SECTION 5 - 510(k) Summary

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: __K 110830_____ JUN 2 1 2011

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Date of Preparation March 24th, 2011

Device names

REAGENT
Trade/proprietary Name: **ELITech Clinical Systems CALCIUM ARSENAZO**
Common or Usual Name: Calcium, **"CALCIUM ARSENAZO"**
Device Class: Class II
Classification name: Calcium test system (Sec.862.1145)
Product code: **CJY**– Azo Dye, Calcium

Predicate device Stanbio Calcium LiquiColor® (Arsenazo III) (K921625)

Device description The device for this submission is available as kit only. It consists of 1 reagent "R".
Reagent R contains: MES buffer (pH 6.50), Arsenazo III [2,7-(bis(2-arsonophenylazo))-1,8-dihydronaphtalene-3,6-disulphonic acid].

Intended Use ELITech Clinical Systems CALCIUM ARSENAZO is intended for the quantitative *in vitro* diagnostic determination of total calcium in human serum and plasma on ELITech Clinical Systems Selectra analyzers.
It is not intended for use in Point of Care settings.

Indication for use Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Comparison to Predicate device

	ELITech Clinical Systems Device (CALCIUM ARSENAZO)	Predicate device (Stanbio Calcium LiquiColor® (Arsenazo III) K921625)
Intended use	Intended for the quantitative *in vitro* diagnostic determination of total calcium in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	For the quantitative colorimetric determination of calcium in human serum and plasma on Stanbio Laboratory Sirrus Chemistry Analyzer.
Indication for Use	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).	Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
Assay protocol	Colorimetric test	Colorimetric test
Composition	Reagent R: MES buffer (pH 6.50) 100 mmol/L ; Arsenazo III 200 µmol/L ;	Reagent : Buffer ; Arsenazo III > 0.15 mmol/L ; 8-Hydroxyquinoline sulfonate 5.0 mM; Surfactant
Appearance of reagents	Liquid form, ready to use	Liquid form, ready to use
Sample type	Serum Plasma	Serum Plasma
Reagent storage	Store at 2-8 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Store at 2-30 °C the reagent is stable until the expiry date stated on the label.
Expected values	Serum/plasma: 8.6 – 10.3 mg/dL	Serum/plasma: 8.5 – 10.4 mg/dL
Instrument	Selectra ProM Analyzer	Sirrus Chemistry Analyzer
Measuring range	5.0 – 15.0 mg/dL	0 to 15 mg/dL
Limit of detection (LoD)	0.36 mg/dL	-
Limit of quantification (LoQ)	5.00 mg/dL	
Precision	**Within run** Level 8.75 mg/dL CV= 1.3% Level 9.68 mg/dL CV= 0.9% Level 11.97 mg/dL CV= 0.7% **Total** Level 8.75 mg/dL CV= 1.9% Level 9.68 mg/dL CV= 1.9% Level 11.97 mg/dL CV= 1.9%	**Within run** Level 11.0 mg/dL CV=1.3% Level 14.3 mg/dL CV=0.9% **Run to run** Level 11.2 mg/dL CV=1.1% Level 14.3. mg/dL CV=1.3%
Method comparison	y= 1.008 x – 0 mg/dL r= 0.996 range: 4.90 to 14.37 mg/dL	y= 0.99 x + 0.10 mg/dL r= 0.989 range: 4.7 to 15.9 mg/dL
Limitations	**Hemoglobin**: No significant interference up to 500 mg/dL.	**Bilirubin**: No interference up to 20 mg/dL.

