SECTION 5 - 510(k) Summary
ELITech Clinical Systems CHOLESTEROL HDL SL 2G   AUG 3 1 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: **K103747**

Submitter	SEPPIM S.A.S.
Address	Zone Industrielle, 61500 SEES, FRANCE
Phone number	+ 33 (0)2 33 81 21 00
Fax number	+ 33 (0)2 33 28 77 51
Contact	Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation	November, 23rd, 2010

Device names

REAGENT :
Trade/proprietary Name:	**ELITech Clinical Systems CHOLESTEROL HDL SL 2G**
Common or Usual Name:	High Density Lipoprotein (HDL) Cholesterol, "**CHOLESTEROL HDL SL 2G**"
Device Class	Class I,
Classification name	Lipoprotein test system (Sec.862.1475)
Product code	LBS – LDL & VLDL Precipitation, Cholesterol Via Esterase-Oxidase,

Predicate device	ABX PENTRA HDL Direct CP (K060854)

Device description	The device for this submission is available as kit only. It consists of 2 reagents, "R1" and "R2".
	Reagent R1 contains: Good's buffer, Cholesterol oxidase (CO bacterial), Peroxidase (horseradish), Ascorbate oxidase (bacterial), N,N-bis(4-sulphobutyl)-m-toluidine-disodium (DSBmT), Accelerator.
	Reagent R2 contains: Good's buffer, Cholesterol esterase (CHE bacterial), 4-Amino-Antipyrine (4-AA), detergent.

Intended Use	ELITech Clinical Systems CHOLESTEROL HDL SL 2G is intended for use with ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II on ELITech Clinical Systems Selectra analyzers for the quantitative *in vitro* diagnostic determination of High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. It is not intended for use in Point of Care settings.

Indication(s) for Use	ELITech Clinical Systems CHOLESTEROL HDL SL 2G is intended to measure High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Comparison to Predicate device

	ELITech Clinical Systems Device CHOLESTEROL HDL SL 2G	Predicate device (ABX PENTRA HDL Direct CP, K060854)
Intended use	Intended for use with ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II on ELITech Clinical Systems Selectra analyzers for the quantitative *in vitro* diagnostic determination of High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. It is not intended for use in Point of Care settings.	For quantitative in Vitro determination of High-Density Lipoprotein Cholesterol (HDL-C) in human serum or plasma by colorimetry.
Indication(s) for Use	Intended to measure High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.	Intended to measure High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
Assay protocol	Enzymatic colorimetric test with accelerator selective detergent	Enzymatic colorimetric test based on accelerator Selective Detergent (without the need for any off-line pretreatment or centrifugation steps)
Composition	Reagent R1: Good's buffer ,pH 6.0 ; Cholesterol oxidase < 1000 U/L ; Peroxidase < 1300 ppg U/L ; Ascorbate oxidase < 3000 U/L ; N,N-bis(4-sulphobutyl)-*m*-toluidine-disodium (DSBmT) < 1 mmol/L ; Accelerator < 1 mmol/L Preservative < 0.06 % Reagent R2: Good's buffer, pH 6.0 ; Cholesterol esterase < 1500 U/L ; 4-Amino-Antipyrine < 1 mmol/L ; Detergent < 2% Preservative < 0.06 %	Reagent R1: Good's buffer Cholesterol oxidase < 1000 U/L ; Peroxidase < 1300 ppg U/L ; N,N-bis(4-sulphobutyl)-m-toluidine-disodium (DSBmT) < 1 mmol/L ; Accelerator < 1 mmol/L Preservative < 0.06 % Reagent R2: Good's buffer Cholesterol esterase < 1500 U/L ; 4-Amino-Antipyrine < 1 mmol/L ; Detergent < 2% Restrainer < 0.15 % Preservative < 0.06 % Ascorbic acid oxidase < 3000 U/L
Appearance of reagent	Liquid form, ready to use	Same
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin
Reagent storage	Store at 2-8 °C and protected from	Reagents, in unopened cassette, are

