SECTION 5 - 510(k) Summary

MAR 2 4 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: k102647

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Date of Preparation Thursday, September 9th 2010

Device name

Trade/proprietary Name: **ELITech Clinical Systems Selectra ProM**
Common or Usual Name: Clinical analyzer, "**ProM**"
Regulatory:

Code	Name	Class	Regulation	Regulation Name	Panel
JJE	analyzer, chemistry (photometric, discrete), for clinical use	I	21 CFR 862.2160	Discrete photometric chemistry analyzer for clinical use	75 Clinical Chemistry
JGS	Electrode, Ion-Specific, Sodium	II	21 CFR 862.1665	Sodium test system	75 Clinical Chemistry
CEM	Electrode, Ion-Specific, Potassium	II	21 CFR 862.1600	Potassium test system	75 Clinical Chemistry
CGZ	Electrode, Ion-Specific, Chloride	II	21 CFR 862.1170	Chloride test system	75 Clinical Chemistry
CIT	NADH oxidation/NAD reduction, AST/SGOT	II	21 CFR 862.1100	Aspartate amino transferase (AST/SGOT) Test system	75 Clinical Chemistry
JIX	calibrator, multi-analyte mixture	II	21 CFR 862.1150	Calibrator	75 Clinical Chemistry
JJY	multi-analyte controls, all kinds (assayed)	I	21 CFR 862.1660	Quality control material (assayed and unassayed)	75 Clinical Chemistry

Establishment Information:

The establishment registration number for ELITech Vital Scientific BV is 8030478.
The establishment registration number for ELITech SEPPIM SAS is 3007662974.
The establishment registration number for ELITech Wescor USA is 1717966.
The owner operator number for ELITech North America (Wescor, Logan, UT, USA) is 1717966.

Predicate device:

Predicate Instrument or reagent	*510(k) Number*	*Product code(s)*
HORIBA ABX PENTRA 400	K052007	JJE JIX (also CEM CGZ JGS)
ROCHE cobas c111	K071211	JGS CEM CGZ CIT CFR JJE DCN
ABX PENTRA AST CP	K060318	CIT JIX JJY
Roche Diagnostics Precinorn Universal and Precipath Universal Control Sera	K041227	JJY
Roche Diagnostics Calibrator for Automatic Systems (C.f.a.s.)	K033501	JIX
Roche Standards for the Cobas ISE Module	K897071	JIX

Substantial Equivalence: The ELITech Clinical Systems Selectra ProM is a new device developed by ELITech Vital Scientific BV. It has been demonstrated that the Selectra ProM is substantially equivalent to the predicate device, Horiba ABX PENTRA 400. The ISE Module is similarly demonstrated to be substantially equivalent to the ROCHE cobas c111 ISE. The ELITech Clinical Systems AST/GOT 4+1 SL, calibrated with ELITech Clinical Systems ELICAL 2 and controlled with ELITech Clinical Systems ELITROL I and ELITROL II, is substantially equivalent to HORIBA ABX AST CP, calibrated with Multical and controlled with N Control and P Control.

Device description The Selectra ProM is an automated, in-vitro diagnostic analyzer capable of performing clinical chemistry, specific protein and electrolyte tests. Analytes are measured photometrically or turbidimetrically; the analyzer also has an ISE module for measuring sodium, potassium and chloride electrometrically.

The Selectra ProM instrument is a random access analyzer designed to be operated on a bench top in the professional environment using a combination of a photometric analysis unit and an ion selective electrodes (ISE).

AST/GOT 4+1 SL is available as kit only. It consists of 2 reagents: *Reagent 1* contains Tris buffer, L-Aspartate; Lactate dehydrogenase (LDH) (microorganisms), Malate dehydrogenase (MDH) (bacterial) and sodium azide. *Reagent 2* contains α-Ketoglutarate, NADH and sodium azide.

The Sodium, Potassium and Chloride ISE Electrodes are comprised of the electrodes plus ISE Reference Solution, ISE Diluent, ISE Calibrators.

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.

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.

Performance Standards To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

Intended Use

See Indications for Use following

Indications for Use:

Selectra ProM analyzer:
The ELITech Clinical system Selectra ProM is an automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques. The system has two core modules: one consisting of a spectrophotometric system for measurement of analytes using spectrophotometric techniques, such as end point, rate and turbidimetric assays. The second module is an electrometer used for measurement of electrolytes.