	ELITech Clinical Systems Device (CALCIUM ARSENAZO)	Predicate device (Stanbio Calcium LiquiColor® (Arsenazo III) K921625)
	Triglycerides: No significant interference up to 1119 mg/dL. A positive bias is observed with triglycerides concentratsion above 1119 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Magnesium:** No significant interference up to 10.91 mg/dL. **Ascorbic acid:** No significant interference up to 20 mg/dL. **Acetaminophen:** No significant interference up to 30 mg/dL. **Acetylsalicylic acid:** No significant interference up to 200 mg/dL.	**Hemoglobin:** No interference up to 500 mg/dL **Lipemia:** May cause elevated results.
Calibration Frequency	28 days	30 days
On board stability	refrigerated area : 28 days	30 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Ser-T-Cal® MultiCalibrator
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): Ser-T-Fy® I (Normal control) Ser-T-Fy® II (Abnormal control)

Device names

REAGENT

Trade/proprietary Name:	**ELITech Clinical Systems ALBUMIN**
Common or Usual Name:	Albumin, **"ALBUMIN"**
Device Class	Class II
Classification name	Albumin test system (Sec.862.1035)
Product code	**CIX** – Bromcresol green dye-binding, Albumin

Predicate device Roche Diagnostics Albumin Gen.2 (K063744)

Device description The device for this submission is available as kit only. It consists of 1 reagent "R".
Reagent R contains: Succinate buffer (pH 4.20), Bromocresol green, Brij 35.

Intended Use ELITech Clinical Systems ALBUMIN is intended for the quantitative *in vitro* diagnostic determination of albumin in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.

Indication for use Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Comparison to Predicate device

	ELITech Clinical Systems Device (ALBUMIN)	Predicate device (Roche Diagnostics Albumin Gen.2 K063744)
Intended use	Intended for the quantitative *in vitro* diagnostic determination of albumin in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of albumin in human serum and plasma on the cobas c111 system.
Indication for Use	Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.	Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.
Assay protocol	Colorimetric test	Colorimetric test
Composition	Reagent R: Succinate buffer (pH 4.20) 87 mmol/L ; Bromocresol green 0.2 mmol/L ; Brij 35 7.35 mL/L;	Reagent R1: Citrate (pH 4.1) 95 mmol/L ; Preservative Reagent R2: Citrate (pH 4.1) 95 mmol/L ; Bromocresol green 0.66 mmol/L; Preservative
Appearance of reagents	Liquid form, ready to use	Liquid form, ready for use
Sample type	Serum Plasma	Serum Plasma
Reagent storage	Store at 2-25 °C and protect from light. The reagent is stable until the expiry date stated on the label.	Stored at 15-25 °C. Reagents are stable until the expiry date stated on the label.
Expected values	Serum, plasma: Adults: 3.5-5.2 g/dL 60-90 years : 3.2-4.6 g/dL > 90 years: 2.9-4.5 g/dL In ambulatory patients, values average ~0.3 g/dL higher.	Serum/plasma: Adults (reference range study) : 3.97-4.94 g/dL Adults (consensus values) : 3.5-5.2 g/dL Tietz: 0-4 days : 2.8-4.4 g/dL 4 days-14 years: 3.8-5.4 g/dL 14 -18 years: 3.2-4.5 g/dL
Instrument	Selectra ProM Analyzer	Cobas c111
Measuring range	1.6 – 6.0 g/dL	0.2 to 6.0 g/dL
Limit of detection (LoD)	0.003 g/dL	0.2 g/dL
Limit of quantification (LoQ)	0.50 g/dL	
Precision	**Within run** Level 2.54 g/dL CV= 0.9% Level 3.53 g/dL CV= 0.5% Level 4.98 g/dL CV= 0.8% **Total**	**Within run** Level 4.67 g/dL CV=0.52% Level 2.99 g/dL CV=0.76% Level 3.01 g/dL CV=0.56% Level 5.48 g/dL CV=0.61% **Run to run**

