510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:
k100525

B. Purpose for Submission:
New device

C. Measurand:
Glucose

D. Type of Test:
Quantitative enzymatic assay

E. Applicant:
Seppim S.A.S.

F. Proprietary and Established Names:
ELITech Clinical Systems Glucose PAP SL
ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL 1 and ELITROL 2

G. Regulatory Information:

Product Code	Device Classification	Regulation Section	Panel
CGA – Glucose Oxidase, Glucose	Class II	21 CFR § 862.1345, Glucose test system	Clinical Chemistry (75)
JIX - Calibrator, multi-analyte mixture	Class II	21 CFR § 862.1150, Calibrator	Clinical Chemistry (75)
JJX - single (specified) analyte controls (assayed and unassayed)	Class I, reserved	21 CFR § 862.1660, Quality control material (assayed and unassayed).	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
   See indications for use below.

2. Indication(s) 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.

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.

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.

3. Special conditions for use statement(s):
   This device is intended for prescription use and *in vitro* diagnostic use only.

4. Special instrument requirements:
   Performance was provided for Vital Scientific Selectra Junior Analyzer which is also trademarked as the Vital Scientific Flexor Junior Analyzer.

I. Device Description:

Glucose PAP SL reagent is composed exclusively of Reagent R, which is in liquid ready-to-use form and contains Phosphate buffer (pH 7.4), Phenol, 4-Aminoantipyrine (4-AAP), Glucose oxidase (Aspergillus sp), Peroxidase (horseradish) and sodium azide.

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.

ELITech Clinical Systems ELITROL I and ELITROL II are normal and high levels of quality control solutions 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.

J. Substantial Equivalence Information:

Predicate device name	Predicate 510(k) number
HORIBA ABX PENTRA GLUCOSE PAP CP	k052007
Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)	k033501
Roche Diagnostics Precinorm Universal and Precipath Universal Control Sera	k041227

Comparison with predicate

Glucose PAP SL Reagent Similarities and Differences		
Item	Device	Predicate (k052007) ABX PENTRA GLUCOSE PAP CP
Indication(s) for use	Same	For the quantitative in vitro diagnostic determination of glucose in human serum and plasma
Methodology	Same	Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).
Sample Matrix	Same	Serum, Plasma
Measuring Range	20.0 to 400.0 mg/dL	1.8 to 432 mg/dL
Analyzer	Vital Scientific Selectra/Flexor analyzers	ABX PENTRA 400 Analyzer

ELICAL 2 Similarities and Differences		
Item	Device	Predicate (k033501) Roche Calibrator f.a.s.
Indication(s) for use	Same	For *in vitro* diagnostic use in the calibration of quantitative clinical chemistry analyzers
Format	Same	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels

Level	Same	Single level

ELITROL 1 and ELITROL 2 Similarities and Differences		
Item	Device	Predicate (k041227) Roche Precinorm Universal and Precipath Universal Control Sera
Indication(s) for use	Same	For use in quality control by monitoring accuracy and precision for the quantitative methods
Format	Same	Lyophilized human sera with constituents added as required to obtain desired components levels
Level	Same	Two levels

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods.
CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures.
CLSI EP7-A2: Interference Testing in Clinical Chemistry.
CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples.
CLSI EP17-A: Protocols for Determination of Limits of Detection and Limits of Quantification.

L. Test Principle:

For Glucose PAP SL reagent, gluconic acid and hydrogen peroxide (H_2O_2) are formed when glucose oxidase enzymatically oxidizes glucose. H_2O_2 reacts with 4-aminoantipyrine (4-AAP) and phenol under the catalytic action of peroxidase to form a colored quinoneimine. The absorbance of the quinoneimine at 505 nanometers is proportional to the concentration of glucose in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Glucose PAP SL reagent: Within-run and Total precision results were obtained by performing two runs per day, two measures per run, on sera at low, medium and high concentrations on the Vital Scientific Selectra Junior Analyzer during twenty days according to CLSI protocol EP5-A2. The results are presented in the table below:

Sample	n	Mean (g/dL)	Within-run		Total precision	
			SD	%CV	SD	%CV
Low level	80	36.5	0.6	1.6	1.05	2.9
Medium level	80	107.4	1.5	1.4	2.73	2.5
High level	80	301.5	3.1	1.0	6.30	2.1

b. *Linearity/assay reportable range:*
For Glucose PAP SL reagent, a linearity study was performed using ten samples ranging from 18.0 to 400 mg/dL, which were prepared by dilution of spiked high and low combination serum samples. All samples were assayed in triplicate. Data was analyzed using 1st, 2nd, and 3rd order least square regressions according to CLSI Protocol EP6-A. The sponsor selected a first order model since it demonstrated linearity; 1st order: $y = x + 2e^{-13}$, $r^2 = 0.999$. Based on the data, the sponsor claimed a linearity range from 20.0 to 400.0 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
Control material was purchased from commercial available sources. Elitrol I and II control solutions are value assigned using two Vital Scientific Flexor Junior Analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range (n =36). After validation of the target value, a confidence range (high and low values) is calculated. The sponsor claimed an open vial stability of 12 hours at 15 to 25°C, 5 days at 2 to 8°C or 4 weeks at -15 to -25°C.

