated area : 28 days	refrigerated area: 70 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Elical 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems Elitrol I (Normal control) ELITech Clinical Systems Elitrol II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

Conclusion The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary

ELITech Clinical Systems URIC ACID MONO SL reagent

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

The assigned 510(k) number is: **K100263**

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Date of Preparation Friday, January 22nd 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems URIC ACID MONO SL**
Common or Usual Name:	Uric acid, **"URIC ACID MONO SL"**
Device Class	Class I
Classification name	Uric acid test system (Sec.862.1775)
Product code	KNK – Acid, Uric, Uricase (colorimetric)

Predicate device ABX PENTRA Uric acid CP (K060205, K081276)

Device description The device for this submission is available as kit only. It consists of 1 reagent R. Reagent R consists of Phosphate buffer (pH 7.0), N-Ethyl-N-(2-Hydroxy-3-Sulfopropyl) *m*-Toluidine (EHSPT), Ferrocyanide, Amino-4-antipyrine (4-AAP), Uricase (microorganisms), Peroxidase (horseradich) and sodium azide.

Intended Use ELITech Clinical Systems URIC ACID MONO SL is intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative *in vitro* diagnostic determination of uric acid in human serum and plasma.
It is not intended for use in Point of Care settings.

Indication(s) for Use ELITech Clinical Systems URIC ACID MONO SL is intended to measure uric acid in human serum and plasma. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Comparison to Predicate device

	ELITech Clinical Systems Device URIC ACID MONO SL	Predicate device (ABX PENTRA URIC ACID CP)
Intended use	Intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative in vitro diagnostic determination of uric acid in human serum and plasma. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of uric acid in serum, plasma and urine.
Indication(s) for Use	Intended to measure uric acid in human serum and plasma. Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.	Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.
Assay protocol	Enzymatic determination using a chromgenic system in the presence of peroxidase and uricase (Trinder method).	Enzymatic determination using a chromgenic system in the presence of peroxidase and uricase (Trinder method).
Composition	Reagent R: Phosphate buffer; pH 7.0 100 mmol/L ; EHSPT 0.72 mmol/L ; Ferrocyanide 0.03 mmol/L ; Amino-4-antipyrine 0.37 mmol/L ; Uricase ≥ 150 U/L ; Peroxidase ≥ 12 000 U/L ; Sodium azide < 0.1%;	Reagent 1: Phosphate buffer, pH 7.0 125 mmol/L ; EHSPT 1.38 mmol/L ; Ascorbate oxidase ≥ 1 100 U/L ; Bovine albumin 0.2 %; Sodium azide < 0.1%; Reagent 2: 4-Aminoantipyrine 1.8 mmol/L ; Uricase ≥ 700 U/L ; Peroxidase ≥ 7 500 U/L Ferrocyanide 250 µmol/L ; Bovine albumin 0.2 %; Sodium azide < 0.1%;
Appearance of reagent	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin Urine
Reagent storage	Store at 2-8 °C and protected from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8 °C.
Expected values	Serum, plasma Women: 2.6 – 6.0 mg/dL Men: 3.5 – 7.2 mg/dL	Serum, plasma Women: 2.6 – 6.0 mg/dL Men: 3.5 – 7.2 mg/dL

	ELITech Clinical Systems Device URIC ACID MONO SL	Predicate device (ABX PENTRA URIC ACID CP)
Instrument	SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	1.5 to 25.0 mg/dL Extended measuring range : 25 to 78 mg/dL	0.18 to 25.00 mg/dL Automatic post-dilution: 75.00 mg/dL
Limit of detection (LoD)	0.02 mg/dL	0.19 mg/dL
Limit of quantification (LoQ)	0.50 mg/dL	
Precision	**Within run** Level 2.49 mg/dL CV=0.8% Level 5.19 mg/dL CV=1.3% Level 7.63 mg/dL CV=1.1% **Total** Level 2.49 mg/dL CV=2.6% Level 5.19 mg/dL CV=2.0% Level 7.63 mg/dL CV=2.1%	**Within run** Level 4.62 mg/dL CV=0.45% Level 11.63 mg/dL CV=0.34% Level 2.53 mg/dL CV=1.24% Level 4.58 mg/dL CV=0.91% Level 7.19 mg/dL CV=1.02% **Total** Level 4.64 mg/dL CV=2.81% Level 11.73 mg/dL CV=1.39% Level 4.67 mg/dL CV=2.64% Level 6.74 mg/dL CV=2.51%
Method comparison	y=1.015 x + 0.03 mg/dL r= 0.999 range: 1.49 to 24.40 mg/dL	y=0.95 x + 0.09 mg/dL r^2= 0.996 range: 0.18 to 23.59 mg/dL
Limitations	**Hemoglobin:** No significant interference up to 50 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30 mg/dL **Conjugated bilirubin:** No significant interference up to 14.8 mg/dL. **Glucose:** No significant interference up to 500 mg/dL. **Ascorbic acid:** Significant interference on samples containing ascorbic acid. **Triglycerides:**. No significant interference up to 1070 mg/dL. **Methyldopa:** No significant interference up to 1 mg/dL. **Calcium dobesilate:** Induces falsely low results on individuals taking calcium dobesilate.	**Hemoglobin:** No significant influence is observed up to 500 mg/dL. **Triglycerides:** No significant influence is observed up to 612.5 mg/dL. **Total bilirubin:** No significant influence is observed up to 36 mg/dL. **Direct bilirubin:** No significant influence is observed up to 30 mg/dL.
Calibration Frequency	28 days	15 days

