SECTION 5 - 510(k) Summary

MAY 19 2011

ELITech Clinical Systems TRIGLYCERIDES SL reagent

Introduction

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

The assigned 510(k) number is:__**K102993**__

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 September 30th, 2010

Device name

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems TRIGLYCERIDES SL**
Common or Usual Name:	Triglycerides, "**TRIGLYCERIDES SL**"
Device Class	Class I
Classification name	Triglyceride test system (Sec.862.1705)
Product code	CDT – Lipase Hydrolysis/Glycerol kinase enzyme, Triglycerides

Predicate device ABX PENTRA TRIGLYCERIDES CP (K060854)

Device description

The device for this submission is available as kit only. It consists of 1 reagent, "R".
Reagent R contains: Pipes buffer, *p*-chlorophenol, ATP, Amino-4-antipyrine (4-AAP), Lipoprotein lipase (bacterial), Glycerol kinase (bacterial), Glycerol-3-phosphate oxidase (microorganisms), Peroxidase (horseradish), Potassium ferrocyanide, Magnesium (Mg^{2+}) and Sodium azide.

Intended Use

ELITech Clinical Systems TRIGLYCERIDES SL is intended for the quantitative in vitro diagnostic determination of triglycerides in human serum and plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings

Indication for use

ELITech Clinical Systems TRIGLYCERIDES SL is intended to measure triglycerides in human serum and plasma. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

Comparison to Predicate device

	ELITech Clinical Systems Device TRIGLYCERIDES SL	Predicate device (ABX PENTRA TRIGLYCERIDES CP)
Intended use	For *in vitro* diagnostic use in the quantitative determination of triglycerides in serum or plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of triglycerides in serum or plasma.
Indication for Use	Intended to measure triglycerides in human serum and plasma. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.	Intended to measure triglycerides in human serum and plasma. Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.
Assay protocol	Enzymatic colorimetric test	Enzymatic colorimetric test
Composition	Reagent: Pipes buffer 50 mmol/L ; Magnesium (Mg^{2+}) 14.8 mmol/L ; *p*-chlorophenol 2.7 mmol/L ; ATP 3.15 mmol/L ; Potassium ferrocyanide 10 µmol/L ; Amino-4-antipyrine 0.31 mmol/L ; Lipoprotein lipase ≥ 2000 U/L ; Glycerol kinase ≥ 500 U/L ; Glycerol-3-phosphate oxidase ≥ 4000 U/L ; Peroxidase ≥ 500 U/L ; Sodium azide < 0.1 %	Reagent: Pipes free acid 50 mmol/L; Sodium hydroxide 3.36 g/L; Triton X-100 1 ml/L; Magnesium salt 14.8 mmol/L; *p*-chlorophenol 2.7 mmol/L; ATP 3.15 mmol/L; Sodium azide 7.99 mmol/L; Potassium ferrocyanide 10 µmol/L; 4-aminoantipyrine 0.31 mmol/L; Lipoprotein lipase ≥ 2000 U/L; Glycerokinase ≥ 500 U/L; Peroxidase ≥ 500 U/L; Glycerol phosphate Oxidase ≥ 4000 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 protect 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	Normal : < 150 mg/dL Bordeline high : 150-199 mg/dL High : 200-499 mg/dL Very high : ≥ 500 mg/dL	Normal: < 150 mg/dl Low risk: 150 - 200 mg/dl High: 200 - 500 mg/dl Extremely high: > 500 mg/dl
Instrument	Vital Scientific SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	30 to 1000 mg/dL	3.1 to 1470 mg/dL
Precision	**Within run** Level 48 mg/dL CV=1.5% Level 142 mg/dL CV=1.0% Level 273 mg/dL CV=0.7% **Total** Level 48 mg/dL CV=3.9%	**Within run** Level 126 mg/dL CV=2.52% Level 214 mg/dL CV=0.82% Level 60 mg/dL CV=2.83% Level 108 mg/dL CV=1.84% Level 232 mg/dL CV=1.00% **Total** Level 128 mg/dL CV=1.91%