	ELITech Clinical Systems Device CHOLESTEROL HDL SL 2G	Predicate device (ABX PENTRA HDL Direct CP, K060854)
	light. The reagents are stable until the expiry date stated on the label.	stable up to expiry date on the label if stored at 2-8 °C.
Expected values	According to NCEP , classification according to the risk of developping coronary heart disease High : < 40 mg/dL Low : ≥ 60 mg/dL	According to NCEP , classification according to the risk of developping coronary heart disease High : < 40 mg/dL Low : ≥ 60 mg/dL
Instrument	SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	5 to 105 mg/dL	5.4 to 151.9 mg/dL
Limit of detection (LoD)	0.7 mg/dL	1.16 mg/dL
Limit of quantification (LoQ)	5.0 mg/dL	
Precision	**Within run** Level 31 mg/dL CV=1.4% Level 56 mg/dL CV=0.7% Level 87 mg/dL CV=1.4% **Total** Level 31 mg/dL CV=3.0% Level 56 mg/dL CV=2.8% Level 87 mg/dL CV=3.3%	**Within run** Level 35.82 mg/dL CV=1.29% Level 81.72 mg/dL CV=0.79% Level 27.94 mg/dL CV=1.32% Level 48.59 mg/dL CV=1.91% Level 97.39 mg/dL CV=0.62% **Total** Level 35.85 mg/dL CV=2.88% Level 80.35 mg/dL CV=3.06% Level 47.07 mg/dL CV=3.52% Level 80.16 mg/dL CV=2.69%
Method comparison	y=1.09x – 2.5 mg/dL r^2= 0.972 range: 5 to 105 mg/dL	y=0.91x + 1.98 mg/dL r^2= 0.9768 range: 5.4 to 151.9 mg/dL
Limitations	No significant interference for the following components : **Unconjugated bilirubin** (up to 30 mg/dL) **Conjugated bilirubin** (up to 29.5 mg/dL) **Hemoglobin** (up to 500 mg/dL) **Turbidity** : Negative bias from 439 mg/dL triglycerides equivalent.	**Hemoglobin:** No significant influence is observed up to 479 mg/dL. **Triglycerides:** No significant influence is observed up to 612.5 mg/dL. **Total bilirubin:** No significant influence is observed up to 11.7 mg/dL. **Direct bilirubin:** No significant influence is observed up to 28.1 mg/dL.
On board stability	refrigerated area : 28 days	refrigerated area: 31 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Cholesterol HDL 2G Calibrator	Recommended calibration material (not included): ABX Pentra HDL Cal

	ELITech Clinical Systems Device CHOLESTEROL HDL SL 2G	Predicate device (ABX PENTRA HDL Direct CP, K060854)
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 CHOLESTEROL HDL 2G CALIBRATOR

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: **K103747**

Submitter	SEPPIM S.A.S.
Address	Zone Industrielle, 61500 SEES, FRANCE
Phone number	+ 33 (0)2 33 81 21 00
Fax number	+ 33 (0)2 33 28 77 51
Contact	Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation	November, 23rd, 2010

Device names

Trade/proprietary Name	**ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR**
Common or Usual Name	**Calibrator "CHOLESTEROL HDL 2G CALIBRATOR"**
Device Class	Class II
Classification name	Calibrator (Sec.862.1150)
Product code	**JIS- Calibrator, Primary**

Predicate device	Ultra N-Geneous HDL Calibrator from Genzyme (K021316)

Device description	ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR is a lyophilized calibrator based on human serum containing lipoprotein from the various lipoprotein classes including high density lipoproteins and sodium azide as preservative.
	CHOLESTEROL HDL 2G CALIBRATOR 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.

Intended Use	ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR is a calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems CHOLESTEROL HDL SL 2G on ELITech Clinical Systems Selectra analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (CHOLESTEROL HDL 2G CALIBRATOR)	Predicate device (Genzyme Ultra N-Geneous CHOLESTEROL HDL Calibrator)
Intended use	For *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems CHOLESTEROL HDL SL 2G on ELITech Clinical Systems Selectra analyzers.	For the calibration of Ultra N-Genous HDL Cholesterol
Format	Lyophilized calibrator based on human serum on human serum containing lipoprotein from the various lipoprotein classes including high density lipoproteins. This calibrator contains sodium azide as preservative.	Lyophilized calibrator based on human serum on human serum containing lipoprotein from the various lipoprotein classes including high density lipoproteins. This calibrator contains sodium azide as preservative.
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 1 mL of distilled/deionized water. Carefully close the vial and dissolve the content by successive swirling. Wait for around 20 minutes until the complete dissolution and homogenize again. Do not shake strongly to avoid formation of foam.	Carefully open the vial, avoiding the loss of lyophilizate, and reconstitute with 1 mL of deionized water. Close the vial and let stand for 20 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake.
Stability	Lyophilized: To store at 2-8 °C and protected from light until the expiry date After reconstitution, the stabilities are : - 14 days between 2 - 8 °C. - 4 weeks at less than - 80 °C (when frozen once)	Lyophilized: To store at 2-8 °C and protected from light until the expiry date After reconstitution, the stabilities are : - 14 days between 2 - 8 °C. - 4 weeks between -70 °C (when frozen once)