Calibrator material was purchased from commercial available sources. Elical 2 calibrator is value assigned using multiple runs on two Vital Scientific Flexor Junior Analyzers. The target value of Elical 2 calibrator is the mean of the observed values range (n = 42). After validation of the target value, a confidence range (high and low values) is calculated. The sponsor claimed an open vial stability of 8 hours at 15 to 25°C, 2 days at 2 to 8°C or 4 weeks at -15 to -25°C.

Real-time and on-board stability studies for the Glucose PAP SL reagent were conducted. The sponsor claims a shelf life of 27 months and on-board stability of 28 days.

d. *Detection limit:*
For Glucose PAP SL reagent, a detection limit study was evaluated according to CLSI EP17-A guideline. The limit of blank (LoB) was determined by running a blank sample 60 times on the Vital Scientific Selectra Junior analyzer. The limit of detection (LoD) was determined by 15 measurements of four low analyte samples (~0.30 mg/dL) on the Selectra Junior analyzer. Limit of Quantitation (LoQ) was determined by 15 measurements of four analyte samples (~10 mg/dL) on the Selectra Junior analyzer. Based on the data, the sponsor claimed the following LoB, LoD and LoQ.

	LoB	LoD	LoQ
Limits	0.1 mg/dL	0.9 mg/dL	10.0 mg/dL

d. Analytical specificity:

For Glucose PAP SL reagent, the sponsor evaluated the effect of triglycerides (0-1,018 mg/dL), unconjugated bilirubin (0–30 mg/dL), conjugated bilirubin (0–29.5 mg/dL), hemoglobin (0-500 mg/dL), uric acid (2.4 -24 mg/dL), ascorbic acid (0-20 mg/dL), Methyl dopa (0-1 mg/dL), L-Dopa (0-30 mg/dL), tolazamide (0-50 mg/dL) and acetaminophen (0-30 mg/dL) on sera at low, medium and high glucose concentrations (36, 108 and 400 mg/dL) spiked with the interferents, and then compared with unspiked control. The results are presented below.

Interfering Substance	Low Glucose [36 mg/dL]	Medium Glucose [108 mg/dL]	High Glucose [400 mg/dL]
Triglycerides	≥ 814 mg/dL	-	-
Unconjugated bilirubin	≥ 10 mg/dL	≥ 22.5 mg/dL	-
Conjugated bilirubin	≥ 8 mg/dL	≥ 18 mg/dL	-
Hemoglobin	≥ 250 mg/dL	-	-
Uric Acid	≥ 19 mg/dL	-	-
Ascorbic Acid	> 2 mg/dL	≥ 12 mg/dL	-
Methyl dopa	≥ 0.9 mg/dL	-	-
L-Dopa	≥ 0.6 mg/dL	≥ 2 mg/dL	≥ 5 mg/dL
Tolazamide	≥ 50 mg/dL	-	-
Acetaminophen	-	-	-

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The performance of the Glucose PAP SL reagent on the Vital Scientific Selectra Junior analyzer was compared with the predicate device, HORIBA ABX PENTRA Glucose PAP CP Reagent (k052007) on the HORIBA ABX PENTRA 400 Analyzer. This study was performed according to CLSI protocol EP9-A2 using 100 serum samples covering the measuring range. Data analysis was done using least-squares regression. The following linear regression was obtained.

$y = 0.972x + 2.4$, $r = 0.999$

b. Matrix comparison:
To demonstrate comparable performance between serum and lithium-heparin plasma, the sponsor compared 40 paired samples ranging from 22.7 to 398.6 mg/dL for the Glucose PAP SL reagent using a Vital Scientific Selectra Junior analyzer. Linear regression analysis for the Glucose PAP SL reagent linear regression analysis yielded linear regression equation for lithium-heparin of y = 1.002x - 0.8; r = 0.998.

3. Clinical studies:

a. Clinical Sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
The expected serum levels for glucose are 74 – 106 mg/dL[§].

§ Sacks, D.B., *Carbohydrates.* Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 427.

N. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.