K100525

SECTION 5 - 510(k) Summary

DEC 15 2010

ELITech Clinical Systems GLUCOSE PAP 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: K100525

Submitter SEPPIM S.A.S.
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Contact Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation Monday, February 15th 2010

Device names

REAGENT :

Trade/proprietary Name:	**ELITech Clinical Systems GLUCOSE PAP SL**
Common or Usual Name:	Glucose, **"GLUCOSE PAP SL"**
Device Class	Class II
Classification name	Glucose test system (Sec.862.1345)
Product code	CGA – Glucose Oxidase, Glucose

Predicate device ABX PENTRA GLUCOSE PAP CP (K052007)

Device description

The device for this submission is available as kit only. It consists of 1 reagent, "R."
Reagent R consists of Phosphate buffer (pH 7.4), Phenol, 4-Aminoantipyrine (4-AAP), Glucose oxidase (*Aspergillus sp.*), Peroxidase (horseradish) and sodium azide.

Intended Use

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

Indication(s) for Use

ELITech Clinical Systems GLUCOSE PAP SL is intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma

Comparison to Predicate device

	ELITech Clinical Systems Device GLUCOSE PAP SL	Predicate device (ABX PENTRA GLUCOSE PAP CP)
Intended use	Intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative in vitro diagnostic determination of glucose in human serum and plasma. It is not intended for use in Point of Care settings.	For *in vitro* diagnostic use in the quantitative determination of glucose in serum and plasma.
Indication(s) for Use	Intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.	Intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
Assay protocol	Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).	Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).
Composition	Reagent R: Phosphate buffer; pH 7.4 13.8 mmol/L ; Phenol 10 mmol/L ; 4-Aminoantipyrine 0.3 mmol/L ; Glucose oxidase ≥ 10 000 U/L ; Peroxidase ≥ 700 U/L ; Sodium azide < 0.1%;	Reagent : Phosphate buffer; pH 7.4 13.8 mmol/L ; Phenol 10 mmol/L ; 4-Aminoantipyrine 0.3 mmol/L ; Glucose oxidase ≥ 10 000 U/L ; Peroxidase ≥ 700 U/L ; Sodium azide < 0.1%;
Appearance of reagent	Liquid form, ready to use	Same
Sample type	Serum Plasma	Serum Plasma
Reagent storage	Store at 2-8 °C and protected from light. The reagent is stable until the expiry date stated on the label.	Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8 °C.
Expected values	Serum, plasma 74 – 106 mg/dL	Serum, plasma 74 – 106 mg/dL
Instrument	SELECTRA JUNIOR	ABX PENTRA 400
Measuring range	20.0 to 400.0 mg/dL Rerun: 800.0 mg/dL	1.8 to 432 mg/dL Automatic post-dilution: 1296 mg/dL
Detection	0.5 mg/dL	1.8 mg/dL
Precision	**Within run** Level 36.5 mg/dL CV=1.6% Level 107.4 mg/dL CV=1.4% Level 301.5 mg/dL CV=1.0%	**Within run** Level 89.36 mg/dL CV=0.41% Level 230.53 mg/dL CV=0.40% Level 42.76 mg/dL CV=0.62% Level 111.47 mg/dL CV=0.30% Level 296.22 mg/dL CV=0.49%

	ELITech Clinical Systems Device GLUCOSE PAP SL	Predicate device (ABX PENTRA GLUCOSE PAP CP)
	Total Level 36.5 mg/dL CV=2.9% Level 107.4 mg/dL CV=2.5% Level 301.5 mg/dL CV=2.1%	**Total** Level 90.20 mg/dL CV=1.23% Level 235.44 mg/dL CV=1.12% Level 107.18 mg/dL CV=1.44% Level 298.97 mg/dL CV=1.05%
Method comparison	y=0.953 x + 3.05 mg/dL r^2= 0.997 range: 17.9 to 417.2 mg/dL	y= 0.98 x + 0.72 mg/dL r^2= 0.9974
Limitations	**Hemoglobin:** Positive bias from 250 mg/dL on low human serum. No significant interference up to 500 mg/dL on medium human serum. **Triglycerides:** Positive bias from 814 mg/dL. **Unconjugated bilirubin:** Positive bias from 15 mg/dL on low human serum. Negative bias from 18 mg/dL on medium human serum. **Conjugated bilirubin:** Negative bias from 8 mg/dL on low human serum and from 18 mg/dL on medium human serum. **Ascorbic acid:** Negative bias from 2 mg/dL on low human serum and from 12 mg/dL on medium human serum. **Uric acid:** Negative bias from 19 mg/dL on low human serum. No significant interference up to 24 mg/dL on medium human serum. **Methyldopa:** Negative bias from 0.9 mg/dL on low human serum. No significant interference up to 1 mg/dL on medium human serum.	**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	11 days
On board stability	refrigerated area : 28 days	refrigerated area: 83 days
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems Elical 2	Recommended calibration material (not included): ABX Pentra Multical
Controls	Recommended quality control material (not included): ELITech Clinical Systems Elitrol I (Normal control) ELITech Clinical Systems Elitrol II (Pathologic control)	Recommended quality control material (not included): ABX Pentra N Control (Normal control) ABX Pentra P Control (Pathologic control)

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

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

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: K100525

Submitter SEPPIM S.A.S.
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Date of Preparation Monday, February 15th 2010

Device names

REAGENT :

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

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

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

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

Comparison to Predicate device

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

Elical 2 assigned values are the following ones:

Components	Under review	Included in this submission	Cleared
AST-GOT			K093883
Glucose		X	
Phosphorus	K100263		
Total Protein		X	
Urea	K100263		
BUN	K100263		

Uric acid	K100263		
Cholesterol	K102993		
Triglycerides	K102993		

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: K100525

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Date of Preparation Monday, February 15th 2010

Device names

CONTROLS:

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

Predicate device

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

Device description

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

Intended Use

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

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

Comparison to Predicate device

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

Elitrol I & Elitrol II assigned values are the following ones:

Components	Under review	Included in this submission	Cleared
AST-GOT			K093883
Glucose		X	
Phosphorus	K100263		

Total Protein		X	
Urea	K100263		
BUN	K100263		
Uric acid	K100263		
Cholesterol	K102993		
Triglycerides	K102993		

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

Seppim S.A.S.
c/o Debra K. Hutson
ELITechGroup Epoch Biosciences
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Bothell, Washington 98021

DEC 15 2010

Re: k100525
Trade Name: ELITech Clinical Systems Glucose PAP SL, ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL 1 and ELITROL 2
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, JIX, JJX
Dated: December 13, 2010
Received: December 15, 2010

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

DEC 15 2010

Indications for Use Form

510(k) Number (if known): _K100525_____

Device Name: _____ ELITech Clinical Systems GLUCOSE PAP SL _____

Indications for Use:

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

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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) K100525

Indications for Use Form

510(k) Number (if known): _K100525_____

DEC 15 2010

Device Name: ____ELITech Clinical Systems ELICAL 2_____

Indications for Use:

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

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

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

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

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

510(k) K100525

Indications for Use Form

DEC 15 2010

510(k) Number (if known): _K100525_____

Device Name: __ELITech Clinical Systems ELITROL 1 and ELITROL 2____

Indications for Use:

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

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

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

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

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

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

510(k) K100525