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 CHOLESTEROL LDL SL 2G

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: **K103747**

Submitter	SEPPIM S.A.S.
Address	Zone Industrielle, 61500 SEES, FRANCE
Phone number	+ 33 (0)2 33 81 21 00
Fax number	+ 33 (0)2 33 28 77 51
Contact	Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation	November, 23rd, 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems CHOLESTEROL LDL SL 2G**
Common or Usual Name:	Low Density Lipoprotein (LDL) Cholesterol, "**CHOLESTEROL HDL SL 2G**"
Device Class	Class I
Classification name	Lipoprotein test system (Sec.862.1475)
Product code	LBS – LDL & VLDL Precipitation, Cholesterol Via Esterase

Predicate device	ABX PENTRA LDL Direct CP (K060854)

Device description	The device for this submission is available as kit only. It consists of 2 reagents, "R1" and "R2". Reagent R1 contains: MES buffer, Detergent 1, Cholesterol esterase (CHE bacterial), Cholesterol oxidase (CO bacterial), Peroxidase (horseradish), 4-Amino-Antipyrine (4-AA), Ascorbate oxidase (vegetal). Reagent R2 contains: MES buffer, Detergent 2, N,N-bis(4-sulphobutyl)-*m*-toluidine-disodium (DSBmT).

Intended Use	ELITech Clinical Systems CHOLESTEROL LDL SL 2G is intended for use with ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II for the quantitative *in vitro* diagnostic determination of Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.
Indication(s) for Use	ELITech Clinical Systems CHOLESTEROL LDL SL 2G is intended to measure Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Comparison to Predicate device

	ELITech Clinical Systems Device CHOLESTEROL LDL SL 2G	Predicate device (ABX PENTRA LDL DIRECT CP)
Intended use	Intended for use with ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II for the quantitative *in vitro* diagnostic determination of Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.	For quantitative *in vitro* determination of Low Density Lipoprotein Cholesterol (LDL-C) in serum or plasma by colorimetry.
Indication(s) for Use	Intended to measure Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.	Intended to measure Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma. Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.
Assay protocol	Enzymatic colorimetric test with selective detergent	Enzymatic colorimetric test with selective detergent
Composition	Reagent R1: MES buffer ,pH 6.3 ; Detergent 1 < 1.0 %, Cholesterol esterase < 1500 U/L, Cholesterol oxidase < 1500 U/L; Peroxidase < 1300 ppg U/L; 4-Amino-Antipyrine < 0.1 %, Ascorbate oxidase < 3000 U/L Preservative Reagent R2: MES buffer, pH 6.3 ; Detergent 2 < 1.0 %, N,N-bis(4-sulphobutyl)-*m*-toluidine-disodium < 1 mmol/L Preservative	Reagent R1: MES buffer ,pH 6.3 ; Detergent 1 < 1.0 %, Cholesterol esterase < 1500 U/L, Cholesterol oxidase < 1500 U/L; Peroxidase < 1300 ppg U/L; 4-Amino-Antipyrine < 0.1 %, Ascorbate oxidase < 3000 U/L Preservative Reagent R2: MES buffer, pH 6.3 ; Detergent 2 < 1.0 %, N,N-bis(4-sulphobutyl)-*m*-toluidine-disodium < 1 mmol/L Preservative
Appearance of reagent	Liquid form, ready to use	Same
Sample type	Serum Plasma in lithium heparin	Serum Plasma in lithium heparin
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	According to NCEP, classification according to the risk of developing coronary heart disease: Optimal : < 100 mg/dL Near or above optimal: 100-129 mg/dL Borderline High : 130-159 mg/dL High: 160-189 mg/dL Very high : ≥ 190 mg/dL	Following NCEP cutpoints for patient classification are used for the prevention and management of coronary artery disease: Desirable : < 130 mg/dL Borderline High risk: 130 -159 mg/dL High risk : 160 mg/dL