	ELITech Clinical Systems Device URIC ACID MONO SL	Predicate device (ABX PENTRA URIC ACID CP)
On board stability	refrigerated area : 28 days	refrigerated area: 41 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Elical 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems Elitrol I (Normal control) ELITech Clinical Systems Elitrol II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

Conclusion The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELITROL I and ELITROL II

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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Date of Preparation Friday, January 22nd 2010

Device names

CONTROLS:

Trade/proprietary Name:	**ELITech Clinical Systems ELITROL I and ELITROL II**
Common or Usual Name:	Multi-analyte controls – all kinds, **"ELITROL I"- "ELITROL II"**
Device Class	Class I
Classification name	Quality control material (assayed and unassayed). (21 CFR 862.1660)
Product code	JJX- Multi-analyte controls – all kinds

Predicate device

Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

Device description

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.
Elitrol I and Elitrol II are prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use

ELITech Clinical Systems ELITROL I is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

Comparison to Predicate device

	ELITech Clinical Systems Device ELITROL I / ELITROL II	Predicate Device Roche Precinorm U / Precipath U
Intended use	ELITech Clinical Systems ELITROL I is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer. ELITech Clinical Systems ELITROL II is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.	For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.
Format	Lyophilized human sera with constituents added as required to obtain desired components levels	Lyophilized human sera with constituents added as required to obtain desired components levels
Levels	Two levels	Two levels
Handling	Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open the bottle, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : - 12 hours between 15-25 °C. - 5 days between 2-8 °C. - 4 weeks between -25 and -15 °C (when frozen once)	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 12 hours at 15-25 °C. - 5 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once) *Exception for bilirubin total & direct as noted in package insert

Conclusion The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

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Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Re: k100263
Trade/Device Name: ELITech Clinical Systems Urea UV SL
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDQ, KNK, CEO, JIX, JJY
Dated: 30 March 2011
Received: 04 April 2011

MAY - 6 2011

Dear: Ms. Hutson,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _K100263_____

Device Name: ____ELITech Clinical Systems PHOSPHORUS_____

Indications for Use:

ELITech Clinical Systems PHOSPHORUS reagent is for the quantitative *in vitro* diagnostic determination of inorganic phosphorus in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers.

It is not intended for use in Point of Care settings.

Measurements of phosphorus (inorganic) are used in the diagnosis and treatment of various disorders, including parathyroid gland and kidney diseases, and vitamin D imbalance.

Prescription Use __X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100263

Indications for Use Form

510(k) Number (if known): _K100263_____

Device Name: _____ ELITech Clinical Systems URIC ACID MONO SL _____

Indications for Use:

ELITech Clinical Systems URIC ACID MONO SL reagent is for the quantitative *in vitro* diagnostic determination of uric acid in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers.

It is not intended for use in Point of Care settings.

Measurements obtained by this device are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100263

Indications for Use Form

510(k) Number (if known): __K100263_____

Device Name: _____ ELITech Clinical Systems UREA UV SL _____

Indications for Use:

ELITech Clinical Systems UREA UV SL reagent is for the quantitative *in vitro* diagnostic determination of urea nitrogen in human serum and plasma on the Vital Scientific Selectra/Flexor analyzers.

It is not intended for use in Point of Care settings.

Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Evaluation and Safety

510(k) K100263

Indications for Use Form

510(k) Number (if known): __K100263_____

Device Name: _____ ELITech Clinical Systems ELICAL 2_____

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100263

Indications for Use Form

510(k) Number (if known): __K100263_____

Device Name: _____ ELITech Clinical Systems ELITROL 1 and ELITROL 2___

Indications for Use:

ELITech Clinical Systems ELITROL I is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior Analyzer and the Vital Scientific Flexor Junior Analyzer.

ELITech Clinical Systems ELITROL II is a multi-parametric control serum for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on the Vital Scientific Selectra Junior analyzer and the Vital Scientific Flexor Junior analyzers.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Evaluation and Safety

510(k) K100263