	ELITech Clinical Systems Device (ALBUMIN)	Predicate device (Roche Diagnostics Albumin Gen.2 K063744)
	Level 2.54 g/dL CV= 2.3% Level 3.53 g/dL CV= 2.1% Level 4.98 mg/dL CV= 2.1%	Level 4.62 g/dL CV=1.87% Level 2.97 g/dL CV=1.45% Level 2.98 g/dL CV=1.83% Level 5.40 g/dL CV=1.24%
Method comparison	y= 0.961x + 0.12 g/dL r= 0.997 range: 1.43 to 5.89 g/dL.	y= 1.017 x + 0.0164 g/dL r= 0.9997 range: 0.26 to 5.93 g/dL
Limitations	**Hemoglobin:** No significant interference up to 500 mg/dL. **Triglyceride:** No significant interference up to 3000 mg/dL. **Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Ascorbic acid:** No significant interference up to 20 mg/dL. **Acetaminophen:** No significant interference up to 30 mg/dL. **Acetylsalicylic acid:** No significant interference up to 200 mg/dL. **γ-globulin:** No significant interference up to 1500 mg/dL.	**Hemoglobin:** No significant interference up to an H Index of 420 (approximate 420 mg/dL). **Lipemia (Intralipid):** No significant influence up to an L index of 900. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. **Icterus:** No significant influence up to I Index of 60 (approximate conjugated and unconjugated bilirubin concentration of 60 mg/dL (1026 µmol/L)). **γ-globulin:** No significant interference.
Calibration Frequency	28 days	Each lot and as required following quality control procedures.
On board stability	refrigerated area : 28 days	4 weeks
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Roche Calibrator f.a.s.
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): Roche Precinorm U Roche Precipath U

Device name

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 ELITech Clinical Systems Selectra 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 ELITech Clinical Systems Selectra 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 lyophilizate, 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 lyophilizate, 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 :* Between 15-25 °C : 8 hours	Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are : - 8 hours at 15-25 °C.

	Between 2-8 °C : 2 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions :* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	- 2 days at 2-8 °C. - 4 weeks at Between (-25)-(-15) °C (when frozen once) Exception for bilirubin total & direct - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)

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	**JJY**- 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 and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.

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 and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	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 lyophilizate, 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 lyophilizate, 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 : Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions:* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (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: - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

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.

Device name

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 ELITech Clinical Systems Selectra 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 ELITech Clinical Systems Selectra 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 lyophilizate, 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 lyophilizate, 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 :* Between 15-25 °C : 8 hours Between 2-8 °C : 2 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions :* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (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 Between (-25)-(-15) °C (when frozen once) Exception for bilirubin total & direct - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)

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	**JJY**- 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 and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.

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 and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	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 lyophilizate, 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 lyophilizate, 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	Lyophilized: Stable at 2-8°C up to expiration date.

	ELITech Clinical Systems Device (ELITROL I / ELITROL II)	Predicate Device (Roche Precinorm U / Precipath U K041227)
	After reconstitution, the stabilities are : Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions:* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	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: - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JUN 21 2011

SEPPIM S.A.S.
Elitech Group Epoch Biosciences
c/o Ms. Debra Hutson
Director, Quality Assurance/Regulatory Affairs
21720 23rd Drive, S.E., Suite 150
Bothell, Washington 98021

Re: k110830
Trade Name: ELITech Clinical Systems Albumin, ELITech Clinical Systems Calcium Arsenazo, ELITech Clinical Systems Elical 2, ELITech Clinical Systems Elitrol I and II
Regulation Number: 21 CFR §862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Codes: CIX, CJY, JIX, JJY
Dated: May 18, 2011
Received: May 19, 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

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): K110830

Device Name: ELITech Clinical Systems CALCIUM ARSENAZO

Indications for Use:

ELITech Clinical Systems CALCIUM ARSENAZO is intended for the quantitative *in vitro* diagnostic determination of total calcium in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

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

Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

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) K110830

Indications for Use Form

510(k) Number (if known): K110830

Device Name: _____ ELITech Clinical Systems ALBUMIN

Indications for Use:

ELITech Clinical Systems ALBUMIN is intended for the quantitative *in vitro* diagnostic determination of albumin in human serum and plasma on ELITech Clinical Systems Selectra analyzers.

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

Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110830

Indications for Use Form

510(k) Number (if known): K110830

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 ELITech Clinical Systems Selectra 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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510(k) k110830

Indications for Use Form

510(k) Number (if known): K110830

Device Name: _____ ELITech Clinical Systems ELITROL I & ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra 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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