For *in vitro* diagnostic use only.

Reagents:
ELITech Clinical Systems AST/GOT 4+1 SL is a reagent for the quantitative in vitro diagnostic determination of the activity of the enzyme Aspartate Amino Transferase (AST) in human serum and plasma on ELITech Clinical Systems Selectra ProM analyzer. Aspartate Amino Transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

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 ELITech Clinical Systems Selectra ProM analyzers.

ELITech Clinical Systems ELITROL I & ELITROL II are multiparametric control sera for in vitro diagnostic use in accuracy and precision of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

ELITech Clinical Systems ISE Calibrators are used for the calibration of sodium (Na+), potassium (K+), and chloride (Cl-) on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

ISE:
ISE Sodium Electrode
The sodium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of sodium in serum and plasma. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion or other diseases involving electrolyte imbalance.

ISE Potassium Electrode
The potassium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of potassium in serum and plasma. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

ISE Chloride Electrode
The Chloride electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of chloride in serum and plasma. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Comparison to Predicate device
ANALYZER

Similarities and Differences		
	ELITech Clinical Systems Device (Selectra ProM) (AST/GOT 4+1 SL)	Predicate device (ABX PENTRA 400 K052007) (ABX PENTRA AST CP K060318)
Intended Use	The ELITech Clinical system Selectra ProM is an automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques. The system has two core modules: one consisting of a spectrophotometric system for measurement of analytes using spectrophotometric techniques, such as end point, rate and turbidimetric assays. The second module is an electrometer used for measurement of electrolytes. For *in vitro* diagnostic use only.	An automated clinical chemistry system intended for use in centralized laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques.
Operators	Professional setting	Professional setting

REAGENT

Similarities and Differences		
	ELITech Clinical Systems Device (Selectra ProM) (AST/GOT 4+1 SL)	Predicate device (ABX PENTRA 400 K052007) (ABX PENTRA AST CP K060318)
Intended use/Indications for Use	The Selectra ProM is an automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques.	Same
Indication for Use for reagent	Measurements of aspartate amino transferase used in the diagnosis and treatment of certain types of liver and heart disease.	Same
Assay protocol	Modified IFCC method without pyridoxal - phosphate	Optimized UV test according to IFCC modified method without pyridoxal phosphate.
Composition	Reagent R1 : TRIS pH 7.8, 100 mmol/L; L- Aspartate 330 mmol/L; MDH ≥ 1000 U/L; LDH ≥ 2000 U/L; Sodium azide < 1g/L Reagent R2 : α-Ketoglutarate 78 mmol/L ; NADH 1.1 mmol/L ; Sodium azide < 1g/L	Reagent R1 : TRIS pH 7.8 110 mmol/L; L- Aspartate 340 mmol/L; MDH ≥ 900 U/L; LDH ≥ 900 U/L; Sodium azide < 1g/L Reagent R2 : 2-oxoglutarate 85 mmol/L ; NADH 1.09 mmol/L ; Sodium azide < 1g/L
Appearance of reagents	Liquid form, ready to use	Liquid form, ready to use

Traceability/Standardization	IFCC formulation (Schumann, 2002), manual measurement	IFCC Reference Measurement Procedure (37°C) for ASAT
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin
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 is avoided.
Expected values	Serum, Plasma (37°C) :< 40 U/L	Women < 31 U/L Men < 35 U/L } 37°C
Measuring range	10 to 250 U/L	3.70 U/L to 600 U/L Automatic post-dilution:1800 U/L
Limit of detection (LoD)	0.8 U/L	4 U/L
Limit of quantification (LoQ)	5.0 U/L	
Precision	**Within run** Level 21.0 U/L CV=1.6% Level 54.1 U/L CV=0.6% Level 201.0 U/L CV=0.2% **Total** Level 21.0 U/L CV=2.1% Level 54.1 U/L CV=1.5% Level 201.0 U/L CV=1.4%	**Within run** Level 42 U/L CV=2.7% Level 123 U/L CV=1.4% Level 22 U/L CV=2.3% Level 38 U/L CV=2.0% Level 145 U/L CV=1.1% **Total** Level 42 U/L CV=3.1% Level 126 U/L CV=2.5% Level 43 U/L CV=3.6% Level 348 U/L CV=5.0%
Method comparison	y=1.028x - 0.16 U/L r^2= 0.996 range: 9.9 to 248.1 U/L	y=0.99x +1.01 U/L r^2= 0.9966 range: 3.70 to 671.80 U/L
Limitations	**Turbidity:** No significant interference up to 614 mg/dL (7 mmol/L). **Pyruvate:** No significant interference up to 3 mg/dL. **Ascorbic acid:** No significant interference up to 20 mg/dL (1.1 mmol/L). **Unconjugated bilirubin:** No significant interference up to 30 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). *NOTE: Hemolyzed samples should not be used since significant hemolysis may increase AST concentration because of high levels of AST in Erythrocytes.*	**Hemoglobin:** No significant influence is observed up to 95 mg/dL. **Triglycerides:** No significant influence is observed up to 402.5 mg/dL (as Intralipid®, representative of lipemia). **Total bilirubin:** No significant influence is observed up to 415 µmol/L. **Direct bilirubin:** No significant influence is observed up to 362 µmol/L.
Calibration Frequency	28 days	8 days
On board stability	refrigerated area : 28 days	refrigerated area: 55 days