	ELITech Clinical Systems Device CHOLESTEROL LDL SL 2G	Predicate device (ABX PENTRA LDL DIRECT CP)
Instrument	Vital Scientific SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	15 to 380 mg/dL	1.35 to 369.39 mg/dL
Limit of Detection (LoD)	0.3 mg/dL	1.55 mg/dL
Limit of Quantification (LoQ)	10.0 mg/dL	
Precision	**Within run** Level 108 mg/dL CV=1.4% Level 122 mg/dL CV=1.3% Level 162 mg/dL CV=2.0% **Total** Level 108 mg/dL CV=2.6% Level 122 mg/dL CV=2.7% Level 162 mg/dL CV=4.0%	**Within run** Level 61.26 mg/dL CV=1.01% Level 75.08 mg/dL CV=2.82% Level 111.26 mg/dL CV=0.91% Level 141.45 mg/dL CV=1.00% Level 191.16 mg/dL CV=0.63% **Total** Level 60.64 mg/dL CV=5.59% Level 74.27 mg/dL CV=6.39% Level 156.58 mg/dL CV=3.94% Level 191.62 mg/dL CV=4.04%
Method comparison	$y= 0.999 x - 0.5$ mg/dL $r^2= 0.993$ range: 16-378 mg/dL	$y=0.96x - 0.21$ mg/dL $r^2= 0.9963$ range: 1.35 to 369.39 mg/dL
Limitations	**Hemoglobin:** No significant interference up to 500 mg/dL. **Turbidity:** No significant interference up to 614 mg/dL triglycerides equivalent. **Unconjugated bilirubin:** No significant interference up to 30 mg/dL. **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL.	**Hemoglobin:** No significant influence is observed up to 460 mg/dL. **Triglycerides:** No significant influence is observed up to 613 mg/dL. **Total bilirubin:** No significant influence is observed up to 8.19 mg/dL. **Direct bilirubin:** No significant influence is observed up to 5.63 mg/dL.
Calibration Frequency	28 days	14 days
On board stability	refrigerated area : 28 days	refrigerated area: 97 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Cholesterol LDL 2G Calibrator	Recommended calibration material (not included): ABX Pentra LDL Cal
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 CHOLESTEROL LDL 2G CALIBRATOR

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: **K103747**

Submitter	SEPPIM S.A.S.
Address	Zone Industrielle, 61500 SEES, FRANCE
Phone number	+ 33 (0)2 33 81 21 00
Fax number	+ 33 (0)2 33 28 77 51
Contact	Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation	November, 23rd, 2010

Trade/proprietary Name:	**ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR**
Common or Usual Name:	**Calibrator "CHOLESTEROL LDL 2G CALIBRATOR"**
Device Class	Class II
Classification name	Calibrator (Sec.862.1150)
Product code	**JIS- Calibrator, Primary**

Predicate device	N-geneous LDL Calibrator from Genzyme (K971573)

Device description	ELITech Clinical Systems CHOLESTEROL LDL 2GCALIBRATOR is a lyophilized calibrator based on human serum containing lipoprotein from the various lipoprotein classes including low density lipoproteins and sodium azide as preservative. CHOLESTEROL LDL 2G CALIBRATOR is prepared from plasma donor units tested individually by FDA - approved methods and found to be negative for HbsAg, anti-HCV antibody and anti-HIV1&2 antibodies.

Intended Use	ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR intended for use with ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II for the quantitative *in vitro* diagnostic determination of Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.