	ELITech Clinical Systems Device TRIGLYCERIDES SL	Predicate device (ABX PENTRA TRIGLYCERIDES CP)
	Level 142 mg/dL CV=2.7% Level 273 mg/dL CV=4.5%	Level 216 mg/dL CV=1.70% Level 132 mg/dL CV=1.57% Level 243 mg/dL CV=1.37%
Method comparison	y=1.040x + 0.339 mg/dL r^2= 0.998 range: 22 to 936 mg/dL	y=0.99x + 0.20 mg/dL r^2= 0.9994 range: 3.1 to 1434.1 mg/dL
Limitations	**Unconjugated bilirubin:** No significant interference up to 15 mg/dL . **Conjugated bilirubin:** No significant interference up to 5.9 mg/dL **Hemoglobin:** No significant interference up to 250 mg/dL . **Uric acid:** No significant interference up to 23.6 mg/dL **Ascorbic acid:** No significant interference up to 2.0 mg/dL. Concentrations above the therapeutic levels will interfere and cause erroneous results. **Methyl-dopa:** No significant interference up to 1.0 mg/dL	**Hemoglobin:** No significant influence is observed up to 500 mg/dL. **Total bilirubin:** No significant influence is observed up to 22.5 mg/dL. **Direct bilirubin:** No significant influence is observed up to 22.5 mg/dL.
Calibration Frequency	14 days	14 days
On board stability	refrigerated area : 28 days	refrigerated area: 48 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

Device name

REAGENT:

Trade/proprietary Name:	**ELITech Clinical Systems CHOLESTEROL SL**
Common or Usual Name:	Cholesterol (total), "**CHOLESTEROL SL**"
Device Class	Class I
Classification name	Cholesterol (total) test system (Sec.862.1175)
Product code	**CHH** – Enzymatic Esterase-Oxidase, Cholesterol

Predicate device ABX PENTRA CHOLESTEROL CP (K060854)

Device description

The device for this submission is available as kit only. It consists of 1 reagent, "R".
Reagent R contains: Pipes buffer, 4-Aminoantipyrine (4-AAP), Cholesterol esterase (CHE bacterial), Cholesterol oxidase (CHO microorganims), Peroxidase (POD horseradish), Sodium cholate, Phenol and Sodium azide.

Intended Use

ELITech Clinical Systems CHOLESTEROL SL is intended for the quantitative in vitro diagnostic determination of cholesterol in human serum and plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.

Indication for use

ELITech Clinical Systems CHOLESTEROL SL is intended to measure cholesterol in human serum and plasma. Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Comparison to Predicate device

	ELITech Clinical Systems Device CHOLESTEROL SL	Predicate device (ABX PENTRA CHOLESTEROL CP)
Intended use	For *in vitro* diagnostic use in the quantitative determination of cholesterol in serum or plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of cholesterol in serum or plasma.
Indication for Use	Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.	Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.
Assay protocol	Enzymatic colorimetric method using cholesterol esterase/ cholesterol oxidase coupled with peroxidase (Trinder method).	Enzymatic colorimetric method using cholesterol esterase/ cholesterol oxidase coupled with peroxidase (Trinder method).
Composition	Reagent: Pipes buffer 50 mmol/L ; Phenol 24 mmol/L ; Sodium cholate 5 mmol/L ; 4-Aminoantipyrine 0.5 mmol/L ; Cholesterol esterase ≥ 180 U/L ; Cholesterol oxidase ≥ 200 U/L ; Peroxidase ≥ 1 000 U/L ; Sodium azide < 1 g/L	Reagent: Good's buffer 50 mmol/L; Phenol 5 mmol/L ; 4-Aminoantipyrine 0.3 mmol/L ; Cholesterol esterase ≥ 200 U/L ; Cholesterol oxidase ≥ 50 U/L ; Peroxidase ≥ 3 000 U/L ; Sodium azide 0.95 g/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 protect 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 and contamination is avoided.
Expected values	Desirable: < 200 mg/dL Bordeline high: 200-239 mg/dL High: ≥ 240 mg/dL	Desirable: ≤ 200 mg/dl Borderline high risk: 200-239 mg/dL High risk: > 240 mg/dL