CALIBRATOR:

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 ELITech Clinical Systems Selectra ProM analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
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 ELITech Clinical Systems Selectra ProM analyzers.	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	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 avoiding the formation of foam.	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

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 ELITech Clinical Systems ProM.

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 ProM.

Comparison to Predicate device

	ELITech Clinical Systems Device ELITROL I / ELITROL II	Predicate Device Roche Precinorm U / Precipath U K041227
Intended use	ELITech Clinical Systems ELITROL I & ELITROL II are multiparametric control sera for *in vitro* diagnostic use in accuracy and precision of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.	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

Similarities and Differences		
ISE MODULE	ELITech Clinical Systems Device (Selectra ProM ISE Module)	Predicate device (ROCHE cobas C111 K071211)
Intended use/Indications for Use	The Selectra ProM ISE module is an electrometer used for measurement of electrolytes.	Same
Intended use	used for the quantitative *in vitro* diagnostic determination of sodium (Na^+), potassium (K^+), and chloride (Cl^-) in human serum and plasma	used for the quantitative *in vitro* diagnostic determination of sodium (Na^+), potassium (K^+), and chloride (Cl^-) in diluted serum, plasma and urine
Indication for Use	Sodium measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.	Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Test principle		
Assay protocol	Indirect potentiometry measurement with Ion-Selective Electrode	Indirect potentiometry measurement with Ion Selective Electrode
Sample type	Serum and hemolysis-free plasma	Serum, plasma
General information		
Expected values	Sodium: Serum/plasma : 136-145 mmol/L Potassium: Serum: 3.5 -5.1 mmol/L Plasma: 3.4 – 4.5 mmol/L Chloride: Serum/Plasma: 98 – 107 mmol/L	Sodium (adults): Serum/plasma: 136-145 mmol/L Potassium (adults): Serum: 3.5 -5.1 mmol/L Plasma: 3.4 – 4.5 mmol/L Chloride (adults): Serum/plasma: 98 – 107 mmol/L