Comparison to Predicate device

	ELITech Clinical Systems Device (CHOLESTEROL LDL 2G CALIBRATOR)	Predicate device (Genzyme N-geneous LDL Cholesterol Calibrator)
Intended use	For *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems CHOLESTEROL LDL SL 2G on ELITech Clinical Systems Selectra analyzers.	For the calibration of Ultra N-Genous LDL Cholesterol assay in serum or plasma.
Format	Lyophilized calibrator based on human serum on human serum containing lipoprotein from the various lipoprotein classes including low density lipoproteins. This calibrator contains sodium azide as preservative.	Lyophilized calibrator based on human serum on human serum containing lipoprotein from the various lipoprotein classes including low density lipoproteins. This calibrator contains sodium azide as preservative
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilizate, and pipette in exactly 1 mL of distilled/deionized water. Carefully close the vial and dissolve the content by successive swirling. Wait for around 5 minutes until the complete dissolution and homogenize again. Do not shake strongly to avoid formation of foam.	Reconstitute by adding 1 mL of distilled or deionized water. Close the vial and let stand for 5 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake.
Stability	Lyophilized: To store at 2-8 °C and protected from light until the expiry date After reconstitution, the stabilities are : - 14 days between 2 - 8 °C. - 4 weeks at less than -80 °C (frozen only once)	Lyophilized: To store at 2-8 °C and protected from light until the expiry date After reconstitution, the stabilities are : - 2 weeks at 2 - 8 °C. - the reconstituted calibrator may be aliquoted and stored at -80 °C.

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. The assigned 510(k) number is: **K103747**

Submitter	SEPPIM S.A.S.
Address	Zone Industrielle, 61500 SEES, FRANCE
Phone number	+ 33 (0)2 33 81 21 00
Fax number	+ 33 (0)2 33 28 77 51
Contact	Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation	November, 23rd, 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 & 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
Intended 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.	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.

ELITech SEPPIM S.A.S.
c/o Debra K Hutson
21720 23rd Dr SE, Suite 150
Bothell, WA 98021

AUG 3 1 2011

Re: k103747

Trade/Device Name:
    ELITech Clinical Systems CHOLESTEROL HDL SL 2G,
    ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR,
    ELITech Clinical Systems CHOLESTEROL LDL SL 2G,
    ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR, and
    ELITech Clinical Systems ELITROL I and ELITROL II
Regulation Number: 21 CFR 862.1475
Regulation Name: LDL & VLDL Precipitation, Cholesterol Via Esterase-Oxidase, HDL
Regulatory Class: Class I, meets limitations per 21 CFR 862.9(c)(4)
Product Codes: LBS, JIT, JJY, MRR
Dated: August 25, 2011
Received: August 30, 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.
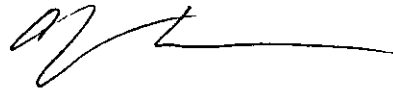
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

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

Indications for Use Form

510(k) Number (if known): _ K103747_____

Device Name: ELITech Clinical Systems CHOLESTEROL HDL SL 2G
                ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR

Indications for Use:

Reagent:

ELITech Clinical Systems CHOLESTEROL HDL SL 2G is intended for use with ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II on ELITech Clinical Systems Selectra analyzers for the quantitative *in vitro* diagnostic determination of High Density Lipoprotein (HDL) Cholesterol in human serum and plasma. It is not intended for use in Point of Care settings.

Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

Calibrator

ELITech Clinical Systems CHOLESTEROL HDL 2G CALIBRATOR is a calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems CHOLESTEROL HDL SL 2G on the ELITech Clinical Systems Selectra analyzers.

Prescription Use ___ X ____   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   AND/OR   (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)_ K103747_____

Indications for Use Form

510(k) Number (if known): _K103747_____

Device Name: ELITech Clinical Systems CHOLESTEROL LDL SL 2G
                ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR

Indications for Use:

<u>Reagent:</u>

ELITech Clinical Systems CHOLESTEROL LDL SL 2G is intended for use with ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR and ELITech Clinical Systems ELITROL I and ELITROL II for the quantitative *in vitro* diagnostic determination of Low Density Lipoprotein (LDL) Cholesterol in human serum and plasma on ELITech Clinical Systems Selectra analyzers. It is not intended for use in Point of Care settings.

Lipoprotein measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases.

<u>Calibrator:</u>

ELITech Clinical Systems CHOLESTEROL LDL 2G CALIBRATOR is a calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems CHOLESTEROL LDL SL 2G on ELITech Clinical Systems Selectra Analyzers.

Prescription Use ___X____   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (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)_____K103747_____

Indications for Use Form

510(k) Number (if known): _K103747 _____

Device Name: _____ ELITech Clinical Systems ELITROL I and 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____   AND/OR   Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)   (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) K103747 ·