	ELITech Clinical Systems Device CHOLESTEROL SL	Predicate device (ABX PENTRA CHOLESTEROL CP)
Instrument	Vital Scientific SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	20 to 600 mg/dL	2.55 to 580 mg/dL
Precision	**Within run** Level 116 mg/dL CV=2.4% Level 190 mg/dL CV=1.9% Level 298 mg/dL CV=1.7% **Total** Level 116 mg/dL CV=2.6% Level 190 mg/dL CV=2.7% Level 298 mg/dL CV=2.7%	**Within run** Level 113 mg/dL CV=0.82% Level 186 mg/dL CV=0.74% Level 117 mg/dL CV=1.21% Level 191 mg/dL CV=0.53% Level 389 mg/dL CV=0.62% **Total** Level 109 mg/dL CV=2.96% Level 183 mg/dL CV=2.34% Level 170 mg/dL CV=2.80% Level 250 mg/dL CV=3.01%
Method comparison	y=1.006 x – 1.734 mg/dL r^2= 0.999 range: 20 to 579 mg/dL	y=0.95x + 1.90 mg/dL r^2= 0.9943 range: 2.55 to 583.26 mg/dL
Cholesterol Reference Laboratory Network (CRMLN) certification	Certified	Certified
Limitations	**Unconjugated bilirubin:** No significant interference up to 6.0 mg/dL. **Conjugated bilirubin:** No significant interference up to 5.9 mg/dL. **Hemoglobin:** No significant interference up to 250 mg/dL. **Turbidity:** No significant interference up to 614 mg/dL triglyceride equivalent. **Ascorbic acid:** No significant interference up to 2.0 mg/dL. Concentrations above the therapeutic levels will interfere and cause erroneous results. **Methyl-dopa:** No significant interference up to 0.8 mg/dL. Concentrations above the therapeutic levels will interfere and cause erroneous results. **Uric acid:** No significant interference up to 23.4 mg/dL.	**Hemoglobin:** No significant influence is observed up to 336 mg/dL. **Total bilirubin:** No significant influence is observed up to 20.5 mg/dL. **Direct bilirubin:** No significant influence is observed up to 6.8 mg/dL. **Triglycerides:** No significant influence is observed up to 612.5 mg/dL
Calibration Frequency	28 days	8 days
On board stability	refrigerated area : 28 days	refrigerated area: 48 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

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 the ELITech Vital Scientific Selectra/Flexor Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s.)
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on the ELITech Vital Scientific Selectra/Flexor 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 occasional gentle swirling within 30 minutes avoiding the formation of foam.	Carefully open one bottle, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s.)
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

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 & ELITROL II are multiparametric control sera for use in quality control of ELITech Clinical Systems methods on ELITech Vital Scientific Selectra/Flexor 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 multiparametric control sera for use in quality control of ELITech Clinical Systems methods on ELITech Vital Scientific	For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet

	Selectra/Flexor Analyzers.	
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 their respective predicate devices are not compromised, and that they met all acceptance criteria, demonstrating that the devices are substantially equivalent to their respective predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAY 19 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: k102993
Trade Name: ELITech Clinical Systems Cholesterol SL, ELITech Clinical Systems Triglycerides SL, ELITech Clinical Systems Elical 2, ELITech Clinical Systems Elitrol I and II
Regulation Number: 21 CFR §862.1175
Regulation Name: Cholesterol Test System.
Regulatory Class: Class I, meets the limitations to exemptions 21 CFR 862.9 (c)(4)
Product Codes: CHH, CDT, JIX, JJY
Dated: April 29, 2011
Received: May 03, 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): __K102993_____

Device Name: _____ ELITech Clinical Systems TRIGLYCERIDES SL _____

Indications for Use:

ELITech Clinical Systems TRIGLYCERIDES SL is intended for the quantitative *in vitro* diagnostic determination of triglycerides in human serum and plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings

Triglycerides measurements are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

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) K102993

Indications for Use Form

510(k) Number (if known): __K102993_____

Device Name: _____ ELITech Clinical Systems CHOLESTEROL SL _____

Indications for Use:

ELITech Clinical Systems CHOLESTEROL SL is intended for the quantitative *in vitro* diagnostic determination of cholesterol in human serum and plasma on ELITech Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.

Cholesterol measurements are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Prescription Usé __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) K102993

Indications for Use Form

510(k) Number (if known): __K102993_____

Device Name: _____ ELITech Clinical Systems ELICAL 2_____

Indications for Use:

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

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

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

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

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

510(k) K102993

Indications for Use Form

510(k) Number (if known): __K102993_____

Device Name: _____ELITROL I and ELITROL II_____

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multiparametric control sera for use in quality control of ELITech Clinical Systems methods on ELITech Vital Scientific Selectra/Flexor Analyzers.

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

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

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

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

510(k) K102993