Performance characteristics		
Method comparison	<u>Sodium on serum</u> y=1.042 x – 6.9 mEq/L r= 0.996 range: 83 to 196.2 mEq/L <u>Potassium on serum</u> y=1.008 x – 0.08 mEq/L r= 0.997 range: 2.06 to 11.75 mEq/L <u>Chloride on serum</u> y=0.950 x + 3.5 mEq/L r= 0.992 range: 70.2 to 166.8 mEq/L	<u>Sodium on serum</u> y=0.986 x – 0.364 mmol/L r= 0.983 range: 130 to 146 mmol/L <u>Potassium on serum</u> y=0.984 x – 0.003 mmol/L r= 1.000 range: 3.3 to 11.83 mmol/L <u>Chloride on serum</u> y=1.014 x – 3.236 mmol/L r= 0.982 range: 91 to 106 mmol/L
Limitations	<u>Sodium:</u> **Unconjugated bilirubin:** No significant interference up to 36 mg/dL (616 µmol/L). **Conjugated bilirubin:** No significant interference up to 25 mg/dL (427 µmol/L). **Turbidity:** No significant interference up to 614 mg/dL (7 mmol/L). **Acetylsalicylate:** No significant interference up to 50 mg/dL (2.7 mmol/L). **Ascorbic acid:** No significant interference up to 20 mg/dL (1.1 mmol/L). *Hyperlipemia or hyperproteinemia lead to a negative bias in the measurement of electrolyte because of dilution effect.* <u>Potassium:</u> **Unconjugated bilirubin:** No significant interference up to 36 mg/dL (616 µmol/L). **Conjugated bilirubin:** No significant interference up to 25 mg/dL (427 µmol/L). **Turbidity:** No significant interference up to 614 mg/dL (7 mmol/L). **Acetylsalicylate:** No significant interference up to 50 mg/dL (2.7 mmol/L). **Ascorbic acid:** No significant interference up to 20 mg/dL (1.1 mmol/L). *Hemolysis may increase the potassium concentration of 0.5 mmol/L*	<u>Sodium : Serum/plasma</u> **Hemolysis**: Avoid hemolyzed specimens. No significant interference up to 1000 mg/dL of hemoglobin **Icterus**: No significant interference up to 60 mg/dL bilirubin **Lipemia**: No significant interference up to 2000 mg/dL of triglycerides **Dysproteinemia**: No significant interference up to 3000 mg/dL **Drugs:** A panel of drugs was tested and caused no significant interferences when added to aliquots of pooled normal human serum/plasma up to the indicated concentration. <u>Potassium : Serum/plasma</u> **Hemolysis**: Avoid hemolyzed specimens. No significant interference up to 100 mg/dL of hemoglobin. *Potassium concentration in erythrocytes is 25 times higher than in normal plasma. The level of interference may be variable depending on the exact content of erythrocytes* **Icterus**: No significant interference up to 60 mg/dL bilirubin. **Lipemia**: No significant interference up to 2000 mg/dL of triglycerides. **Dysproteinemia**: No significant interference up to 3000 mg/dL.

	because of high potassium concentration in erythrocytes. *Hyperlipemia or hyperproteinemia lead to a negative bias in the measurement of electrolyte because of dilution effect.* Chloride: **Unconjugated bilirubin:** No significant interference up to 36 mg/dL (616 µmol/L). **Conjugated bilirubin:** No significant interference up to 25 mg/dL (427 µmol/L). **Turbidity:** No significant interference up to 614 mg/dL (7 mmol/L). **Acetylsalicylate:** No significant interference up to 50 mg/dL (2.7 mmol/L). **Ascorbic acid:** No significant interference up to 20 mg/dL (1.1 mmol/L). *Hyperlipemia or hyperproteinemia lead to a negative bias in the measurement of electrolyte because of dilution effect.*	**Drugs**: A panel of drugs was tested and caused no significant interferences when added to aliquots of pooled normal human serum/plasma up to the indicated concentration. Chloride: Serum/plasma **Hemolysis**: Avoid hemolyzed specimens. No significant interference up to 1000 mg/dL of hemoglobin. **Icterus**: No significant interference up to 60 mg/dL bilirubin. **Lipemia**: No significant interference up to 2000 mg/dL of triglycerides **Dysproteinemia**: No significant interference up to 3000 mg/dL. **Drugs**: A panel of drugs was tested and caused no significant interferences when added to aliquots of pooled normal human serum/plasma up to the indicated concentration. In addition to the tested drug panel, salicylic acid measured. The highest concentration (5 mmol/L) causes artificially elevated chloride concentrations
Traceability	According the following reference material : Na^+ : NIST SRM 919b K^+ : NIST SRM 918b Cl^- : NIST SRM 918b/919b	This method has been standardized against primary calibrators prepared gravimetrically from purified salts.
Calibration Frequency	It is recommended to recalibrate after setting-up of a new vial of ISE Reference Solution or of ISE Diluent then every 4 hours when quality control results fall outside the established range, after replacing electrode, and after ISE cleaning and maintenance	24 hours (main calibration) after ISE cleaning and maintenance, after changing the reagent bottles after replacing electrodes
ISE CALIBRATOR	ELITech Clinical Systems Device (ISE Calibrator)	Predicate device Roche Standards for the Cobas ISE Module K897071
ISE Calibrators	**Composition**: Aqueous solutions containing sodium, potassium and chloride with 2 different levels of concentrations. Concentrations are lot-specific. The values are given in the vial labels.	ISE Calibration kit **Composition**: Aqueous preparations with different levels of concentrations level 1 and level 2 ISE Solution 1 : Na^+ : 150 mmol/L K^+ : 5 mmol/L

		Cl^-: 115 mmol/L ISE Solution 2 : Na^+: 110 mmol/L K^+: 1.8 mmol/L Cl^-: 72 mmol/L **Storage:** Store at 2-8 °C. These calibrators are stable until the expiry date stated on the label. **Stability:** - Calibrators are stable until the expiry date stated on the label. - After opening, calibrators is stable 4 weeks when stored at 2-8 °C *Note: Close opened bottles immediately after use and store at 2-8 °C.* ISE Calibrator indirect /urine **Composition:** Sodium (Na^+) : 25 mmol/L Potassium (K^+) : 0.83 mmol/L Chloride (Cl^-): 19.2 mmol/L **Storage:** Store at 15-25 °C. This solution is stable until the expiry date stated on the label.
	Storage: Store at 2-30 °C. These calibrators are stable until the expiry date stated on the label. Do not freeze. **Stability:** - Calibrators are stable until the expiry date stated on the label. - After opening, calibrators is stable 30 days when stored at 2-30 °C *Note: Calibrators should be immediately and tightly capped to prevent contamination and evaporation.*	

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 devices in its intended use locations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ELITech Group Vital Scientific BV
c/o Debra Hutson
ELITech Group Epoch Biosciences
21720 23rd Dr. SE, Suite 150
Bothell, Washington 98021

MAR 24 2011

Re: k102647
Trade Name: AST/GOT 4+1 SL
Regulation Number: 21 CFR §862.1100
Regulation Name: Aspartate aminotransferase (AST/SGOT) Test System
Regulatory Class: Class II
Product Codes: CIT, JGS, CEM, CGZ, JIX, JJY and JJE
Dated: March 4, 2011
Received: March 7, 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 either class II (Special Controls) or class III (PMA), 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).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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): K102647

Device Name: ELITech Clinical Systems Selectra ProM

Indications for Use:

The ELITech Clinical system Selectra ProM is an automated clinical chemistry system intended for use in clinical laboratories. It is intended to be used for a variety of assay methods that have been applied to spectrophotometric and electrochemical techniques. The system has two core modules: one consisting of a spectrophotometric system for measurement of analytes using spectrophotometric techniques, such as end point, rate and turbidimetric assays. The second module is an electrometer used for measurement of electrolytes.

For *in vitro* diagnostic use only.

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

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

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

510(k) K102647

Indications for Use Form

510(k) Number (if known): K102647

Device Name: ELITech Clinical Systems AST/GOT 4+1 SL

Indications for Use:

ELITech Clinical Systems AST/GOT 4+1 SL is a reagent for the quantitative *in vitro* diagnostic determination of the activity of the enzyme Aspartate Amino Transferase (AST) in human serum and plasma on ELITech Clinical Systems Selectra ProM analyzer. Aspartate Amino Transferase measurements are used in the diagnosis and treatment of certain types of liver and heart disease.

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

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510(k) K102647

Indications for Use Form

510(k) Number (if known): K102647

Device Name: ELITech Clinical Systems ISE Na, K, Cl Electrodes

Indications for Use:

ISE Sodium Electrode

The sodium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of sodium in serum and plasma. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion or other diseases involving electrolyte imbalance.

ISE Potassium Electrode

The potassium electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of potassium in serum and plasma. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

ISE Chloride Electrode

The Chloride electrode for the ELITech Clinical Systems Selectra ProM is intended for the quantitative determination of chloride in serum and plasma. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

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

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510(k) K102647

Indications for Use Form

510(k) Number (if known): _ K102647

Device Name: _____ELITech Clinical Systems ELITROL I & ELITROLII_____

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multiparametric control sera for *in vitro* diagnostic use in accuracy and precision of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

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

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Indications for Use Form

510(k) Number (if known): K102647

Device Name: ELITech Clinical Systems ISE Calibrators

Indications for Use:

ELITech Clinical Systems ISE Calibrators are used for the calibration of sodium (Na+), potassium (K+), and chloride (Cl-) on ELITech Clinical Systems Selectra ProM analyzer equipped with ISE module.

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

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510(k) K102647

Indications for Use Form

510(k) Number (if known): K102647

Device Name: ELITech Clinical Systems ELICAL2

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 ELITech Clinical Systems Selectra ProM analyzers.

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

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